

United States District Court,
D. Kansas.

GREAT PLAINS LABORATORY, INC,
Plaintiff.

v.
METAMETRIX CLINICAL LABORATORY et al,
Defendants.

No. 04-2125-JTM

Sept. 15, 2006.

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MEMORANDUM AND ORDER

J. THOMAS MARTEN, Judge.

This matter comes before the court on the parties' *Markman* briefs. The patent at issue relates to a method for diagnosing the likelihood of autism in patients. The patent includes seven claims. The doctor or examiner is instructed to obtain samples of bodily fluid from the patient and then detect certain marker compounds from a designated list. If the presence of certain compounds is found to be abnormally high as compared with the fluid samples of non-autistic individuals, then a diagnosis of autism may be likely. The patent also includes a method for treating autism with certain antifungal drugs to ameliorate the clinical symptoms of autism, though the inventor later withdrew the treatment claims.

On April 15, 2005, the court held a *Markman* hearing before the late U.S. District Judge G. Thomas VanBebber. After Judge VanBebber's untimely death, this case was transferred to the undersigned. On July 14, 2006, the court held a second *Markman* hearing. The parties contest ten claim terms in U.S. Patent No. 5,686,311 ("the '311 patent"). These terms are: 1) dihydroxyphenylpropionic acid; 2) citramalic acid; 3) 3-oxo-glutaric acid; 4) tartaric acid; 5) quantity; 6) correlating; 7) autism condition; 8) analyzing; 9) normal quantity; and 10) over a period of time. After reviewing the parties' arguments both *Markman* hearings, the court finds as set forth herein.

For the purposes of this motion, the court refers to Great Plains Laboratory and Dr. William Shaw as

plaintiffs and Metamatrix as the defendant.

I. LEGAL STANDARD FOR PATENT CLAIM CONSTRUCTION

The first step in a patent infringement action is for the court to determine as a matter of law the meaning and scope of the claims at issue. *See* *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384 (1996). The touchstone for discerning the usage of claim language is the understanding of those terms among artisans of ordinary skill in the relevant art. *See* *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed.Cir.2001). In construing claims, the court may consider two types of evidence: intrinsic and extrinsic evidence. The court must first consider "intrinsic" evidence of record to construe any disputed language of the claims of the patent. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996). If ambiguity still exists as to the disputed claim term, the court may then rely on extrinsic evidence. *Markman*, 52 F.3d at 981. The Federal Circuit has held "[i]n most situations, an analysis of the intrinsic evidence will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence." *Vitronics*, 90 F.3d at 1583.

A. Intrinsic Evidence

Intrinsic evidence includes the claim language, the patent specification, and the prosecution history and constitutes "the most significant source of the legally operative meaning of disputed claim language." *Vitronics*, 90 F.3d at 1582.

1. Claim Language

To properly construe a claim term, the court starts with the language of the claims. *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1369-70 (Fed.Cir.2005). Generally, claim terms should be construed consistently with their ordinary and customary meanings, as determined by those of ordinary skill in the art. *Id.* at 1370.

2. Specification

The "[c]laims must be read in view of the specification, of which they are a part.... For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims." *Markman*, 52 F.3d at 979. While in some cases there is a presumption that favors the ordinary meaning of a term, the court must first examine the specification to determine whether the patentee acted as his own lexicographer of a term that already has an ordinary meaning to a person of skill in the art:

When a patentee acts as his own lexicographer in redefining the meaning of particular claim terms away from their ordinary meaning, he must clearly express that intent in the written description ... We have repeatedly emphasized that the statement in the specification must have sufficient clarity to put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term.

Merck, 395 F.3d at 1370 (citations omitted).

