

United States District Court,
W.D. Washington, at Seattle.

BIOMEDINO, LLC,
Plaintiff.

v.
WATERS TECHNOLOGIES, CORPORATION, et al,
Defendants.

No. C05-0042L

Nov. 22, 2005.

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ORDER CONSTRUING CLAIMS OF THE '502 PATENT

ROBERT S. LASNIK, District Judge.

Plaintiff Biomedino, LLC, is the owner of United States Patent No. 6,602,502 ("the patent" or "the '502 patent"), which relates to "improved immunoassays of psychotomimetic drugs, tetrahydrocannabinols and other psychoactive drugs." Col. 1, ll. 15-17. Plaintiff's invention utilizes the haptenic properties of psychoactive material (properties which had not previously been recognized or exploited) to develop improved methods of identification, diagnosis, and treatment. Col. 2, ll. 10-41. The claims at issue in this litigation were added to the original patent application over a number of years and are written more broadly than the original claims insofar as they describe an invention capable of removing from an unspecified fluid an unspecified constituent in the fluid. The Patent and Trademark Office ("PTO") initially rejected the new claims at least in part on the ground that the written description of the invention, which focused on its use in removing psychoactive drugs from the blood of living mammals, was of more narrow scope than the new claims. After arguing that one skilled in the art would recognize in the admittedly narrow specification a description of the more general invention now claimed, plaintiff was awarded the '502 patent. Plaintiff alleges that defendants have infringed the '502 patent by making, using, and selling products that utilize separation, affinity, and chromatography systems which embody at least one claim of the patent.

Determining whether a particular product or method infringes an existing patent involves a two-step

analysis. The Court must first identify the proper construction of the asserted patent claim, an exercise which the Supreme Court has determined is a matter of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384-91, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). After the claim has been properly construed, the fact finder determines whether the accused device infringes the claim. The Federal Circuit recently reiterated that, although the claims of the patent define the invention to which the patentee is entitled the right to exclude, the claim construction analysis must focus on how a person of ordinary skill in the art would understand the claim terms after reading the entire patent. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1321, 1323 (Fed.Cir.2005).

It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention-the inventor's lexicography-must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, *viz.*, the patent specification and the prosecution history.

Phillips, 415 F.3d at 1313 (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed.Cir.1998)).

As all parties in this litigation recognize, the *Phillips* decision sets out a framework for claim construction that synthesizes prior law while rejecting the *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193 (Fed.Cir.2002), line of cases because they put too much emphasis on extrinsic evidence. The Federal Circuit highlighted the primacy of intrinsic evidence, rather than dictionaries, encyclopedias, and treatises, in the claim construction analysis. The claims themselves provide "substantial guidance" regarding the meaning of particular terms by providing a context for the contested terms and comparisons against which to measure the scope of the various claims. *Phillips*, 415 F.3d at 1314-15. Unless the meaning of the claim language is "readily apparent even to lay judges" (*Phillips*, 415 F.3d at 1314), the court should "rely heavily" on the patentee's written description of the invention (*Phillips*, 415 F.3d at 1317), giving the claims "their broadest reasonable construction 'in light of the specification as it would be interpreted by one of ordinary skill in the art'" (*Phillips*, 415 F.3d at 1316 (quoting *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed.Cir.2004))). Other evidence of how the patentee and the PTO understood the claims contained in the prosecution history can also inform the meaning of the claim language, although this resource sometimes lacks the clarity of the patent itself. *Phillips*, 415 F.3d at 1317.

Finally, the Federal Circuit has "authorized district courts to rely on extrinsic evidence, which 'consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.'" *Phillips*, 415 F.3d at 1317 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed.Cir.1995)). Such evidence is especially useful for helping the court understand the underlying technology, explaining how an invention works, and establishing the way in which one skilled in the art would use the claim terms. *Phillips*, 415 F.3d at 1318. Courts should not, however, put too much emphasis on extrinsic evidence as the starting point for construing claim terms because such evidence "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Phillips*, 415 F.3d at 1319. The claim construction methodology set forth in *Texas Digital*, which encouraged district courts to rely on dictionary definitions when ascertaining the ordinary meaning of particular claim terms, with recourse to the specification serving only as a check on the dictionary definition, was rejected.

The main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent. Properly viewed, the "ordinary meaning" of a claim term is its meaning to the ordinary artisan after reading the entire patent. Yet heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification.

