United States District Court,
E.D. New York.

CHEMBIO DIAGNOSTIC SYSTEMS, INC,
Plaintiff.
v.
SALIVA DIAGNOSTIC SYSTEMS, INC,
Defendant.

No. 04-CV-1149 (JS)(ETB)

Sept. 27, 2005.

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MEMORANDUM AND ORDER

SEYBERT**, District Judge.**

Currently pending before this Court are motions for summary judgment by Plaintiff, Chembio Diagnostics, Inc. ("Plaintiff" or "Chembio"), and Defendant, Saliva Diagnostics Systems, Inc. ("Defendant" or "Saliva"), seeking a determination, or partial determination, as to the instant action. The instant action was commenced by Chembio against Saliva for declaratory judgment that the Plaintiff's Sure Check HIV Barrel Device ("Barrel Device") did not infringe the Defendant's U.S. Patent No. 5,935,864 ("'864 Patent"), or in the alternative, that the '864 Patent is invalid or unenforceable.

The issue presented to this Court involves the proper scope of the '864 Patent. As will be discussed, the parties are in agreement as to many facets of the instant action. The issue that the parties disagree on, however, is the proper interpretation of the '864 Patent.

BACKGROUND

The '864 Patent, which through assignment is enforceable by Chembio, describes a device which obtains a liquid specimen. Pl.'s 56.1 Stmt. para. 1; Def.'s 56.1 Stmt. para. 1. The patent contains 11 claims which includes two independent claims. Pl.'s 56.1 Stmt. para. 5. Def.'s 56.1 Stmt. para. 5. The first independent claim, Claim 1, provides as follows:

1. A method for collecting a sample of a liquid specimen for analytical testing *consisting essentially of* the steps of:

bringing into contact with a liquid specimen to be tested an open capillary end of a sample container, and drawing said specimen into said capillary end, said sample container having an open top with a chamber disposed between said capillary end and said open top, said chamber including means therein for analytical testing;

placing said capillary end into a vial containing an analytical testing reagent and forcing said reagent into said open end;

mixing said liquid specimen with said reagent in said capillary; and

drawing said liquid specimen and said reagent through said capillary end into said chamber whereby said liquid specimen and said reagent contact said means for analytical testing and said liquid specimen is analyzed.

Pl.'s 56.1 Stmt. para. 6; Def.'s 56.1 Stmt. para. 6 (emphasis added). The second independent claim, Claim 6, provides as follows:

6. A sample collecting kit *consisting essentially of* a sample container having a capillary with an open end and an open top with a chamber disposed there between, said chamber including means therein for analytical testing; and, a vial having an open end for receiving said capillary therein, said vial including an analytical testing reagent therein, said open end including means for forcing the reagent into the capillary and means to mix liquid with the reagent.

Pl.'s 56.1 Stmt. para. 7; Def.'s 56.1 Stmt. para. 7 (emphasis added). These two independent claims were present when the initial patent application was filed. Pl.'s 56.1 Stmt. para.para. 8-10; Def.'s 56.1 Stmt. para.para. 8-10. However, the language "consisting essentially of" was not included in the original claim language.

During the application process of obtaining the patent, commonly referred to as prosecution, the patent examiner required several changes to the patent. In the first office action, the examiner determined that the patent application described two devices, a single capillary device and a double capillary device, and required the applicant to select one of the devices for patenting. Pl.'s 56.1 Stmt. para. 11; Def.'s 56.1 Stmt. para. 11. Thereafter, an election was made to pursue the single capillary device by cancelling the claims related to the double capillary device. Pl.'s 56.1 Stmt. para. 12; Def.'s 56.1 Stmt. para. 12.

The second office action related to indefiniteness for failing to particularly point out and distinctly claim the subject matter of the invention. Pl.'s 56.1 Stmt. para. 13; Def.'s 56.1 Stmt. para. 13. Specifically, the examiner rejected Claims 1 through 5 stating is was "not clear how the sample is removed from the capillary, mixed with the testing reagent and again drawn into the capillary tube for analysis (e.g., there are no steps claimed to accomplish these function[s])." Pl.'s 56.1 Stmt. para. 14; Def.'s 56.1 Stmt. para. 14. The examiner also stated that some of claims were anticipated by a piece of prior art, namely U.S. Patent No. 4,635,488 ("Kremer Patent"). Pl.'s 56.1 Stmt. para. 15; Def.' s 56.1 Stmt. para. 15. According to the examiner, the Kremer Patent described a device with a "capillary nib end (12) attached to a chamber (11) that has an open top and accommodates a means for analytical testing (50).... [A] method of use is taught where the sample is absorbed by the nib which is contacted with a reagent." Further, the examiner rejected Claims 3 through 5 and 7 through 10 as being obvious in light of the Kremer Patent and a PHOSITA. FN1 Pl.'s 56.1 Stmt. para. 16; Def.'s 56.1 Stmt. para. 16. The examiner stated that a PHOSITA would know that a

fragile foil cover would be used to cover reagent containers. *See* id.

