

United States District Court,
D. Maryland.

Dr. Marc L. KOZAM d/b/a MLK Software, et al,
Plaintiffs.

v.

PHASE FORWARD INCORPORATED, et al,
Defendants.

Aug. 29, 2005.

Mark W. Wasserman, Matthew Robertson Sheldon, Richard D. Holzheimer, Reed Smith LLP, Falls Church, VA, for Plaintiffs.

REVISED FN1 MEMORANDUM AND ORDER RE PATENT CLAIM CONSTRUCTION

FN1. In light of the parties' respective comments, the Court hereby revises the Memorandum and Order re Patent Claim Construction issued August 16, 2005.

MARVIN J. GARBIS, District Judge.

In this case, Plaintiffs Dr. Marc L. Kozam ("Kozam") and Datasci, LLC. ("Datasci") sue Defendants Phase Forward Inc. ("Phase Forward") and Quintiles, Inc. ("Quintiles") alleging infringement of claims 11, 12, 14, 16, 25, 27, 29 and 30 of United States Patent No. 6,496,827 ("the Patent"), "Methods and Apparatus for the Centralized Collection and Validation of Geographically Distributed Clinical Study Data with Verification of Input Data to the Distributed System."

Pursuant to the Scheduling Order, the parties have filed materials relating to what they have identified as claim construction issues. The Court has held a hearing regarding claim construction issues and has had the benefit of the arguments of counsel.

The Court now issues its claim construction decision. In so doing, the Court is providing its construction of certain terms in the claims at issue in light of the position of the United States Court of Appeals for the Federal Circuit with respect to claim construction. As stated in *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed.Cir.2004):

This court [] repeatedly and consistently has recognized that courts may not redraft claims, whether to make them operable or to sustain their validity. [Citations omitted.] Even "a nonsensical result does not require the court to redraft the claims of the [] patent" [citation omitted] Thus, in accord with our settled practice we construe the claim as written, not as the patentees wish they had written it.

In this Order the Court does not resolve issues relating to infringement, validity, *etc.*, which may be affected

by the Court's claim construction and likely will be addressed in the summary judgment phase of the case. Rather, the Court presents, for the guidance of the parties as the case progresses, its construction of certain terms used in the claims in the context of the Patent.

I. GENERAL PRINCIPLES

The construction of patent claims is a matter for the Court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). In the process of claim construction, the focus is upon what a person of ordinary skill in the pertinent art would have understood to be the meaning of the claim language. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 986 (Fed.Cir.1995) (*en banc*), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The Court must first look at the basic evidence of record, namely, the language of the Claim, the specification, and the prosecution history. *Insituform Tech., Inc. v. Cat Contracting, Inc.*, 99 F.3d 1098, 1105 (Fed.Cir.1996), *cert. denied* 526 U.S. 1018, 119 S.Ct. 1254, 143 L.Ed.2d 350 (1999). The Claim language itself defines the scope of the Claim. Therefore, "a construing court does not accord the specification, prosecution history, and other relevant evidence the same weight as the claims themselves, but consults these sources to give the necessary context to the claim language." *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1552 (Fed.Cir.1997) (overruled on other grounds).

Patent claims may include limitations written in "means plus function" terms such as "means for entry of information." As expressed in the statute, "[a]n 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 ..." 35 U.S.C. s. 112 para. 6. When a limitation is expressed in terms of "means plus function", it should be construed to "cover the corresponding structure, material, or acts described in the specification and equivalents thereof." *Id.* Accordingly, a "means plus function" limitation essentially incorporates within the literal infringement analysis the doctrine of equivalents.

II. DISCUSSION

a. The Patent and Claims at Issue

As stated in the Patent disclosure,

"The invention provides for a method of gathering data that provides interactivity and uses an existing wide area network in the collection of data, while providing high quality data collection with immediate validation of data."

Thus, for example, a medical researcher in Baltimore seeking data as to a certain procedure, would want to receive, store, and utilize data from a number of hospitals around the world. At each remote location, for example, the Mayo Clinic, a physician performing the procedure on patient X would cause relevant data, e.g., age, weight, blood type, reaction, etc.-to be entered into a computer for transmission to the researcher via a wide area network.

The invention provides for verification of the data as entered, for example, by comparison of the data with designed parameters. Thus, there would be rejection or a query, if the input data reflected age six months and weight of 120 pounds. The invention also provides for validation at the researcher's site prior to acceptance in the data base for such purposes as to avoid duplicative entries.