Phillips, 415 F.3d at 1321.

Even while rejecting the methodology of *Texas Digital*, the Federal Circuit acknowledged that the purpose underlying that decision, namely to avoid "one of the cardinal sins of patent law-reading a limitation from the written description into the claims," was sound. Phillips, 415 F.3d at 1319-20, 1323 (quoting *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1340 (Fed.Cir.2001)). The court also recognized:

that the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice. However, the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on understanding how a person of ordinary skill in the art would understand the claim terms. For instance, although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments. In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment. That is not just because section 112 of the Patent Act requires that the claims themselves set forth the limits of the patent grant, but also because persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments.

Phillips, 415 F.3d at 1323 (citations omitted).

In this litigation, plaintiff alleges that defendants have infringed claims 13-17 and claim 40 of the '502 patent. Independent claim 13 reads as follows:

13. A device comprising a passage; binding means in said device for binding a species substantially specifically, said binding means being in fluid communication with said passage; exposure means in said device for exposing said species to said binding means and for preventing said binding means from leaving said device; closed regeneration means for separating said species from said binding means for reuse of said binding means in said device; valving for selectively connecting said closed regeneration means in fluid communication with said binding means, and control means for automatically operating said valving.

Claims 14-17 add various elements or limitations to the invention described in claim 13. Claim 40 independently claims the closed regeneration device, stating:

40. A closed regeneration device for separating a molecule bound substantially specifically to a binding species for reuse of said binding species, said regeneration device comprising a first reagent, a first valve selectively connecting said first reagent in fluid communication with said molecule bound to the binding species to separate said molecule from said binding species, a second reagent, a second valve selectively

connecting said second reagent in fluid communication with said binding species to return said binding species to a regenerated condition, and control means for automatically operating said valves.

Having reviewed the memoranda, declarations, and exhibits submitted by the parties (including the Joint Claim Chart submitted on September 9, 2005) and having heard the arguments of counsel and the additional evidence offered at the hearing on November 17, 2005, the Court finds as follows:

(1) The term "binding means" is a means-plus-function element of claims 13-17, meaning that the patentee used functional language in the claim without reciting the specific structure that performs the function. Section 112, paragraph 6 of the Patent Act governs the interpretation of means-plus-function elements and the Court must review the specification "as a whole to determine the structure capable of performing the claimed function." FN1 *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1379 (Fed.Cir.2001)). "A structure disclosed in the specification qualifies as 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim." *Default Proof Credit Card Sys., Inc. v. Home Depot USA, Inc.*, 412 F.3d 1291, 1298 (Fed.Cir.2005) (quoting *B. Braun Med. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed.Cir.1997)).

FN1. "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, para. 6.

The function performed by the binding means of claims 13-17 is to bind a species substantially specifically. The specification identifies the structures corresponding to this function in a number of places, the broadest statement of which is at Col. 12, ll. 1-4. The Court finds that the species used for binding purposes (*i.e.*, the "binding means") "is a hapten, antigen including a hapten conjugated to a carrier[] or antibody ..." and the equivalents thereof.

(2) The term "exposure means" is also a mean-plus-function element of claims 13-17. The Court must review the specification to determine whether the patentee adequately disclosed a corresponding structure that performs the identified functions, namely to expose a species to the binding means and to prevent the binding means from leaving the device. Defendants argue that the only structure that is "clearly linked" to the exposure function of claims 13-17 is found in Figure 6 and Examples 11 and 12 (Col.9, 1.41-Col.11, 1.59) wherein the patentee describes a two-chamber device with a semi-permeable membrane separating the first chamber from the second (Col.10, ll.23-27, 47-49). But Example 13 and the referenced Figure 7 also describe alternative structures for exposing a species to the binding means and preventing the binding means from escaping from the device. The patentee disclosed a single column with an internal matrix to which the binding means is attached. The exposure means in this example may include a synthetic polymer such as polystyrene-latex (Col.12, ll.4-7), a solid phase coating (Col.12, ll.7-9), the wall of the column (Col.12, ll.15-18), a honeycomb (open porosity) matrix (Col.12, ll.22-23), a fill of plastic beads (Col.12, 1.23), and the equivalents thereof.

