United States District Court,
D. Maine.

IDEXX LABORATORIES, INC,
Plaintiff.
v.
ABAXIS, INC. and S.A. Scientific, Inc,
Defendants.

No. CIV.02-69-P-H

Sept. 2, 2002.

Suit was brought alleging infringement of patents on a process or method, and apparatus, for detecting antigens in whole blood. On patentee's motion for preliminary injunction, the District Court, Hornby, Chief Judge, held that: (1) term "a salt" included a salt in solution; (2) term "retain" means that filter would hold back, not merely delay, the movement of red blood cells, but did not require that every red cell be held back; (3) "means for detecting" referred to any standard assay technique; (4) alleged infringer could perform additional unrecited steps beyond those listed and still infringe; (5) process or method patent provided an adequate written description; and (6) patentee demonstrated a high likelihood of success on claimed infringement.

Motion granted.

4,939,096, 4,965,187. Construed.

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James G. Goggin, Verrill & Dana, Portland, ME, Brent P. Lorimer, Thomas R. Vuksinick, William R. Richter, Workman, Nydegger & Seeley, Salt Lake City, UT, for Abaxis, Inc., defendant.

James G. Goggin, Verrill & Dana, Portland, ME, Bernard L. Buecker, San Antonio, TX, Peter L. Kilpatrick, Langley & Banack, Inc., San Antonio, TX, for S.A. Scientific, Inc., defendant.

ORDER ON MOTION FOR PRELIMINARY INJUNCTION

HORNBY**, Chief Judge.**

IDEXX Laboratories, Inc. ("IDEXX") accuses S.A. Scientific, Inc. ("SAS") and Abaxis, Inc. ("Abaxis") (hereafter "SAS/Abaxis") of infringing two IDEXX patents useful for detecting antigens in whole blood:

'096, a process or method patent, and '187, an apparatus patent. IDEXX claims that, prior to its invention, testing of whole blood was difficult, because the blood's redness interfered with tests that generally depend upon color identification. As a result, red blood cells had to be removed before testing, using methods that were cumbersome and difficult outside of a laboratory. IDEXX markets its products to veterinarians for immediate use in their clinics. The patents purport to describe an invention that permits easy testing of whole blood in the clinic, with immediate results. The essence of the invention is that a hypertonic solution, applied to a whole blood sample, crenates the red blood cells- *i.e.,* makes them less deformable-so that they can no longer slip through a standard filter, a filter that they would pass if unaltered. The rest of the blood components, including the suspect antigen, pass through the filter, and can then be tested for the presence of the antigen by standard assay techniques, including colorimetric methods, that involve binding with a paired antibody. In this lawsuit, IDEXX says that SAS/Abaxis's product CHAT™ (sometimes called Vetscan by Abaxis), a test for heartworm in dogs, infringes the patents.

[1] On July 31, 2002, I conducted a hearing on IDEXX's motion for a preliminary injunction seeking immediate relief against infringement under claim 1 of each patent. The four factor test for a preliminary injunction is well known. Tate Access Floors, Inc. v. Interface Architectural Resources, Inc., 279 F.3d 1357, 1364-65 (Fed.Cir.2002). In this case, all hinges on the likelihood of success on the merits, for I find no significant public interest affected by my decision (the public does have an interest in the enforcement of patent rights, but that could go either way), and the balance of harms between the plaintiff and the defendants does not lean heavily in either direction. If a valid patent is being infringed, then IDEXX is losing money and perhaps market share without an injunction. If the patents are not valid or not infringed, then an injunction against SAS/Abaxis would result in their losing money/market share to which they are entitled and consumers perhaps paying more for the product because of reduced competition. The fact that IDEXX has been in the pet care business for some time, whereas SAS/Abaxis are new entrants, does not significantly alter that balance. I find that IDEXX has shown the requisite likelihood of success and GRANT the motion.