3. Prosecution History

The Federal Circuit has held that the prosecution history often is "of critical significance in determining the meaning of claims." *Vitronics*, 90 F.3d at 1582. It assists the court to "ascertain the true meaning of the

language used in the patent claim." Markman, 52 F.3d at 980. The prosecution history "contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims." Vitronics, 90 F.3d at 1582. "This 'undisputed public record' of the proceedings in the Patent and Trademark Office is of primary significance in understanding the claims." Markman, 52 F.3d at 980. Arguments made during prosecution about the meaning of a claim term are "relevant to the interpretation of that term in every claim of the patent absent a clear indication to the contrary." CVI/Beta Ventures, Inc. v. Tura, 112 F.3d 1146, 1153 (Fed.Cir.1997) (citation and internal quotation marks omitted). The prosecution history may not, however, be used to "enlarge, diminish, or vary" the limitations in the claims." Markman, 52 F.3d at 980.

B. Extrinsic Evidence

"Extrinsic" evidence is anything outside the specification, claims, and prosecution history. This may include expert testimony, inventor testimony, technical treatises and articles. *See* Markman, 52 F.3d at 980. Where the intrinsic evidence is sufficient, extrinsic evidence is unnecessary and should not be considered. *See* Vitronics, 90 F.3d at 1583; CVI/Beta, 112 F.3d at 1153. Extrinsic evidence may not be used to vary or contradict the intrinsic record. *Trilogy Comm. v. Times Fiber Comm.*, 109 F.3d 739, 744 (Fed.Cir.1997); *Vitronics*, 90 F.3d at 1584.

A court's reliance on extrinsic evidence to construe a claim is proper "only when the claim language remains genuinely ambiguous after consideration of the intrinsic evidence." *Interactive Gift Express, Inc. v. CompuServe Inc.*, 256 F.3d 1323, 1332 (Fed.Cir.2001) (quoting *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706 (Fed.Cir.1997)) (internal quotation marks omitted) (emphasis added). *See Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed.Cir.2000); *Key Pharms. v. Hercon Lab. Corp.*, 161 F.3d 709, 716 (Fed.Cir.1998); *Vitronics*, 90 F.3d at 1583-84. The Federal Circuit has warned, moreover, that "[s]uch instances will rarely, if ever, occur." *Vitronics*, 90 F.3d at 1585 (emphasis added). Consequently, the court should focus on the language in the claims, the patent's specification and, if necessary, standard dictionaries to reach the proper construction of the claims in dispute.

However, ordinary and technical dictionaries are not considered extrinsic evidence to the extent the court uses these aids to educate itself about the scientific principles or technical terms that are at issue in a particular case. *See Teleflex, Inc. v. Ficosa N. Am.*, 299 F.3d 1313, 1325 (Fed.Cir.2002).

II. ANALYSIS

At the outset, the court clarifies that in this case the issues could be determined without the assistance of extrinsic evidence. While the court reviewed dictionaries and treatises to become familiar with the scientific principles and technical terms, the court finds that the claims may be construed with intrinsic evidence such as the claim language, the specification and the prosecution history.

A. Organic Acids

1. Dihydroxyphenylpropionic Acid

The term "dihydroxyphenylpropionic acid" ("DHPPA") appears in Claim 1, Step 2, and Claim 4(h) of the '311 patent. The patent also refers to this acid in its abbreviated form "DHPPA." (Col. 14, line 23). The patent also refers to "DHPPA analog" (Col.15). The only specific reference to a variation of DHPPA is reference to 3,4-dihydroxyphenylpropionic acid (3,4-DHPPA) in example 2 (Col. 14, line 34). Defendant

Metametrix argues that DHPPA is undefined anywhere in the patent claim, specification, or prosecution history except for these brief references. Metametrix argues through its expert Dr. Jeffrey Winkler that DHPPA includes 49 potential and distinct compounds and simply referring to DHPPA creates ambiguity. Specifically, Dr. Winkler argues that Fig. 1 of the '311 patent identifies peak U as DHPPA, but with Gas Chromatography/Mass Spectrometry ("GC/MS") it would be impossible to determine which of the 49 potential compounds is meant to correspond with peak U. In response, Great Plains and Dr. Shaw argue that the term DHPPA may be construed by the patent itself. Plaintiffs argue that DHPPA refers to the genus term and includes the isomers of this compound as well as the conjugate base.