FN1. PHOSITA is an acronym commonly used by patent attorneys as shorthand for a person having ordinary skill in the art which is language directly from the applicable statute. *See* 35 U.S.C. s. 103(a).

In response to the second office action an amendment to the patent was submitted. Pl.'s 56.1 Stmt. para. 17; Def.'s 56.1 Stmt. para. 17. The amendment largely added language to both Claims 1 and 6. Pl.'s 56.1 Stmt. para.para. 18-19; Def.'s 56.1 Stmt. para.para. 18-19. The amendment contained argument to the examiner that the Kremer Patent taught "a body fluid sampling device which includes a hollow tube with a solid, porous, water-wettable body which includes an end tip 28 extending beyond the hollow tube from coming into contact with a liquid specimen to be analyzed." Pl.'s 56.1 Stmt. para. 20; Def.'s 56 .1 Stmt. para. 20. An attempt was also made to distinguish the application from the Kremer Patent. The applicant stated that the Kremer Patent contained a "solid porous body 52 or 52a ... at the distal end of the an analysis element, such as a strip 44 or column 46, which is disposed within the chamber" while the application did not. Pl.'s 56.1 Stmt. para. 21; Def.'s 56.1 Stmt. para. 21. Saliva points out that the applicant did not disclaim an invention that excluded a lower filter, such as the one contained in the Barrel Device. Def.'s 56.1 Stmt. para. 61.

In the third office action-in this case, a final office action-the examiner maintained the unpatentability of the application because of the Kremer Patent. Pl.'s 56.1 Stmt. para. 22; Def.'s 56.1 Stmt. para. 22. The examiner wrote "[a] pplicants state Kremer teaches additional elements, such as porous bodies ... and do not teach the claimed capillary tube. The office maintains that Kremer teaches the porous bodies with the capillary tube. The instant claims are open and do not exclude the additional elements taught by Kremer." Pl.'s 56.1 Stmt. para. 23; Def.'s 56.1 Stmt. para. 23. Thereafter, the applicants, utilizing a procedure known as Amendment After Final Rejection, addressed the examiner's concern by changing the claims to specifically state that the sample container did not include a porous absorbent material. Pl.'s 56.1 Stmt. para. 24; Def.'s 56.1 Stmt. para. 24. They also wrote in the submission that the application was an improvement over Kremer because it did not use a porous absorbent material and, therefore, overcame the several limitations associated with the use of an absorbent material. Pl.'s 56.1 Stmt. para.para. 25-27; Def.'s 56.1 Stmt. para.para. 25-27. The applicants then described where in their specification those limitations were listed. Pl.'s 56.1 Stmt. para. 28; Def.'s 56.1 Stmt. para. 28. According to Saliva, when the applicant distinguished the application from Kremer it was not stated that the absorbent material would not be present in the test chamber. Def.'s 56.1 Stmt. para. 62. Rather, the applicant stated "[i]t also clear that the capillary end of the sample container in the instant invention, being suitable to draw a liquid specimen by capillary action as a result of surface tensions between the liquid and the surface of the capillary tube per se, is neither the same nor equivalent to Kremer's hollow tube. Kremer's hollow tube has a nib ... and the nib is made of an absorbent porous material." Def.'s 56.1 Stmt. para. 63.

In the fourth correspondence from the United States Patent and Trademark Office ("PTO"), the examiner wrote that the amendments would not be made because they were new matter. Pl.'s 56.1 Stmt. para. 29; Def.'s 56.1 Stmt. para. 29. The examiner noted the application did not contain any references to the exclusion of porous absorbent material. *See* id. The applicant then filed a Continued Prosecution Application ("CPA")-a procedural method to continue the prosecution of the patent after a final office action when new matter is found by the PTO-including an amendment which deleted the word porous from the claims as it was not supported by the disclosure. Pl.'s 56.1 Stmt. para. 30; Def.'s 56.1 Stmt. para. 30. The applicant reasserted to the PTO the same arguments which were made in the Amendment after Final Rejection. Pl.'s 56.1 Stmt. para. 31; Def.'s 56.1 Stmt. para. 31. To wit, that the Kremer Patent does not teach

every element of the application including the sample container not including an absorbent material. Pl.'s 56.1 Stmt. para.para. 32-34; Def.'s 56.1 Stmt. para.para. 32-34, 65.