A. MEANING OF CERTAIN TERMS

[2] [3] The preliminary injunction hearing served as a *Markman* hearing, *see* Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), for certain patent terms in dispute. Those terms are: a salt; retain; means for detection; and whereby. I follow the general rules for patent interpretation as established by the Supreme Court and the Federal Circuit. Specifically, I construe these words "in the context of the patent documents[;] ... how a person of experience in the field of this invention would, upon reading the patent documents, understand the words used to define the invention." Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299 (Fed.Cir.1999). I consult the claim, the specification, and the prosecution history, FN1 the so-called intrinsic evidence of patent interpretation.

FN1. I consult the prosecution history of these two patents interchangeably: "When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." Elkay Mfg. Co. v. EBCO Mfg. Co., 192 F.3d 973, 980 (Fed.Cir.1999).

(1) A Salt

[4] Claim 1 of the '096 patent uses the term "a salt." Specifically, the invention involves "treating the [whole blood] sample with a salt to alter the red blood cells." Patent '096, col. 3, 48-49. IDEXX contends that the term "a salt" includes a salt in solution. SAS/Abaxis argue that "a salt" can refer only to a chemical compound, not to a solution in which the compound's component elements exist unbound.

I turn first to the dictionary, to see if a salt in solution is among the generally accepted definitions of a salt. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 & n. 6 (Fed.Cir.1996). The dictionaries cited by Drs. Toone and McDermott, respectively IDEXX's and SAS/Abaxis's expert, show that a salt is commonly understood to exist both as a solid and in solution. *Webster's Third International Dictionary* 2005 (1993) (describing the properties of salt compounds "in solution"); *American Heritage Dictionary of Science* 572-73 FN2 (" '[s]alts [are] usually defined as ionic compounds which in water solution' " yield a positive and a negative ion (quoting Jones, *Inorganic Chemistry*)). Having examined the patent claim, the specification and the prosecution history, I conclude that a person of ordinary skill in the art would understand the '096 patent to embrace that definition.

FN2. SAS/Abaxis do not provide information sufficient for a complete citation.

According to the summary of the invention, "[i]n preferred embodiments of this method, the step of treating the sample with a salt involves mixing the sample with a hypertonic solution to form a dilute solution.... Preferably, the hypertonic solution contains a salt of ionic strength of at least 0.5M. " Patent '096, col. 1, 47-48. The structure of the patent's preferred embodiment explicitly recommends treatment of the blood sample by a salt in a salt solution. Patent '096, col. 2, 47-50 (teaching that a salt should be provided "in any suitable container, e.g. a cylindrical PVC container, preferably as a buffer solution"). That should be sufficient. The Federal Circuit says that "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." Vitronics Corp., 90 F.3d at 1582. Additionally, both the applicant and the patent examiner refer to salt solutions in the prosecution history. *See, e.g.,* Toone Decl., Ex. 2 at 2 (Nucker letter, Jan. 25, 1988); Toone Decl., Ex. 3 at 2 (Clark letter, July 11, 1988); Toone Decl., Ex. 11 at 2 (Freeman letter, Feb. 13, 1989); *see also* Toone Decl., Ex. 5 at 3, 5 (Freeman letter, July 3, 1989) (distinguishing the Fetter patent's use of a dry salt from IDEXX's use of a salt in solution).

But despite all those references to "solution" in the patent documents, SAS/Abaxis argue that, as a matter of law, a salt cannot mean a salt in solution. When dissolved in liquid, they say, a salt molecule separates into its component elements. Thus, a salt solution contains no salt molecules, only a collection of its component elements. It is therefore no longer a salt. For support, they cite a *product* patent case, Exxon Chemical Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553 (Fed.Cir.1995), and Judge Newman's dissent from the denial of rehearing en banc. Exxon Chemical Patents, Inc. v. Lubrizol Corp., 77 F.3d 450, 452 (Fed.Cir.1996). There, Judge Newman argued that the majority's holding meant that a hypothetical product patent for salt water could no longer simply list salt and water, but would have to describe the product's chemical composition: water, sodium and chlorine. Exxon Chemical Patents, 77 F.3d at 452. This dispute about product patents among the judges of the Federal Circuit, as reflected by Judge Newman's effort to demonstrate the wrongheadedness of the majority's approach, does not help SAS/Abaxis. Exxon Chemical Patents's claim explicitly was *not* a process claim like '096; instead, it was a patent of a particular composition: a product patent claim. The court held that a product patent claim, describing the chemical composition as "containing" a list of particularly defined ingredients, protects only a composition that in fact contains the listed chemicals exactly as stated; a product patent is not a patent for a recipe, such that any