A brief introduction to organic chemistry is helpful in determining the scope of the claim term. An organic acid is the form of a molecule in which the acid portion of the molecule retains a proton, usually as part of the carboxylic acid portion of the molecule. Such molecules are denoted with the suffix "ic" and the word acid. When the proton attached to the carboxylic acid, a portion of the molecule is lost. The name of the organic acid is changed by converting the word through the use of the suffix "ate." The "ate" form denotes the conjugate base, which is the form of the acid when a proton has been lost. The ionized form of the acid may also be referred to as anions. In an aqueous solution, both the organic acid and the conjugate base is present. When using a GC/MS or Liquid Chromatography-Mass Spectrometry-Mass Spectrometry (LC/MS/MS), a particular compound will be converted into one form (e .g. the acid form), and the instrument will measure the quantity of the compound.

In reviewing the claim and specification, the court finds that DHPPA should be construed broadly to include its isomers and conjugate bases. In every instance the patent refers to the broader term "DHPPA." The patent appears to acknowledge that this compound may exist in other forms in referring to DHPPA analog, which in chemistry refers to a substance that is similar but not identical to another. This reference thus indicates that the inventor understood variations of the compound existed and should be considered. In both Claims 1 and Claim 4(h), the patent refers to DHPPA rather than a specific isomer or conjugate base. Thus, the court finds that this term should be construed broadly to include its isomers and conjugate bases.

There was much discussion at the *Markman* hearing as to whether Fig. 1, peak U was properly identified. Based on the patent language itself, peak U was only referred to as DHPPA and the specific isomer was not identified. Subsequent research revealed the name of the particular isomer. However, this information is not relevant to the court's claim construction. At present, the court is satisfied that the patent identifies the compound as DHPPA.

Additionally, in Example 2, the patent refers to the general term "DHPPA" but refers to 3,4-DHPPA as the analytical standard. Now, Dr. Shaw identifies 3-hydroxyphenyl-3-hydroxypropionic acid ("HPHPA") as the analytical standard. Since the inventor consistently refers to DHPPA in the patent and 3,4-DHPPA is only referenced as an analytical standard in the embodiment, the court finds no reason to import a limitation to the claim term "DHPPA."

Therefore, "DHPPA" means any form of DHPPA, including any or all of the 49 possible isomer of DHPPA.

2. Citramalic Acid

The parties raise similar arguments in relation to citramalic acid. The term "citramalic acid" is used in Claim 1, Step 2 and Claim 4(a) of the '311 Patent. Metametrix asserts that citramalic acid means only "citramalic acid, 2-hydroxy-2-methylbutanedioic acid, 2-methylmalic acid, 3-methylmalic acid, 2-hydroxy-3-methyl-

butanedioic acid" since these are the only specific forms identified in the patent. Plaintiffs argue that "citramalic acid" means any form of citramalic acid, including citramalic acid, 2-hydroxy-2-methylbutanedioic acid, methylmalic, 2-methylmalic acid, 3-methylmalic acid, 2-hydroxy-3-methylbutanedioic acid, methylmalate, 2-methylmalate, and 3-methylmalate.

Based on the above listing, the parties agree that citramalic acid includes 2-hydroxy-2-methylbutanedioic acid, 2 methylmalic acid, 3-methylmalic acid, and 2-hydroxy-3-methylbutanedioic acid. For ease of understanding, the court includes the follow chart of terms with the disputed terms in bold.