The parties seek the Court's construction of the terms in the claims at issue highlighted below:

11. A computer-based system to gather, transmit, and store geographically distributed information comprising:

input means for entry of information at a remote site; an information center having receiving means for receiving and storing the information;

transmission means for transmitting the entered information to the receiving means from the remote site input means;

first verification means at the remote site for verifying the information for accuracy as the information is being entered with the input means;

second verification means at the information center for verifying the information received from the remote site input means by comparing the information with information previously stored at the information center;

wherein at least one of the first verification means and the second verification means comprises means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

12. The apparatus in accordance with claim 11, wherein both of the first verification means and the second verification means comprise means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

* * *

14. The apparatus of claim 13, wherein the transmission means comprises a browser running in the computer.

* * *

16. The apparatus of claim 15, wherein the transmission means further comprises a **wide area network** connecting the server and the computer.

* * *

25. A computer system for clinical trial management of centralized collection of geographically distributed information, comprising:

a remote site computer having a browser with a **first data verification module** for verifying data entered at the remote, site computer;

a **transmission medium** coupled to the remote site computer; and

a central computer coupled to the transmission medium, and having a database and a **second data verification module** for verifying data received from the remote site computer;

wherein at least one of the first verification module and the second verification module comprises means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

27. The computer system in accordance with claim 25, wherein both of the first verification module and the second verification module comprise means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

29. A **web-enabled** clinical trial management system for gathering, transmitting, and storing geographically distributed information comprising:

input means for entry of information at a remote site;

an information center having receiving means for receiving and storing information;

transmission means for transmitting the entered information to the receiving means from the remote site input means;

first verification means at the remote site for verifying the information for accuracy as the information is being entered with the input means; and

second verification means at the information center for verifying the information received from the remote site input means by comparing the information with information previously stored at the information center;

wherein at least one of the first verification means and the second verification means comprises means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

30. The system in accordance with claim 29, wherein both of the first verification means and the second verification means comprise means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

B. Term Construction

1. First Verification Means (Claim 11)

In regard to the term "first verification means", the parties disagree only as to whether the term should be construed as covering "software" [without modification] that perform the described function or as covering only software of the type described in the specification. Tr. 38. FN2

FN2. Tr. references are to the transcript of the Claim Construction hearing held on May 20, 2005.

As noted above, a means plus function limitation is to be construed to cover the "corresponding structure ... described in the specification and equivalents thereof." 35 U.S.C. s. 112 para. 6. The essential question is what is the "structure ... described in the specification." The Court concludes that in the context of the Patent, and the relevant time frame, FN3 the term "software" was so broad and general as to provide no limitation at all in respect to a claim for a "computer-based system." Whatever might be the meaning in other contexts, in the Patent at issue, the "structure ... described in the specification" should be neither more less than the description presented in the specification. FN4

FN3. Be it 1998 when the application was filed or 2002 when the Patent issued.

FN4. Indeed, if the specification had merely referred to "software [without modification]" there may well have been issues raised in the Patent Office as to the adequacy of the disclosure.

The specification states:

In particular, the invention uses [software] programming language that is: optimized for use with browsers; suited for interactive applications; platform independent; relatively concise; and downloadable through a browser.

Patent, Col. 4, lines 30-34

If this were the only structure description it would be so general as to provide no meaningful guidance for one seeking to practice the invention. However, the specification further states:

The embodiment illustrated provides for two separate validation/verification operations represented by interface filter plug-in block 7 and interface filter scripts block 8. A verification/validation is provided by interface plug-in block 7 at the remote site computer 2, and may be implemented as an add-on party of browser 3.

Id. at Col. 5, lines 61-66.

At this level of specificity FN5, there is meaningful "structure" described. Accordingly, the Court will utilize the claims construction proposed by Plaintiffs to the extent agreed upon by Defendants, and, for the word "software", will utilize the description presented in the specification.

FN5. At argument, Plaintiffs' counsel stated that the "structure that we're talking about is that filtering software." Tr. 75.

The Court notes Plaintiffs' claim differentiation argument based upon the fact that Claim 18, depending from Claim 11 claims the apparatus of Claim 11 FN6 "wherein the first verification means comprises an interface plug in, including a filter." However, Claim 18 is, in fact, narrower than Claim 11. There is no reference in Claim 18 to the equivalents of the specific structure referred to in Claim 18 while Claim 11 covers the specific structure plus equivalents. *See Medtronic, Inc. v. Advanced Cardiovascular Systems, Inc.*, 248 F.3d 1303, 1311 (Fed.Cir.2001). Moreover, the reference in the dependent claim to the structure described in the specification does not add any additional structure description to the specification. Indeed, one reading the Patent for described structure will find only a description of software using an interface plug-in, including a filter.