composition that results from combining the listed chemicals is also covered. Exxon Chemical Patents, 64 F.3d at 1557-58. The *Exxon Chemical Patents* court was very careful to distinguish between product patent claims and process or product-by-process patent claims. Exxon Chemical Patents, 64 F.3d at 1556-57. The Federal Circuit did not implicitly or explicitly rule that solutions cited in process patents must be described in molecular detail. '096 is a process patent, and I conclude that the ordinary meaning of a salt to a person of ordinary skill in the art of the '096 patent is not precluded by *Exxon Chemical Patents*. The intrinsic evidence of the patent makes clear that a salt includes a salt in solution.FN3

FN3. I observe that claim 1 of the apparatus patent, the '187 patent, does not use the term "a salt." Instead it describes use of a "hypertonic solution." '187 Patent, col. 4, 3-7. There is no dispute over this term.

(2) Retain

[5] The use of the term "retain" in claim 1 is essentially the same in both the '096 and the '187 patents. In claim 1 of '096, the process or method patent, the red blood cells are altered by the salt so that their "ability ... to pass through filter media" is "decrease[d]" and thereafter a filter "retains the altered red blood cells but allows passage therethrough of a sample filtrate." '096 Patent, col. 3, 49-53. In claim 1 of '187, the apparatus patent, provision is made, first, for the blood to be mixed with the hypertonic solution, and, next, for a "filter having a porosity to permit said mixture of said sample and said hypertonic solution to pass ... through said filter, said filter being capable of retaining the red blood cells in said sample." '187 Patent, col. 4, 6-10. There really can be little doubt about what "retain" means; in claim 1 of both patents, it means hold back. Therefore under either patent, filter media must hold back red blood cells.

What the parties disagree over is whether *all* the red blood cells must be held back. SAS/Abaxis say yes; IDEXX says no. The actual claim 1 language is not dispositive in either patent. In '096 the red cells' ability to pass is said to be decreased, the filter is said to retain altered red blood cells (no reference is made to rate of retention or to red blood cells that may remain unaltered) and a sample filtrate does pass through. '096 Patent, col. 3, 49-53. In '187, we are told simply that the filter is "capable of retaining the red blood cells" in the sample. '187 Patent, col. 4, 9.

Since the language of claim 1 does not answer the dispute in either patent, I turn to the specifications. According to the abstract, the invention alters red blood cells "to decrease their ability to pass through filter media," and the "filter ... retains the red blood cells, but allows the passage therethrough of filtrate...." '096 Patent, p. 1; '187 Patent, p. 1. According to the summary, the invention alters the red blood cells "to decrease their ability to pass through filter media, exposing the resultant sample to a filter which retains the red blood cells but allows the passage therethrough of filtrate containing the member of the specific binding pair being assayed.... " '096 Patent, col. 1, 24-29; '187 Patent, col. 1, 27-32. "It is believed that the salt causes the red blood cells in the sample to exhibit a change in physical properties, e.g., deformability, so that they are unable to pass through filter media which would have permitted their passage prior to treatment with the salt. A filter having an average pore size small enough to retain untreated red blood cells would become clogged and prevent passage of liquid as well. According to the invention, a filter can be used which has an average pore size ... large enough to prevent clogging, but which still retains the treated red blood cells." '096 Patent, col. 1, 35-45; '187 Patent, col. 1, 39-49. In other words, there still is no indication whether every single red cell must be retained in the filter.