Great Plains		Metamatrix
Compounds	Disputed Terms	Compounds
citramalic acid	citramalate	citramalic acid
2-hydroxy-2-methylbutanedioic acid	methylmalic, methylmalate	2-hydroxy-2-methylbutanedioic acid
2-methylmalic acid	2-methylmalate	2-methylmalic acid
2-hydroxy-3-methylbutanedioic acid		2-hydroxy-3-methylbutanedioic acid
3-methylmalic acid	3-methylmalate	3-methylmalic acid

With the exception of methylmalic, FN1 the disputed terms are the conjugate bases of citramalic acid. Dr. Winkler's report states that the organic acid and conjugate base are two entirely different compounds. However, in Metamatrix's Organic Acid Analysis report defendant refers to citramalic acid as also citramalate. (Dkt. No. 114, Ex. 7 at MX00075). Similarly, Sigma-Aldrich, an organic chemical compounds company, refers to citramalic acid and citramalate as "synonymous." Dkt. No. 114, Ex. 5, at 4.

FN1. Based on the suffix, methylmalic is the acid form.

Although the extrinsic evidence is helpful to the court in determining how terms may be used in the field of organic acid in general, the court returns to the patent in determining what the disputed terms mean in this context. Throughout the patent, "citramalic acid" is referred to in numerous ways including "authentic citramalic acid" (Col. 3, line 24), "citramalic acid TMS derivative" (Col. 3, line 28), "derivative of the citramalic acid" (Col. 4, line 36), "citramalic" (Col. 4, line 62), "2-methylmalic acid" (Col. 12, line 61), and "3-methylmalic acid" (Col. 12, line 62). Use of these terms should not be construed as limiting the scope of the claim terms but rather highlights the flexibility in meaning of citramalic acid as used in this patent.

Moreover, based on the court's understanding of the relation of organic acids and their conjugate bases, citramalate, methylmalate, 2-methylmalate and 3-methylmalate should be construed within the patent term "citramalic acid." Citramalate is the recognized conjugate base of citramalic acid, 2-methylmalate is the conjugate base of 2-methylmalic acid, and 3-methylmalic acid is the conjugate base of 3-methylmalate. Finally, methylmalic acid is recognized as another name for citramalic acid. Thus, methylmalic acid and its conjugate base fall within the scope of the term " citramalic acid" in the '311 patent. *See* Chemical Abstracts Service, a division of the American Chemical Society, SciFinder database *available at* <http://www.cas.org> (subscription required) (last accessed July 12, 2006) (listing the other names of citramalic acid, registry number 597-44-4).

Therefore, the court declines to import limitations from the specification into the claim language of Claims 1

or Claim 4 and adopts plaintiffs' definition of citramalic acid.

3. 3-oxo-glutaric Acid

The term "3-oxo-glutaric acid" is used in Claim 1, Step 2, and Claim 4(g) of the '311 patent. As related to 3-oxo-glutaric acid, Metamatrix argues that this term should only include 3-oxo-glutaric acid and 3-oxo-pentanedioic acid. However, plaintiffs argue for a broader definition and advocate for inclusion of any form of 3-oxo-glutaric acid, including 3-oxoglutarate, 3-ketoglutaric, 3-ketoglutarate, beta-ketoglutarate and 3-oxo-pentanedioic acid. Thus, the parties do not dispute the inclusion of 3-oxo-glutaric acid and 3-oxo-pentanedioic acid. The only issue is whether 3-ketoglutaric acid and the conjugate bases 3-ketoglutarate, betaketoglutarate and 3-oxoglutarate may also fall within the claim term "3-oxo-glutaric acid."

The term "3-oxo-glutaric acid" has several synonyms including 3-ketoglutaric acid, betaketoglutaric acid and 3-oxo-pentanedioic acid. *See* Chemical Abstracts Service, a division of the American Chemical Society, SciFinder database *available at* <http://www.cas.org> (subscription required) (last accessed July 12, 2006) (listing the other names of 3-oxo-glutaric acid, registry number 542-05-2). Since 3-ketoglutaric acid is a synonym of 3-oxo-glutaric acid, 3-ketoglutaric acid should be included in the definition of the claim term. The conjugate base of 3-ketoglutaric acid, 3-ketoglutarate, falls within the claim term. The conjugate base of beta-ketoglutarate and 3-oxoglutarate are also properly construed as within the claim term "3-oxo-glutaric acid." Nothing in the claim language indicates that 3-oxo-glutaric acid should be construed narrowly. The inventor is not required to include every synonym of 3-oxo-glutaric acid. Furthermore, since the patent requires collection of bodily fluids that are inherently aqueous, it is only logical to conclude that the conjugate bases of compounds will be present in the fluids.