The fifth office action again rejected the application. The examiner stated that Claims 1 through 11 of the application made claims as to material which was not disclosed in the specification. Pl.'s 56.1 Stmt. para. 35; Def.'s 56.1 Stmt. para. 35, 66. The examiner wrote that "[t]he original specification does teach disadvantages associated with the use of an absorbent material but never specifically excludes the presence of an absorbent.... If [a]pplicants were to remove the above claim language and use 'consisting essentially of' in the preamble rather than 'comprising' ... the [Kremer Patent] will be overcome." Id. The applicants made the suggested changes to the application and the patent was allowed. Pl.'s 56.1 Stmt. para. 36; Def.'s 56.1 Stmt. para. 36.

The Barrel Device includes a barrel-shaped container with a test strip contained therein. Pl.'s 56.1 Stmt. para.para. 37-38; Def.'s 56.1 Stmt. para.para. 37-38. On the test strip there is a reaction that takes place-described as a diagnostic assay. Pl.'s 56.1 Stmt. para. 39; Def.'s 56.1 Stmt. para. 39. The parties are in some dispute as to whether both ends of the test strip are separated from openings at either end of the barrel by filters. Pl.'s 56.1 Stmt. para. 40; Def.'s 56.1 Stmt. para. 40. Chembio refers to the filters as the upper and lower filters, again Saliva disputes whether the upper filter is truly a filter. Pl.'s 56.1 Stmt. para. 41; Def.'s 56.1 Stmt. para. 41. Chembio lists General Polymeric Corp. and Porex as their suppliers of the lower and upper filters, Saliva states they have had no discovery and reserves all rights. Pl.'s 56.1 Stmt. para. 42; Def.'s 56.1 Stmt. para. 42.

Chembio asserts that the lower and upper filters have porosity of 60 microns and are absorbent. Pl.'s 56.1 Stmt. para. 43; Def.'s 56.1 Stmt. para. 43. Saliva states that they do not have a sample of the device but that the lower filter must be minimally absorbent so that whatever is being sampled by capillary action, can then be sent into the analytical area of the device. Pl.'s 56.1 Stmt. para. 44; Def.'s 56.1 Stmt. para. 44. Chembio further asserts that when a sample is taken with the Barrel Device the lower filter absorbs some of the sample. Pl.'s 56.1 Stmt. para. 45. Saliva counters that the filter is a filter barrier and that while it might "get[ ] wet" it has no absorptive properties. Def.'s 56.1 Stmt. para. 45. Further, the device works equally well with, or without, the lower filter though it splatters less with the filter in place. *See* id.

It is undisputed that after a sample is obtained the tip of the Barrel Device is then forced into a vial that contains a buffering solution, and the solution is forced through the opening of the tip to mix with the sample. Pl.'s 56.1 Stmt. para. 46; Def.'s 56.1 Stmt. para. 46. The following facts are disputed: (1) whether the lower filter absorbs any of the sample when the buffering solution is forced through the opening, (2) the function of the lower filter when the mixture of the solution and sample is within the container, (3) the upper filter's interaction with the sample, and (4) the functionality of the device without the lower filter in place. Pl.'s 56.1 Stmt. para.para. 47-51; Def.'s 56.1 Stmt. para.para. 47-51.

Chembio states that the Barrel Device did not provide valid tests when the lower filter is removed. Pl.'s 56.1 Stmt. para. 52. Tests were performed by Chembio, without the lower filter in place, on the devices. *See* id. In order for a test to be valid a control line must appear on the test strip. Pl.'s 56.1 Stmt. para. 53. According to Chembio, during the tests there were failures where the control line did not appear. Pl.'s 56.1 Stmt. para. 54. Moreover, the tests revealed that the sample was not properly absorbed onto the test strip. Pl.'s 56.1 Stmt. para. 55. Saliva argues that they have not been privy to the test results through discovery and, thus, are unable to fully comment on Chembio's tests. Def.'s 56.1 Stmt. para.para. 52-55.

Finally, Chembio's tests, with the lower filter in place, all had valid results. Pl.'s 56.1 Stmt. para. 57. These valid test results occurred at a rate which is in conformance with the clinical studies. *See* id. Chembio asserts that the tests prove that without the filters the Barrel Device does not properly function. Pl.'s 56.1 Stmt. para.para. 58-59. Saliva again asserts they have not had discovery and cannot meaningfully comment on the tests. Def.'s 56.1 Stmt. para.para. 57-59.