Defendants maintain that the structures identified in Example 13 and Figure 7 do not "correspond" to the exposure function described in claims 13-17 because the invention embodied in Example 13 and Figure 7 does not include all of the elements of claims 13-17, primarily the closed regeneration means. The issue is not whether Figure 7 faithfully depicts all of the elements of claim 13: rather, the Court must determine

what structure is disclosed in the specification that corresponds to the exposure function. The patentee clearly associates the exposure chambers of both Figure 6 and Figure 7 with the exposure function recited in claims 13-17 and is entitled to a construction of "exposure means" which takes into consideration all of the corresponding structures recited in Examples 11-13 and Figures 6 and 7.

(3) The term "closed regeneration means" of claims 13-17 is a means-plus-function element with the function of separating a species from its binding means so that the binding means can be reused. This function, to which all parties subscribe, does not turn on whether the regeneration means is "open" or "closed." The Court therefore agrees with plaintiff that "regeneration means" should be construed using the means-plus-function analysis and that "closed" should be separately construed in keeping with its ordinary meaning to one skilled in the art.

Plaintiff has disclosed two structures in the specification that are capable of performing the regeneration function of claims 13-17: the two-chamber, semi-permeable membrane system described in Figure 6 and Example 12 (Col. 11, ll. 32-35 and 44-50) and the single-chamber device described in Figure 7 and Example 13 (Col. 11, l. 66-Col. 12, ll. 1 and 32-35). "[P]roper application of s. 112, para. 6 generally reads the claim element to embrace distinct and alternative described structures for performing the claimed function ." *Creo Prods., Inc. v. Presstek, Inc.*, 305 F.3d 1337, 1346 (Fed.Cir.2002). Both of the devices disclosed in Figures 6 and 7 can be used to strip a species from its binding means so that the binding means can be reused. Both structures are therefore included in the meaning of "regeneration means."

In the context of the patent at issue here, "closed" means within or part of the device, as opposed to outside or separate from the device.

(4) Claims 13-17 and claim 40 provide for "control means for automatically operating said valving." Plaintiff argues that the phrase "control means" itself identifies sufficient structure to satisfy s. 112, para. 6 because one of skill in the art would understand that "control" refers to an instrument used to operate, regulate, or guide a machine or vehicle. Plaintiff's Opening Brief at 19 (Dkt.# 90). If a claim element contains the word "means" and recites a function, there is a strong presumption that the element is a means-plus-function element. *Enviro Corp. v. Clestra Cleanroom, Inc.*, 209 F.3d 1360, 1364 (Fed.Cir.2000). The presumption can collapse if the claim term recites no function or recites sufficient structure to perform the function. *Apex Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364, 1372 (Fed.Cir.2003). The control means element of the claims at issue here clearly identifies a function: to automatically operate valving. To determine whether the element discloses sufficient structure to perform this function, the court examines whether the term, "as the name for the structure, has a reasonably well understood meaning in the art." *Apex*, 325 F.3d at 1372 (quoting *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed.Cir.1996)). Contrary to plaintiff's argument, claims 13-17 and claim 40 do not recite any structure for operating the valves. The reference to "control" is simply an adjective describing "means:" it is not a structure or material capable of performing the identified function. Where the presumption applies, courts have generally required a fairly detailed recitation of structure to take a "means for" claim element out of the scope of s. 112, para. 6. *See, e.g.*, *Phillips*, 415 F.3d at 1311 (claim element beginning with "further means disposed inside the shell for increasing its load bearing capacity" is not means-plus-function format because the claim subsequently identifies "internal steel baffles" as the structure that performs the function); *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1303-04 (Fed.Cir.1999) (construction of a claim element beginning with a "positioning means for moving said transducer ..." was not governed by s. 112, para. 6 where the claim specifically identified the underlying structures as including "two support arms ... a pivot shaft ... a positioning arm ... a bearing assembly ... a stepper motor ... means for operating said stepper

motor ... and a tensioned steel band ..."). The patentee's inclusion of the word "control" does identify structure and does not overcome the presumption that the "control means" element is subject to the means-plus-function analysis.

Having determined that the "control means" element of claims 13-17 and claim 40 is subject to s. 112, para. 6 of the Patent Act, the Court must determine whether the patentee "set forth in the specification an adequate disclosure showing what is meant by that language." Default Proof, 412 F.3d at 1298 (quoting *In re Donaldson Co.*, 16 F.3d 1189, 1195 (Fed.Cir.1994)). A failure to disclose adequate structure corresponding to the recited function means that the claim is of indefinite scope in violation of s. 112, para. 2 and is therefore invalid. Claims of a patent are afforded a statutory presumption of validity, however, which places the burden on defendants to establish by clear and convincing evidence any facts supporting a holding of invalidity. *Ultra-Tex Surfaces, Inc. v. Hill Bros. Chem. Co.*, 204 F.3d 1360, 1367 (Fed.Cir.2000). "Thus, a challenge to a claim containing a means-plus-function limitation as lacking structural support requires a finding, by clear and convincing evidence, that the specification lacks disclosure of structure sufficient to be understood by one skilled in the art as being adequate to perform the recited function." *Budde*, 250 F.3d at 1376-77.