Accordingly, the court adopts plaintiffs' construction of the claim term "3-oxo-glutaric acid."

4. Tartaric Acid

Finally, the parties dispute the meaning of the claim term "tartaric acid." The term "tartaric acid" is used in Claim 1, Step 2 and Claim 4(e) of the '311 Patent. Metamatrix argues the term only includes tartaric acid (3-OH-malic). Great Plains and Dr. Shaw argue that the claim term not only includes tartaric acid (3-OH-malic) but also tartaric, tartarate, tartrate, 2-3-dihydroxybutanedioic acid, and meso-tartaric acid.

Again, the court is in agreement with plaintiffs. Tartaric acid has several synonyms including tartaric, meso-tartaric acid, and 2-3-dihydroxybutanedioic. *See* Chemical Abstracts Service, a division of the American Chemical Society, SciFinder database *available at* <http://www.cas.org> (subscription required) (last accessed July 12, 2006) (listing the other names of tartaric acid, registry number 87-69-4). The relevant conjugate bases include tartrate, which is also spelled tartarate. The patent appears to view this term broadly, and there is no evidence in the patent that tartaric acid should be construed narrowly. As repeated in the discussion of the various organic acids in question, since the inventor instructed collection of bodily fluids, it is logical to conclude that the aqueous solution includes both the organic acid and its conjugate base. A narrower interpretation is imprudent and counterintuitive. Accordingly, the court adopts plaintiffs' definition of tartaric acid.

B. Non-Technical Claim Terms

1. Quantity

The term "quantity" appears in Claims 1, 2, 4, and 5 of the '311 Patent. Plaintiffs argue that quantity means "a measurable amount" whereas defendant argues it means "a specific, objective, non-arbitrary amount, an amount which is neither subjective nor relative." The court is in agreement with plaintiffs.

In Claim 1, the patent method requires the examiner to obtain bodily fluid from the patient in question and analyze "to determine the quantity therein" (Col. 17, line 1) of at least one of the ten listed compounds. Claims 2 and 4 refer to the "said quantity" (Col. 17, lines 11, 17), and Claim 5 refers to the claim term in plural, instructing that there should be a determination of "the quantities of the plurality of said compounds." (Col 18, lines 19-20).

Based on the claim language, the term "quantity" should be straightforward. However, Metamatrix's definition is problematic for several reasons. First, if quantity is a specific, objective, non-arbitrary amount, as Metamatrix proposes, then a simpler formation is to describe the "quantity" as measurable. Next, Metamatrix's description of "quantity" as "neither subjective nor relative," blurs the line between defining the term "quantity" and describing a process of measuring quantity. On its face, defendant's definition creates a contradiction between the definition of "quantity," and the process of measuring and comparing quantities. For example, if "quantity" cannot be subjective or relative, then the process of measuring and comparing the amount of a particular organic acid in a patient as compared to a non-autistic individual defies Metamatrix's definition of "quantity." Such an approach appears contrary to the claim language and the specification. Therefore, the court adopts plaintiffs' definition and defines quantity as simply "a measurable amount."

2. Correlating

The term "correlating" appears in the final step of Claim 1 of the '311 patent. The relevant language states that "correlating the quantity of said at least one compound with an autism condition or lack thereof in said patient" (Pltf. Exh. 2, at 39, Col. 17, lines 8-9). Metamatrix argues that "correlating" means establishing a definite mutual or reciprocal relationship for predictive or diagnostic purposes. Plaintiffs argue that "correlating" means associating, relating, or co-relating one variable or factor with another, either positively or negatively. In support of their definitions, both parties cite *Metabolite Labs., Inc. v. Laboratory Corp. of America Holdings*, 370 F.3d 1354 (Fed.Cir.2004).