FN6. Claim 18 refers to Claim 12 that, in turn, depends from Claim 11.

Furthermore, there is no merit to Plaintiffs' contention that the defense wrongly seeks to limit the claims to the disclosed preferred embodiment. The only embodiment in the specification is labeled as a "preferred" embodiment. That certainly indicates that there might be another embodiment but does not describe it. Accordingly, the means plus function claim limitation is construed by reference to the described structure and the fact that the specification labels it as "preferred" does not broaden the scope of described structure for means plus function analysis.

Accordingly, the term "first verification means," is construed as:

Software, as described below, that is used for verifying information [at the remote site] for accuracy as the information is being entered, and equivalents thereof. The said software uses a programming language optimized for use with browsers, suited for interactive applications, platform independent, relatively concise and downloadable through a browser and comprises an interface plug-in, including a filter.

Of course, the scope of the construed limitation includes the equivalents of the described structure.

2. *Second Verification Means (Claim 11)*

The term "second verification means" is construed in the same manner as "first verification means" except that the software structure is described as "[a]n interface filter scripts block ... provided as a plug-in at the information center ..." Patent, col. 6, line 30-31.

The defense contends that the Court should include as an additional limitation on "second verification means" the requirement that the verification occur prior to storing the information in the data base. The defense is, however, seeking to inject an issue as to the *function* into the definition of the "*means*."

There is no doubt that a *function* of the second verification *means* is to compare information received from the remote site with information previously stored at the information center. Thus, there is a difference in the respective functions described in the Claim for the first and the second verification means as follows:

FIRST VERIFICATION MEANS	SECOND VERIFICATION MEANS
Function in claim-verifying information [at the remote site] for accuracy as the information is being entered.	Function in claim-verifying [at the information center] the information received from the remote site ... by comparing the information with information previously stored at the information center
Specification-verifies information as it is entered in [the] remote site computer. Patent, Col. 5, lines 64-65- Col. 6, line 2	Specification-to verify information prior to it being committed to and stored in the database at the ... information center. Patent, Col. 6, lines 2-4

The claim limitation is for structure described in the specification that performs the function stated in the Claim. For both the first and second verification means, the limitation is construed, as discussed above, to be software of the type set forth in the foregoing definition that performs the function described in the claim (and equivalents of such software). The claim expresses the function as verification by comparison without reference to whether the verification is prior to, during, or after commitment to and storage in the data base.

The Court is not, in this Claim Construction phase, addressing the scope of equivalents or any issues that

may arise in an infringement or validity context by virtue of the difference between the claimed function and the described structure in the specification or by the differences in function and structure in regard to the first and second verification means FN7. These, and other matters that may be raised hereafter shall be addressed in due course as necessary.

FN7. Note, for example, the use of the term "both of" in Claim 12.

3. Transmission Means (Claim 11)

It appears agreed (Tr. 84) that the term "transmission means" should be construed consistent with the specification FN8 as:

FN8. Patent, Col. 5, lines 39-45.

a browser, either installed in the remote site computer or in a remote site server that connects to a wide area network, such as the internet and World Wide Web.

4. Wide Area Network (Claim 16)

Claim 16 states:

The apparatus of claim 15, wherein the transmission means further comprises a wide area network connecting the server and the computer.

At the hearing, the parties agreed upon a construction that the Court accepts. (Tr. 114-116) Accordingly, the term "wide area network" is construed as:

A communication network that connects geographically separated areas, including the Internet and World Wide Web.

5. Transmission Medium (Claim 25)

Claim 25 states:

A computer system for clinical trial management of centralized collection of geographically distributed information, comprising:

* * *

[A] transmission medium coupled to the remote site computer;

As discussed at the Claim Construction hearing, the parties agreed with the Court's construction of the term transmission medium as

a structure that allows or facilitates the transmitting of information to and from a remote site computer, including the Internet.

(Tr. 104).

6. First & Second Data Verification Module (Claim 25)

Claim 25 states, in relevant part:

A computer system for clinical trial management of centralized collection of geographically distributed information, comprising:

* * *

... a first data verification module for verifying data entered at the remote, site computer;
... a second data verification module for verifying data received from the remote site computer;

The parties debate whether the foregoing constitute means plus function limitations.