The parties agree that the only references in the specification to the "control means" are the box labeled "Control" in Figure 6 and a statement that the regeneration process may be "controlled automatically by known differential pressure, valving and control equipment." Col. 11, ll. 55-58. "Whether or not the specification adequately sets forth structure corresponding to the claimed function necessitates consideration of that disclosure from the viewpoint of one skilled in the art." *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1376 (Fed.Cir.2001). Plaintiff argues that the "control equipment" mentioned at Col. 11, ll. 55-58 is the structure that corresponds with the "control means" element of the claims and that, given the state of the art at the time the patent issued, one skilled in the art could draw on his or her knowledge "to flesh out the '502 patent's reference to 'control.'" Plaintiff's Responsive Brief at 16. In particular, plaintiff identifies two prior art references which, taken together, show that one of ordinary skill in the art would understand that timers, actuators, switches, potentiometers, valves, capacitors, and their equivalents could be used to "control" the valves as described in claims 13-17 and claim 40.

Putting aside the fact that plaintiff failed timely to disclose the extrinsic evidence upon which its proposed construction relies, "[i]t is not proper to look to the knowledge of one skilled in the art apart from and unconnected to the disclosure of the patent." Default Proof, 412 F.3d at 1300 n. 2 (quoting *Med. Instrumentation & Diagnostics Corp. v. Electa AB*, 344 F.3d 1205, 1211-12 (Fed.Cir.2003)). The specification says nothing more than that unspecified equipment may be used to control the regeneration process.FN2 The fact that one skilled in the art could envision various types of equipment capable of automatically operating valves does not change the fact that no structure capable of performing that function was disclosed by the inventor. FN3 The issue is not whether prior art or a skilled artisan could supply a structure corresponding to the identified function: the inquiry under s. 112, para. 2 asks first "whether structure is described in specification, and, if so, whether one skilled in the art would identify the structure from that description." *Atmel Corp. v. Information Storage Devices*, 198 F.2d 1374, 1381 (Fed.Cir.1999)). *See also* Default Proof, 412 F.3d at 1302 ("while it is true that the patentee need not disclose details of structures well known in the art ..., the specification must nonetheless disclose some structure. Stated differently, the testimony of one skilled in the art cannot supplant the total absence of structure from the specification."). Because no structure corresponding to the specified function is described, defendants have shown by clear and convincing evidence that the ' 502 patent fails at the first hurdle. The failure to disclose a structure corresponding to the "control means" function makes claims 13-17 and claim 40 of indefinite

scope in violation of s. 112, para. 2 of the Patent Act. The Court cannot and will not remedy the patentee's failure by reading into the specification prior art references, dictionary definitions, or counsel's observations regarding what one skilled in the art would have understood.

FN2. In this context, the phrase "control equipment" is no more specific or defining than the phrase "control means." Neither phrase identifies the structures, materials, or mechanisms used to operate the valves described in claims 13-17 and claim 40.

FN3. Plaintiff has not offered expert testimony in support of its arguments regarding what one skilled in the art would understand from the phrase "control means" or "control equipment."