[6] SAS/Abaxis point to the use of apparently more restrictive language-"red blood-cell free"-when the

inventor describes the embodiments. According to the description of the structure of the preferred embodiment, the filter "is capable of retaining red blood cells in a mixture of whole blood and salt while allowing passage therethrough of red blood cell-free liquid. " '096 Patent, col. 2, 39-41; '187 Patent, col. 2, 42-44. According to the description of the assay of the preferred embodiment, "[t]he red blood cells in the blood are retained by the filter, and the red cell-free liquid containing the component to be detected passes through the filter to the assay membrane." '096 Patent, col. 2, 66-68 & col. 3, 1; '187 Patent, col. 3, 1-4. In the example, the claim describes other embodiments, stating that it is "preferred that the red cell-free liquid be collected on a solid support.... " '096 Patent, col. 3, 33-34; '187 Patent, col. 3, 36-37. But the Federal Circuit has made clear that embodiments do not limit the patent claims. Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed.Cir.1998).FN4

FN4. Even in the preferred embodiment, one skilled in the art would recognize that the chosen filter (the Gelman A/E) would not retain every single one of the red blood cells. Toone Decl. at 11.

SAS/Abaxis also seek support for the restrictive meaning in the prosecution history.During the application process, the IDEXX inventor undertook to distinguish the already existing Fetter patent.FN5 The Fetter patent described an invention for testing whole blood that used salt to get rid of the red. IDEXX's inventor distinguished Fetter by saying that Fetter's technique involved (1) chromatographic separation of colored portions of the blood through exposure to a dried salt; (2) differential migration rates for the resulting separated parts. Toone Decl., Ex. 5 at 3-4 (Freeman letter, July 3, 1989). According to the IDEXX inventor, Fetter reported that he did not completely understand the chemical/physical action of the salt, but surmised that the chromatographic separation occurred either by lysing of the red blood cells, which removed the red color from the cells in whole or in part; or by removal of the entire red cell. *Id*. at 3. The differential migration rate then allowed the red portion of the blood to move along the testing medium more slowly than the other portions and testing could be conducted during this separation. According to the IDEXX inventor, his invention was different from Fetter's because IDEXX's "hypertonic aqueous solution reduces red blood cell deformability sufficiently to alter passage of the red cells through a filter," so that they have "reduced ability to pass through a critically sized filter," FN6 thus achieving "clean filtration" or "clean separation" as opposed to Fetter's "chromatographic separation ... by differential migration rates." *Id*. at 3-4. But this language distinguishing Fetter's differential migration process does not mean that IDEXX's filtration process holds back every single red cell. "Clean" filtration or separation need not mean 100%. Instead, in another part of the prosecution history, the inventor claimed that in his invention the filtrate contained "substantially no red blood cells." Toone Decl., Ex. 3 at 1 (Clark letter, July 11, 1989). Finally, it is apparent that the IDEXX inventor did not claim that any red blood cells that remained unaltered after application of the hypertonic solution would be stopped. Instead he distinguished Fetter on that ground as well, saying that Fetter's chromatographic medium was not "designed to pass most components (including unaltered red cells) and to retain altered components." Toone Decl., Ex. 5 at 4-5 (Freeman letter, July 3, 1989).

FN5. The question on this motion is not whether Fetter is invalidating prior art, but whether statements the IDEXX inventor made in distinguishing Fetter thereby narrow the scope of IDEXX's claim.

FN6. Before the invention, any filter small enough to remove the red cells would quickly clog and become unusable. Toone Decl., Ex. 5 at 4 (Freeman letter, July 3, 1989).

From the claim, the specification and the prosecution history, I conclude that retain means hold back, not merely delay, the movement of the red blood cells. But neither the term "retain" nor the references to how the Fetter patent differs from IDEXX's and its "clean" filtrate suggests that every single red cell must be removed in the filtering media; indeed, the prosecution history's reference to the filtrate having "substantially no red blood cells" negates such a conclusion. The problem the invention overcame was the clogging of filters by red blood cells. What was important was that filters could be used permitting portions of the blood with the suspect antigen to pass through the filter for testing, but holding back the redness so that the resulting filtrate could be tested by colorimetric methods or their equivalents. Science does not often presume absolutes at this level; that would require assurance that the hypertonic solution reaches every single red blood cell, that each red blood cell is affected in the same manner and that the filter is a perfect blockade.