In *Metabolite*, the court examined claim terms relating "to a method of detecting a deficiency of cobalamin or folate in warm-blooded animals." *Id.* at 1362. The inventor had included this description of the patent in the preamble. *Id.* The original patent in *Metabolite* did not include a correlating step. *Id.* Rather, the patent examiner suggested a correlation requirement for the patent to be approved. *Id.* The inventor in *Metabolite* included the correlation step and received a patent. *Id.* Using the prosecution history, the Federal Circuit in *Metabolite* concluded that the prosecution history tied the preamble directly to the correlating step. *Id.* It found that the word "detecting" in the medical context requires evaluation of all test results, both positive and negative, to evaluate a patient's condition. *Id.* The Circuit noted that the assaying step identified an elevated or unelevated level of total homocysteine and the correlating step identified in elevated cases a relationship or lack thereof to a vitamin deficiency. Thus, the Circuit found that the preamble supported the district court's construction of correlating to include either a mutual or reciprocal relationship. *Id.*

Next, the *Metabolite* court looked at the specification and found that it did not require a confirmatory step, as advocated by the defendant. *Id.* at 1362-63. The court in *Metabolite* rejected the addition of a diagnostic criterion in correlating and limited the definition of correlating as "to establish a mutual or reciprocal

relationship between." *Id.* at 1364.

The court finds *Metabolite* instructive. Much as in *Metabolite*, the ' 311 patent did not include a correlating step. Dr. Shaw only included the correlation step after the examiner said such a step would be needed for the patent to be approved. Much as in *Metabolite*, the parties before this court dispute whether the correlation requirement includes a diagnostic element. Here, although the preamble described the patent as a method for diagnosing the likelihood of autism in a patient, the claim describes the patent as a method of detecting. Based on the claim language (or even the preamble), the diagnosis of autism appears to be a separate step from the correlation of a quantity of a particular compound for an autism condition or lack thereof. It is only if the quantities of one or more compounds are abnormally high that there may likely be an ultimate diagnosis of autism. Thus, correlating and diagnosing appear to be separate steps. The court finds that a diagnostic element should not be added to the term "correlating."

Plaintiffs' definition appears to be unnecessarily repetitive in its description of correlating as "associating, relating or co-relating." Further, the comparison of one variable or fact with another appears to be already described in the claim language so that adding this descriptive language creates redundancy. Finally, the prospect that the correlation may be positive or negative also appears to be accounted for in the claim language. In the final step of Claim 1, the claim language indicates that the examiner correlates "at least one compound with an autism condition or lack thereof in said patient."

Metamatrix's definition also adds unnecessary language. The use of the word "definite" is too strong as the nature of the detection of certain organic compounds appears to be delicate as one or more compounds may correlate with an autism condition. Correlation by its very nature creates an associational relationship rather than a definite relationship. Next, the use of "predictive or diagnostic purposes" appears to be too heavy-handed. The claim language attempts to correlate the presence of compounds with a condition. Thus, the court adopts a modified version of defendant's definition. Correlating means "establishing a mutual or reciprocal relationship."

3. Autism Condition

The term "autism condition" appears in the final step of Claim 1. Metamatrix argues that autism condition means a state of being autistic or having the disorder of autism. Metamatrix disputes that this is synonymous with any alleged "symptom" or other individual component of the disorder of autism. Plaintiffs argue that autism condition means a condition, feature or symptom of autism. The court is in agreement with plaintiffs.

In the discussion of correlating, the court began distinguishing autism and autism condition. In the final step of Claim 1, the inventor instructs that one is to correlate the quantity of said at least one compound with "an autism condition." "An autism condition" is not synonymous with autism. Rather, it may be a part of having autism, such as having elevated levels of certain organic compounds. The claim language differentiates the likelihood of autism with having one of its symptoms by using "autism" to modify "condition."