LEGAL STANDARDS

Resolution of patent infringement claims requires a two-step analysis. First, the court must construe the meaning of the patent claim to determine its meaning; and second, the patent claim must be compared to the accused design to determine if there has been an infringement. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The first question presents a legal question to be resolved by the courts while the second question is generally reserved for a fact finder. *See Markman,* 52 F.2d at 981 (noting, however, that the court may use its construction of the claim in framing its jury charge as well as in deciding dispositive motions).

In order to assist the Court in interpreting the claims set forth in the patent, it may hold an evidentiary hearing. *See id.; see also* MediaCom Corp. v. Rates Technology, Inc., 4 F.Supp.2d 17, 21-22 (D.Mass.1998) ("These hearings run the gamut from mid-trial sidebar conferences that undergird relevance rulings ... to virtual mini-trials extending over several days and generating extensive evidentiary records.") (citations omitted).

As noted by Judge Barbara Jones in the Southern District, "[c]laim construction requires a degree of imagination from the Court." Novo Nordisk A/S v. Becton Dickinson & Co., No. 96-CV-9506, 2000 WL 294852, at (S.D.N.Y. Mar. 21, 2000). Imagination is required because the Court first must obtain "sufficient currency" with the technical aspects of the patent and the accused device in order to determine how the claims would be read by a person of ordinary skill in the art. *Id*. (citing Wiener v. NEC Electronics, Inc., 102 F.3d 534, 549 (Fed.Cir.1996)). Imagination is also required because the Court must construe the claim as of the date of the application for the patent. *See id*. (citing Wiener, 102 F.3d at 539).

In construing a patent claim, a court must first consider intrinsic evidence, but also may resort to extrinsic evidence such as expert testimony if unable to make a determination based solely on the intrinsic evidence. *See* Vitrionics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). Intrinsic evidence consists of the language of the patent itself and its accompanying claims, the specifications accompanying the claims, and the prosecution history before the PTO. *Id*. Together, these sources are "the most significant source of the legally operative meaning of disputed claim language." *Id*.

On the other hand, extrinsic evidence consists of expert testimony, dictionaries, or learned treatises. Extrinsic evidence may only be considered when, after the Court has analyzed the intrinsic evidence, ambiguity remains. *Id*. at 1583; *see* TM Patents, L.P. v. Int'l Bus. Mach. Corp., 72 F.Supp.2d 370, 374 (S.D.N.Y.1999). "The court may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." Karlin Tech. Inc. v. Surgical Instruments, Inc., 177 F.3d 968, 971 (Fed.Cir.1999). Thus, extrinsic evidence may not "contradict the manifest meaning of the claims as set forth, even by implication, in the specifications and prosecution history." Novo Nordisk, 2000 WL 294852, at *2 (citing Vitrionics, 90 F.3d at 1584-85).

It is axiomatic that the language of the claim defines its scope. *See* Mantech Environ. Corp. v. Hudson Environ. Servs., Inc., 152 F.3d 1368, 1373 (Fed.Cir.1998). Interpretation of claims is similar to statutory construction. The language and phrasing of the claims is the starting point of the analysis. *See* Bell Commc'n Research, Inc. v. Vitalink Comm. Corp., 55 F.3d 615, 620 (Fed.Cir.1996). "[W]ords of a claim are to be construed in accordance with their ordinary meaning to persons in the relevant field of technology, unless it appears that the inventor used them otherwise." T.M. Patents, 72 F.Supp.2d at 380 (citing Bell Commc'n Research, Inc., 55 F.3d 615, 620 (Fed.Cir.1995)). However, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition is clearly stated in the patent specification or file history. Novo Nordisk, 2000 WL 294852, at *1.

DISCUSSION

At issue in this case is the proper scope of the '864 Patent. The scope of the patent must be determined in light of the prosecution history and the phrase "consisting essentially of" which the patent was amended to include. The parties agree in large part as to the procedural history of the '864 Patent' s prosecution. They disagree, however, in how to interpret the final change to the patent application which caused the examiner to allow the patent.

The '864 Patent relates to a device which can obtain a liquid sample and to the method for collecting a sample of liquid. The prior art, and in fact the '864 Patent, disclose that devices that currently existed used a material to absorb the liquid to be tested. The '864 Patent's disclosure discussed the disadvantages of absorbent material and sought to invent a better apparatus and method. According to the patent, capillary action was to be used to draw the liquid sample into the device. After the liquid sample was in the device an analytical material would be exposed to the liquid and a reagent. Indication lines would then appear on the material to provide results.