Therefore, I conclude, retain means hold back, not merely delay, but does not require that every red cell be held back.

(3) Means for Detecting

[7] In describing the claimed apparatus, Patent 187, claim 1, begins by claiming "[a] kit for assaying a sample of whole blood for one member of a specific binding pair." '187 Patent, col. 4, 1-2. For our purposes, the binding pairs are antigens and antibodies. '187 then goes on to describe the technique for getting the red out of the whole blood in the sample to be tested. It ends the list of procedures with "means for detecting said one member of a specific binding pair with the second member of the binding pair," but does not specify what the "means for detecting" is/are. '187 Patent, col. 4, 11-13. Such a claim technique is permitted by statute:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. s. 112 (2001). Here, the specification describes the means for detecting as "any standard immunoassay, e.g., as described by Gerber et al. U.S. Pat. No. 4,503,143, hereby incorporated by reference, which describes a colorimetric method of detection of bindable substances such as antigens, using chromogenic agents such as tetramethyl benzidine." '187 Patent, col. 1, 16-21. The Assay portion of the patent also says that a "standard technique [is used] to detect the blood component being assayed. " '187 Patent, col. 3, 8-9. The prosecution history confirms that "the member of the specific binding pair can be assayed by any standard technique." Toone Decl., Ex. 3 at 2 (Clark letter, July 11, 1988). "This invention provides those in the art with a simple way to treat whole blood to provide a readily assayable filtrate. Assay of the filtrate, following such treatment, involves standard procedures not related to the invention." Id. at 3. "[A]ny routine method" can be used and "there are numerous other detection methods, well known to those skilled in the art...." Id. at 4.

There can be no serious dispute, therefore, that "means for detecting" refers to any standard assay technique effective for determining the first member of a specific binding pair and known at the time of the patent. In such a case, the standard is the "understanding of one skilled in the art." Atmel Corp. v. Information Storage Devices, 198 F.3d 1374, 1378 (Fed.Cir.1999).

(4) Whereby

[8] Patent '096, the process patent, begins claim 1 by claiming "[a] method for assaying a sample of whole blood for a first member of a specific binding pair." '096 Patent, col. 3, 46-47. It goes on to describe that method with a list that begins with the word "comprising." The list includes (1) treatment with a salt, (2) filtration and (3) "contacting any of the first member in the filtrate with a second member of the specific binding pair to permit binding of the first member with the second member, whereby said first member is determined." '096 Patent, col. 3, 53-57. SAS/Abaxis contend that the "whereby" clause in this excerpt modifies only the three steps explicitly recounted (treatment with a salt, filtration, binding), and that IDEXX's claim is thereby limited to a process that identifies the antigen in question immediately upon the final listed step, contact between the two members (antigen and antibody) of the specific binding pair. IDEXX argues that the "whereby" clause modifies the entire description of the claimed method, including most importantly the word "comprising," and that the word "comprising" at the beginning of the text signals that the claim is not limited to a process using just the three steps listed but also includes any process that uses these three steps and more. In other words, IDEXX says the patent claims an assay for determining the first member (antigen) of a binding pair in a sample of whole blood, but that it is *not* limited to assays where the identification is achieved immediately upon binding of the antigen and antibody.