The claim specification continues to distinguish "autism" from "an autism condition." For instance, Example 1 describes the analysis performed on the urine of two brothers "with autistic features" to determine whether there was "the presence of elevated amounts of abnormal Krebs cycle metabolites. These metabolites include citramalic, tartaric acid (3-OH-malic), and 3-oxo-glutaric acids...." (Col. 4, lines 59-63). Additionally, in discussing the observed correlation between high levels of tartaric acid and certain conditions of autism, the specification states that "[a] much smaller peak at 12.1 min. was also detected in some of the urine samples

of the siblings with autistic features." (Col. 6, lines 48-50). The patent repeatedly uses the terms "autistic features" (Col. 10, lines 63-65; Col. 7, lines 1-5) or "symptoms of autism" (Col. 15, lines 22-27). Thus, the use of autism condition is distinct from reference to autism.

Therefore, the court finds "autism condition" means "a condition, feature, or symptom of autism."

C. Non-Technical Claim Terms Identified after January 24, 2005

After January 24, 2005, the parties disputed several additional claim terms. Each party claims that the other party was responsible for the delay in identifying the remaining terms. Metamatrix states that the parties were able to come to an agreement on the construction of some of these new terms. However, disputes remain as to three claim terms, that being "analyzing," "normal quantity," and "over a period of time." Despite the delay, Metamatrix concedes the court should now construe these new terms, though it objects to plaintiffs' introduction of extrinsic evidence to determine the meaning of the terms. Great Plains and Dr. Shaw object to the court construing the three terms, claiming Metamatrix did not identify these terms prior to the applicable deadline. Plaintiffs also argue that if the court decides to define these terms, then Metamatrix should not be permitted to introduce extrinsic evidence. The court declines to assist the parties in assigning blame and will construe the remaining terms.

1. Analyzing

The term "analyzing" appears in Claims 1 and 5. Metamatrix argues that analyzing means "using Gas Chromatography-Mass Spectrometry (GC/MS) to identify compounds by comparison to a library of known compounds." Plaintiffs argue that analyzing means "using Gas Chromatography-Mass Spectrometry (GC/MS) or a similar means to identify compounds by comparison to a library or database of known compounds." Plaintiffs' definition is broader in two key respects: 1) plaintiffs' definition includes the possibility that "other similar means" may be used in analyzing; and 2) plaintiffs' definition includes the possibility that the standards may be drawn from a "database" of known compounds and not just a library. Metamatrix argues that plaintiffs are attempting to expand the definition beyond the specification.

The court is in agreement with plaintiffs. Although the inventor identified one means of measuring quantities of organic compounds, this was not to the exclusion of other existing technology. The identification of the use of GC/MS in the preferred embodiment should not be used to limit the type of instrument used to make measurements. "References to a preferred embodiment, such as those often present in a specification, are not claim limitations." *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 865 (Fed.Cir.1988) (citing *Int'l. v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121, 227 USPQ 577, 589 (Fed.Cir.1985) (en banc)). Importing such a limitation would be equivalent to arguing that the patent specifies using a wooden ruler, and thus the use of a tape measurer is not contemplated by the patent. Such an approach is counterintuitive and unduly restricts an inventor's patent.

Therefore, the court adopts plaintiffs' definition.

2. Normal Quantity

The term "normal quantity" appears in Claim 2. Metamatrix argues that normal quantity is an indefinite and undefined term and advocates that the court adopt the definition of "normal" level from the specification as meaning "the mean of a given marker compound ... determined from the analysis of ... samples from a statistically significant sampling of non-autistic individuals." Metamatrix raises three objections: 1) Dr.

Shaw expressly defined normal in the specification; 2) plaintiffs' proposed definition of quantity conflicts with plaintiffs' own definition of quantity; and 3) using "normal quantity" is tautological as it includes "normal individuals" in the definition. Plaintiffs argue that "normal quantity" means "about the average measured of the particular compound in question in normal individuals."