(5) The term "species" as used in claims 13-17 is not clearly defined in the specification. Although the inventor discusses haptens, antigens including a hapten conjugated to a carrier, and antibodies in the specification, there is no indication that the term "species" must be or should be limited to those molecules. The same term is used in claim 1 and subsequently narrowed in dependent claim 10 to include only haptens and antigens that are bound immunologically. "The presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips, 415 F.3d at 1315. In addition, the prosecution history clearly shows that the inventor was broadly claiming an invention capable of removing a constituent from a fluid, without limitation on the type of constituent. *See* Decl. of Wallace Wu, Ex. B at GE 00011495 ("claimed invention relates to a method and a device for removing a constituent from fluid"), GE 00011505-08 (claiming non-immunological specific binding systems of chemical species). Rather than simply using the specification to interpret the meaning of the disputed term, defendants seek improperly to import limitations from the specification into the claim. Defendants argue that cases such as *Nystrom v. Trex Co., Inc.*, 424 F.3d 1136 (Fed.Cir.2005), support such an importation. In *Nystrom*, however, both the specification and the prosecution history showed that the patentee intended to limit the broad language used in the claims. In the case at hand, the intrinsic record does not speak clearly as to the intent of the patentee: the claim language and the prosecution history support a broad reading of the term "species" while the examples provided in the specification could be read to narrow the claim terms. In such circumstances, the limitations of the preferred embodiment should not be read into broad claims that were presented to, debated with, and finally approved by the PTO after considering the very overbreadth objections raised by defendants here. Nor does the extrinsic evidence provided by Dr. Hermodson alter the analysis. Such evidence is generally less reliable than the patent and the prosecution history (Phillips, 415 F.3d at 1318) and, in this case, Dr. Hermodson's opinion that one skilled in the art would understand the term "species" to mean only "a hapten, antibody [sic], or antibody from the blood of a living mammal" is unsupported. He offers no explanation for such a limitation other than his apparent belief that it is compelled by the specification.

Defendants' argument that "species" must be limited to constituents from the blood of a living mammal fails for similar reasons. Although the specification discloses uses of the invention with catheters connected to the artery of a living mammal, there is nothing about the term "species" which requires such a limitation. The fact that the same term is used in claim 1 and further limited in claim 9 to describe the removal of "a species from the blood of the mammal" raises a presumption that this limitation is not inherent in the term "species." The prosecution history contains the patentee's argument that the invention is not limited to devices designed to draw blood from a living mammal and is instead capable of purifying any number of fluids from any number or sources. Decl. of Wallace Wu, Ex. B at GE 00011508-10.

Although the specification describes very specific embodiments of the invention, the intrinsic evidence does not support defendants' argument that the claims should be confined to those embodiments. As noted by the Federal Circuit in *Phillips*, such a finding is necessary "not just because section 112 of the Patent Act requires that the claims themselves set forth the limits of the patent grant, but also because persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments." *Phillips*, 415 F.3d at 1323.

(6) Defendants' proposed construction of the term "molecule" in claim 40 is equally unavailing. The term itself is not ordinarily limited to immunological constituents found in the blood of a living mammal and the intrinsic evidence neither compels nor supports such a limitation. The limitation in dependent claim 41 to a device "wherein the binding species binds the molecule immunologically" suggests that the molecule mentioned in claim 40 is not so limited. To the extent that the term "species" as used in claims 13-17 is the equivalent of the term "molecule" as used in claim 40, the patentee's express intent to claim an invention broad enough to cover non-immunological binding systems shows that defendants' importation of a limitation from the specification is not warranted.

(7) The term "passage" as used in claims 13-17 is not limited to a blood passage traveling from a living mammal through a dialysis system and back to the living mammal. "Passage" has a much broader ordinary meaning that is consistent with the broad nature of the claimed invention and the patentee's arguments before the PTO. The examples provided in the specification should not be imported into the claim, especially where other claims expressly limit the term "passage" to a "passage means for said blood." *See* claim 1.

(8) The phrases "binding a species substantially specifically" in claims 13-17 and "bound substantially specifically" in claim 40 mean that the constituent in the fluid is bound with a high specificity. The phrase does not require anything other than substantial specificity: defendants' attempt to require a strong or immunologic interaction based on the examples provided in the specification is improper in light of the broad claim language, other claims that require immunological binding (*see* claim 41), and the patentee's statements to the PTO regarding his intent to claim an invention broad enough to cover non-immunological binding systems.

(9) In light of the Court's construction of "closed regeneration means," no further construction of the phrase "closed regeneration device" is necessary.

(10) In light of the Court's construction of "species" and "binding a species substantially specifically," no further construction of the phrase "binding species" is necessary.

(11) In light of the Court's construction of "species," "binding means," "binding a species substantially specifically," and "molecule," no further construction of the phrases "a first reagent ... to release said species from said binding means" or "a first reagent ... to separate said molecule from said binding species" is necessary.

(12) In light of the Court's construction of "exposure means," "binding means," and "species," no further construction of the phrase "means for exposing said binding means to a reagent to release said species from said binding means" is necessary.

It is so ORDERED.

W.D.Wash.,2005.

Biomedino, LLC v. Waters Technologies, Corp.

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