The syntax of the sentence alone does not answer this debate, but the law of the Federal Circuit and the patent specification do. First, because the list of stages begins with "comprising," IDEXX is correct that SAS/Abaxis can perform additional unrecited steps and still infringe. Kustom Signals, Inc. v. Applied Concepts, Inc., 264 F.3d 1326, 1332 (Fed.Cir.2001); Herbert F. Schwartz, *Patent Law & Practice* 125 (3d ed., Fed. Judicial Center 2001). Second, as I have already observed, the invention here was the ability to test whole blood in a clinical setting. Once the whole blood had been treated as prescribed by the invention to get the red out (treatment with a salt and filtration), any testing technique capable of determining the first member in a specific binding pair would do: in the patent's words, "any standard immunoassay, e.g., as described by Gerber et al. U.S. Pat. No. 4,503,143, hereby incorporated by reference, which describes a colorimetric method of detection of bindable substances such as antigens, using chromogenic agents such as tetramethyl benzidine." '096 Patent, col. 1, 13-18. Example A in the patent makes clear that the patent is not limited to a process that identifies the antigen immediately upon contact with the antibody, for it expressly describes identification that uses an extra step: "Generally, after the leukemia antigen has bound to anti-leukemia antibody on the membrane, enzyme-labeled anti-leukemia antibody is added to form a 'sandwich', and color is developed using an enzyme substrate and colormetric indicator." '096 Patent, col. 3, 27-31. Thus, the specification does not indicate that the "whereby" clause narrowly limits the ultimate assay technique to identification immediately upon binding, as SAS/Abaxis would have it.FN7

FN7. The third element of the list, including the whereby clause, was added at the Examiner's request after she initially rejected claim 1 when it said nothing about the testing technique except "assaying for said member of the filtrate," the "member" being "one of a specific binding pair." Toone Decl. Ex. 11 at 1 (Freeman letter, Feb. 13, 1989).

[9] I also reject the validity issue that SAS/Abaxis raises on this claim.FN8 SAS/Abaxis argue that the '096 patent fails to satisfy the statutory "written description" requirement, 35 U.S.C. s. 112, because it omits steps necessary for detection of the first member. In light of the discussion above, I conclude that the inventor provided an adequate written description of his invention: a method of assaying whole blood through treatment with a salt, filtration and detection using specific binding pairs. FN9

FN8. The patent examiner initially raised similar validity concerns, *see* Toone Decl., Ex. 10 at 2 (Nucker letter, Sept. 23, 1989), but withdrew her opposition after reference to the specific binding pair and the word "whereby" were added.

FN9. This is the only validity issue raised on this preliminary injunction motion.

B. INFRINGEMENT

[10] Having defined the contested terms, I turn to the likelihood of success on the claimed infringement. First, I repeat claim 1 of each patent:

A method for assaying a sample of whole blood for a first member of a specific binding pair, said method comprising treating the sample with a salt to alter the red blood cells in the sample to decrease the ability of the red blood cells to pass through filter media, exposing the treated sample to a filter which retains the altered red blood cells but allows passage therethrough of a sample filtrate, and contacting any of the first member in the filtrate with a second member of the specific binding pair to permit binding of the first member with the second member, whereby said first member is determined.

'096 Patent, col. 3, 46-57.

A kit for assaying a sample of whole blood for one member of a specific binding pair, said kit comprising a first container holding a hypertonic solution, a second container suitable for containing a mixture of said hypertonic solution from said first container with the sample, a filter having a porosity to permit said mixture of said sample and said hypertonic solution to pass from said second container through said filter, said filter being capable of retaining the red blood cells in said sample, means for collecting the filtrate containing the first member of the binding pair, and means for detecting said one member of a specific binding pair with the second member of the binding pair.

'187 Patent, col. 4, 1-13.

It is undisputed that SAS/Abaxis's CHAT^{TM} is a kit for assaying a sample of whole blood, that it uses specific binding pairs (heartworm antigens and antibodies) and that it tests for the dog heartworm antigen (*d.immitis*). For purposes of the motion, the following issues are disputed on the likelihood of success on infringement: (1) whether CHAT^{TM} uses a salt to achieve its results (the '096 patent); (2) whether the CHAT^{TM} filter media actually retain the red blood cells (both patents); (3) whether the CHAT^{TM} colloidal gold technique is (a) a "means for detecting" the antigen claimed by the '187 patent or (b) within the method of the '096 patent "whereby said first member is determined."