As described above, there was a somewhat lengthy prosecution of the instant patent with several written comments, and responses to, the PTO. Most importantly, the examiner cited the Kremer Patent and rejected the application. The Kremer Patent describes a similar device that does not utilize capillary action. Apparently, based on the multiple rejections from the examiner, there was a concern that the claims did not specifically exclude the use of the absorbent material in obtaining the sample. Both the examiner's comments to the applicant and the applicant's responses back to the PTO were directed at this issue.

On December 21, 1998, the examiner again rejected the applicant's claims but stated that the claims would be allowable if the claim language was changed from "said sample container not including an absorbent" to "consisting essentially of." The examiner's comments are noteworthy because the examiner was solving an issue with the patent. The issue with the patent was that it contained a negative limitation which, although possible, should be avoided. The suggested phrase is known as a partially open phrase that allows the inclusion of components not listed in the claim as long as they do not "materially affect the basic and novel properties of the invention." PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351 (Fed.Cir.1998). Here, the examiner was moving the application to allowability by showing one way the applicant could avoid the prior teachings of the Kremer Patent without having a negative limitation contained in the claims.

The effects of the wording change are significant, but not as drastic as Saliva suggests. The change limits the '864 Patent's claims to a device which only utilizes capillary action in the capture of a sample. Chembio argues that the change should be more broadly construed to preclude the '864 Patent from containing any absorbent material in the collection area in the analytical area of the device. This Court does not agree.

This Court notes in patent law, as in most other substantive areas of law, a disclaimer can only be made if the scope is clear and unambiguous. *See* Middleton Inc. v. Minnesota Mining and Mfg. Co., 311 F.3d 1384 (Fed.Cir.2002); Northern Telecom Ltd. v. Samsung Elec. Co., 215 F.3d 1281 (Fed.Cir.2000) (stating that a court cannot narrow a claim where the prosecution history supports multiple interpretations). Chembio argues that the matter disclaimed from the patent included any absorbent material contained in the device. However, that argument does not comport with the prosecution history. Rather, having read and reviewed the correspondence between the applicant and the PTO, this Court finds that the disclaimer was limited to the tip of the device where the sample is drawn into the device. The absorbent material described in the Kremer Patent, the discussion of the Kremer Patent, and the applicant's submissions to the PTO all discuss the sample location. There is nothing in the record before this Court to conclude that the applicant or the examiner was referring to absorbent material throughout the device.

Moreover, as Saliva argues to the Court, Chembio's suggested interpretation would render the patent internally inconsistent. Saliva argues that if the amendment to the application precluded any absorbent material from being present in the device it would cease to have function. The claim includes a "chamber including means therein for analytical testing." The language "means therein" implicates the means plus function rules. 35 U.S.C. s. 112. Thus, the specification of the '864 Patent must contain the manner in which the device is to function. IMS Tech., Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1430 (Fed.Cir.2000) ("[C]laim construction of a s. 112, P6 limitation includes identifying the claimed function and determining the corresponding structure or act disclosed in the specification."). The '864 Patent specification describes test strips which are absorptive. Both parties state in their briefs that the analytical strips are anticipated by the claim language. Thus, this Court finds that the exclusion of absorptive material cannot include the entire device.

Chembio also argues to this Court that any errors in drafting, vis-a-vis amendments, by Saliva should be construed against them. *See* Hoganas AB v. Dresser Indus. Inc., 9 F.3d 948, 951 (Fed.Cir.1993). Thus, Chembio asserts the final amendment where Saliva utilized the "consisting essentially of" language should be construed broadly to imply that no material with absorbent properties can be present in the device. This argument is not convincing. As discussed above, if Chembio's interpretation of the language were adopted it would render the patent meaningless. In addition, the prosecution history clearly evinces the intent of the examiner and the applicant to only exclude absorbent material from the tip of the device.

The parties are in disagreement as to the construction and operation of the allegedly infringing Barrel Device. This issue, however, is not yet ripe for adjudication. The 56.1 statements of facts contain disputed findings relative to the design and operation of the Barrel Device. Since there was no discovery prior to the instant motion being filed, this Court is unable to make any ruling with regard to the device. Accordingly, the instant decision is limited to claim construction.

CONCLUSION

For the reasons stated herein, the Court finds that the '842 Patent is limited in scope by the prosecution history. The proper interpretation of the prosecution history is that the sampling part of the invention does not contain absorbent material. There may be absorbent material, however, in another part of the device. Having made a determination relative to claim construction, the motions for summary judgement are terminated.

SO ORDERED

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