Based on the claim language and the specification, the court adopts defendant's definition. The inventor did include a definition of "normal" level but prefaced it as an example and described it for only urine samples. At the same time, this definition includes language that is valuable in determining the meaning of "normal quantity." First, while using slightly different language, both parties agree that the mean or average of a particular compound or marker compound should be determined. The relevant language is best taken from the specification as "the mean of a given marker compound." (Col. 2, lines 7-8). Plaintiffs' use of "about" in their proposed definition injects ambiguity. Next, the specification uses "statistically significant" in describing the sample to be collected. Again, this was used in the example of urine, but the principle appears to be based on good scientific practice that the inventor advocated in the specification.

The court will also address Metamatrix's remaining objections. First, the court finds that plaintiffs' did not contradict their proposed definition. Metamatrix does not elaborate on this argument in its opening brief. Next, the court is in agreement with Metamatrix that using the term "normal individuals" may lead to ambiguity, particularly where it is clear that normal will be determined based on the sampling of non-autistic individuals. The more specific and less ambiguous definition, as found in the specification, is preferred under these circumstances.

Thus, the court adopts Metamatrix's definition. Normal quantity means "the mean of a given marker compound determined from an analysis of samples of a statistically significant sampling of non-autistic individuals." This definition incorporates the substantive aspects of the cited example in the specification without importing its limitations. It also avoids the ambiguity injected in repeating the use of the word "normal" in describing the individuals sampled.

3. Over a Period of Time

The term "over a period of time" appears in Claim 6. The claim states, in part, "the step of collecting a plurality of said samples over a period of time." (Col. 18, lines 21-22). Metamatrix argues that "over a period of time" is "over a period of at least seven days, separated by non-insignificant time intervals." Plaintiffs contend that over a period of time means "separately and not during the same occurrence."

The claim language does not define "over a period of time," though the specification includes reference to the term. For example, in the summary of the invention, the inventor states that "the urine samples should be collected over a period of time, e.g., on a daily basis over a period of at least seven days." (Col. 2, lines 49-51). The notation "e.g." indicates that as an example the inventor suggests on a daily basis over a period of at least seven days. The example should be considered only one possible approach rather than an attempt to limit the claim. Thus, any definition should not include a specific timetable of days.

Besides the specification of a minimum period of time, the court does not see a significant difference between the parties' proposed definitions. Both definitions note that the time is separated, with Metamatrix emphasizing that the intervals are "non-insignificant" and plaintiffs emphasizing the intervals are "not during the same occurrence." The meanings are slightly different, the significance of which the court cannot fully appreciate at this stage of the litigation. Both definitions, however, do not contradict the claim

language and specification and may co-exist. Thus, the court incorporates elements of both definitions and defines "over a period of time" as "separated by non-insignificant time intervals and not during the same occurrence." The court does not find it appropriate to include a specific time limitation. There is no evidence that the inventor intended this time limitation to occur in every instance and in every claim step.

III. EXPERT TESTIMONY

Prior to the hearing, the parties filed objections to the expert testimony submitted with the briefs. In issuing this opinion, the court took into account the expert testimony to the extent it assisted the court in understanding the basic scientific principles and methods employed. The court also employed this approach in considering the inventor testimony. As is apparent from this memorandum and order, the court did not rely on expert testimony in forming the claim definitions. Instead, the court relied exclusively on intrinsic evidence. Thus, the court denies the pending motions to strike the expert report and the testimony of Dr. Shaw (Dkt.Nos.116, 127).

IT IS ACCORDINGLY ORDERED this 15th day of September 2006, that the court finds as set forth herein on the *Markman* briefs.

IT IS FURTHER ORDERED the court denies the Motions to Strike (Dkt .Nos.116, 127).

D.Kan.,2006.

Great Plains Laboratory, Inc. v. Metamatrix Clinical Laboratory

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