(1) A Salt

The '096 patent claim involves "treating the sample with a salt to alter the red blood cells in the sample to decrease the ability of the red blood cells to pass through the filter media." Patent '096, col. 3, 48-50. On the current record, IDEXX has a strong case that use of the SAS/Abaxis kit literally infringes this element of the '096 patent as I have defined the terms, (*i.e.*, that a salt includes a salt solution). The SAS/Abaxis device

requires the use of a buffer solution of tris base, sodium azide (a preservative), deionized water and hydrochloric acid. Pl.'s Am. Mem., Exs. G, H. According to the definition supplied by SAS/Abaxis, a salt forms "when an acid and a base neutralize each other." McDermott Decl., Ex. H. By this definition, the tris base and the hydrochloric acid when mixed neutralize each other and form a salt solution.FN10 Therefore, this element of the CHAT ^{TM} kit does what '096, the process patent, prescribes.

FN10. At his deposition, Ricardo Martinez, SAS's Director of New Ventures and Regulatory Affairs, stated that SAS's buffer solution includes tris base purchased from Sigma. Pl.'s Am. Memo., Ex. H. IDEXX has provided a technical bulletin from Sigma regarding tris base and other tris products. Id., Ex. F. The bulletin notes that trizma-HC1 (the same combination as SAS's buffer) "is the completely neutralized crystalline hydrochloride salt of tris." Id. I take this to mean that tris and HC1 neutralize each other in solution, and that the result of their interaction is a salt in solution.

(2) Retaining the Red Blood Cells

Both sides are frustratingly coy on the actual process that occurs in the CHAT^{TM} test after the buffer solution is added.FN11 What is clear is that the Tris solution with the addition of HCL creates a hypertonic salt solution that can crenate the red blood cells as described by the patents. SAS/Abaxis use a series of media (the sample pad, where the blood and buffer are deposited; followed by a conjugate pad, which holds the colloidal gold antibodies; followed by a CytoSep strip; in turn followed by a nitrocellulose pad; and finally an absorbent pad) through which blood or portions of blood pass. But are they using the filtration parts of these media to "retain" the red blood cells? According to the CytoSep advertising materials, the CytoSep strip "separate[s] plasma from whole blood," and "[p]lasma will separate from the cell fraction of the blood and wick vertically." Steck Decl., Ex. 4. This certainly connotes filtration to hold back the red cells, as IDEXX claims. FN12 Moreover, there is no evidence in the record of actual lysing or removal of the cells by the salt as the Fetter patent describes. SAS/Abaxis's expert McDermott does say that the red blood cell components are not "retained" in any filter medium, but merely travel through the CHAT^{TM} kit at a slower migration rate than the plasma. McDermott Decl. at 13-14. He reaches that conclusion by observing that after ten minutes a red stain begins to appear on the nitrocellulose pad beyond the CytoSep strip and by electron microscope examination that shows the red stain is actually composed of red blood cells. Id. at 14 & Ex. K.FN13 In turn, however, IDEXX's expert Toone points out that the red blood cells McDermott sees are almost exclusively normal red blood cells, ones that have not been crenated by the hypertonic salt solution. Toone Decl. at 13; McDermott Decl., Ex. K. In other words, ordinary red blood cells are getting through some stages of the filtering media, though not enough of them or not fast enough to stop the assay from working farther down the line.

FN11. For example, neither party introduced scientific evidence of what happened to red cells in either the sample pad or the CytoSep strip in an actual heartworm test. There may be a number of explanations: (1) The science may not be fully understood; (2) At this point in the litigation, not all discovery and investigation have been completed; (3) Because IDEXX was involved in creating the process used by SAS/Abaxis during an aborted IDEXX joint venture with SAS, it may have perceived less need to develop independent science of what is actually occurring; and (4) SAS/Abaxis and IDEXX may not want to know or divulge exactly how the process works.

FN12. IDEXX employee Clark who during the aborted collaboration helped design the filter that

SAS/Abaxis use, stated by affidavit that IDEXX designed it so that most of the crenated blood cells would be trapped in the sample pad and that the CytoSep strip would trap the remainder as a safety. Clark Decl. at 3.

FN13. The same photograph seems to show redness still present in the sample pad, suggesting that retention is going on as well.