Plaintiffs contend that there is a rebuttable presumption that the absence of the word "means" indicates the absence of a means plus function claim. Plaintiffs refer to a case FN9 in which the word "circuit" is a claim was held, in context, to present sufficient structure to avoid treatment as a means plus function claim. Plaintiffs, however, acknowledge that the word "module" is "well known in the art as a software component. That's all it means." Tr. 90.

FN9. At the hearing, Plaintiffs' counsel referred to the decision as "this Leading Edge Technology case which came out in December." Tr. 95. The Court could find no such decision but, since the defense did not disagree that there was such a case, assumes that there is a decision in some case so holding.

The Court concludes that the word "module," in context, refers to a part (or component) of a larger software program. The term "module", therefore, expresses only that there is a claim limitation for a part of a software program that verifies data. There is no meaningful structure described. As stated in an analogous context in the unpublished decision FN10 of the Federal Circuit in *Ranpak Corp. v. Storopak, Inc.*, No. 98-1009, 1998 U.S.App. LEXIS 16348 (Fed.Cir. July 15, 1998) "settable control module [in a claim] merely sets forth the same black box as settable context means without recitation of structure for providing the same specified function. *Id.* at *6. *See Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1375-76 (Fed.Cir.2003) (claim element referring to first and second "set of commands" was to be treated as a means plus function claim under s. 112(6) because the claim did not recite sufficient structure to perform the entirety of the claim function.

FN10. Cited not as binding precedent, but as a persuasive quotation.

The Court concludes that, in the context of the Patent Claim at issue, the terms "first data verification *module*" and "second data verification *module*" are construed as the same as "first data verification *means*" and "second data verification *means*." Accordingly, the subject limitations are subject to s. 112 para. 6 as means plus function limitations and have the same construction as "first data verification means and "second data verification means."

7. Web Enabled (Claim 29)

Claim 29 refers to:

29. A web-enabled clinical trial management system for gathering, transmitting, and storing geographically distributed information.

The defense is concerned about a limitation FN11 to Internet use that could narrow the claim so as to avoid certain potential prior art. However, the parties presented constructions for "web enabled" that did not appear to have any meaningful difference.

FN11. The Court is not now addressing whether the use of "web-enabled" in the preamble to Claim 29 limits the size of the Claim. *See Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1376 (Fed.Cir.2001)

Plaintiffs	Defendant
Capable of using the Internet or the World Wide Web, or being accessible by users through the Internet or the World Wide Web, or being capable of exporting data in way that can be viewed on the a Internet or the World Wide Web. PI Proposed Claim Construction.	Equipped with hardware or software that allows it to communicate or transmit information over the Internet. Tr. 108.

At the hearing the parties reached agreement on a construction with which the Court agrees. (Tr. 110-11). The Court, therefore, construes the term "web-enabled" to mean:

Having software and/or hardware that allows the transmitting or communicating of information over the Internet or the World Wide Web.

III. CONCLUSION

For the foregoing reasons, the Court concludes the following with regard to the construction of the Claim terms placed at issue:

1. The term "first verification means," is construed as software, as described below, that is used for verifying information [at the remote site] for accuracy as the information is being entered, and equivalents thereof. The said software uses a programming language optimized for use with browsers, suited for interactive applications, platform independent, relatively concise and downloadable through a browser and comprises an interface plug-in, including a filter.
2. The term "second verification means," is construed as software, as described below, that is used for verifying [at the information center] the information received from the remote site ... by comparing the information with information previously stored at the information center and equivalents thereof. The said software comprises an interface filter scripts block ... provided as a plug-in at the information center.
3. The term "transmission means" is construed as a browser, either installed in the remote site computer or in a remote site server that connects to a wide area network, such as the internet and World Wide Web.
4. The term "wide area network" is construed as a communication network that connects geographically

separated areas, including the Internet and World Wide Web.

5. The term "transmission medium" is construed as a structure that allows or facilitates the transmitting of information to and from a remote site computer, including the Internet.

6. The term "second data verification *module*" is construed as the same as "second data verification *means*."

7. The term "web-enabled" is construed as having software and/or hardware that allows the transmitting or communicating of information over the Internet or the World Wide Web.

8. By August 26, 2005 Plaintiffs shall either advise the Court that no party wishes a stay of the case to explore settlement and/or to change the scheduling of further proceedings or arrange a telephone conference to discuss such matters.

SO ORDERED.

D.Md.,2005.

Kozam v. Phase Forward Inc.

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