Thus, on this record, I find that there is a reasonable likelihood that IDEXX will prove that SAS/Abaxis's CHAT^{TM} uses the hypertonic salt solution to crenate red blood cells and uses filtering media to retain them, but does not succeed in retaining them all. I conclude that letting enough red blood cells escape crenation and/or the filter to stain the nitrocellulose pad after ten minutes does not save the kit from infringing the patent; a clumsier practice of the claimed art still amounts to infringement.FN14

FN14. There is no scientific evidence in the record at this stage to support the assertion that the CHAT^{TM} kit is doing something different to the blood than the patented process/apparatus.

(3) Colloidal Gold

I use SAS/Abaxis's expert to describe their colloidal gold method of testing for heartworm antigen:

The SAS/Abaxis kit is based on using heartworm specific antibodies in an immuno-chromatographic assay. Colloidal gold particles coated with antibodies that are specific for *D. immitis* antigen bind to *D. immitis* antigens in the sample. The colloidal gold bound antigen/antibody complexes flow through the strip and are then captured by *D. immitis* specific antibodies that are immobilized in the test area of the strip. The accumulation of large numbers of the antibody-gold particle/antigen/antibody complex causes a color to become visible in the S (sample) area. To serve as a procedural control, a colored line in the C (control) area will always appear regardless if the sample is positive or negative. This line forms when excess antibody-coated colloidal gold particles accumulate due to capture by specific antibodies immobilized in the control line area.

McDermott Decl., at 4-5.

In other words, the testing relies on the binding of specific binding pairs: heartworm antigens and antibodies. Color identification occurs through the use of colloidal gold particles that hold the antigen-specific antibodies; when the colloidal gold particles with their antibodies bind to the specific antigens and are then trapped by additional antibodies at a test site, the accumulated color signals a positive result.

(a) Means for Detecting

For infringement of the '187 patent, which uses 35 U.S.C. s. 112's "means plus function" method of claiming ("means for detecting"), the question is whether SAS/Abaxis use a means for detection "described in the specification" of '187 or an "equivalent thereof." 35 U.S.C. s. 112. As I have said, the specification refers to "any standard immunoassay" and as an example refers to another patent describing a "colorimetric method of detection of bindable substances such as antigens." The record reveals that colloidal gold

technology was a standard substitute for colorimetric assaying technique, interchangeable with it and known from 1986-90 when these patents were processed and issued. Toone Decl. at 20 & Exs. 12, 13. I conclude that IDEXX has a strong likelihood of proving that it therefore falls within the "means for detecting said one member of a specific binding pair with the second member of the binding pair" of Patent '187 and infringes.

(b) Whereby

For infringement of the '096 patent, the question is whether SAS/Abaxis's use of steps additional to the three listed steps (treatment with a salt, filtration, and binding of a specific binding pair) means that CHAT^{TM} avoids infringing the '096 patent. For the reasons I gave in (A)(4), the word "whereby" does not excuse infringing behavior that involves additional steps, so long as each listed claim limitation is met. I conclude that IDEXX has a strong likelihood of proving that use of the CHAT^{TM} kit performs all three steps and, therefore, that use of the CHAT^{TM} kit does infringe, even though the colloidal gold technology requires an additional step (second binding) before the heartworm antigen is identified.

* * * * * *

Consequently I conclude that IDEXX has a high likelihood of success of proving infringement on claim 1 of both patents, at least upon the issues and the record presented to me on the motion for preliminary injunction. An injunction therefore will issue. IDEXX's lawyers shall draft a proposed injunction consistent with this opinionand submit it to SAS/Abaxis's lawyers for approval as to form and consistency with the opinion, and then submit it to the Clerk's Office for presentation to me. A bond is appropriate under Fed.R.Civ.P. 65 and the standards for such a bond were discussed at oral argument. Both sides may present to me their proposals on a bond in that light. I will be unavailable from September 6 through September 25, 2002.

SO ORDERED.

D.Me.,2002.
Idexx Laboratories, Inc. v. Abaxis, Inc.

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