

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

v.

KURIN, INC.,

Defendant.

Civil Action No. 19-97-CFC-CJB

Douglas E. McCann and Robert M. Oakes, FISH & RICHARDSON P.C.,
Wilmington, Delaware; Mathias W. Samuel, FISH & RICHARDSON PC.,
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Counsel for Defendant

MEMORANDUM OPINION

May 20, 2020
Wilmington, Delaware


COLM F. CONNOLLY
UNITED STATES DISTRICT JUDGE

Plaintiff Magnolia Medical Technologies, Inc. has sued Defendant Kurin, Inc. for infringing four patents that teach apparatus, methods, and/or systems related to the collection of bodily fluids for laboratory analysis. I held a claim construction hearing on April 15, 2020 and made a number of oral rulings. Two claim construction issues remain in dispute.

A. “Diverter”

The first issue concerns the term “diverter” in claims 1 and 21 of U.S. Patent No. 9,855,001 (the #001 patent). Claim 1 reads as follows:

An apparatus for obtaining a bodily fluid sample from a patient with reduced contamination, the apparatus comprising:

- a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient; and
- a diverter having an inlet, a first outlet in fluid communication with the reservoir, and a second outlet, the inlet configured to be fluidically coupled to the patient, the diverter operable in a first operating mode in which an initial volume of bodily fluid can flow from the inlet to the first outlet, and a second operating mode in which: a) a subsequent volume of bodily fluid can flow from the inlet to the second outlet, and b) the initial volume of bodily fluid is prevented from flowing to the second outlet,*

the diverter configured to transition from the first operating mode to the second operating mode as a result of the initial volume of bodily fluid flowing from the patient and substantial pressure equalization, thereby sequestering in the reservoir contaminants present in the initial volume of bodily fluid, thereby reducing contamination of the subsequent volume of bodily fluid withdrawn from the patient.

#001 patent at 11:8–32 (emphasis added).

Claim 21 teaches a similar apparatus that has

a diverter fluidically coupled to the needle, the diverter including an inlet, an outlet, and a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient, the diverter defining a first fluid flow path that allows the initial volume of bodily fluid to flow from the patient until pressure substantially equalizes, and a second fluid flow path that allows a subsequent volume of bodily fluid to flow from the inlet to the outlet after the initial volume of bodily fluid has been sequestered, the diverter configured to divert the flow of bodily fluid to the second fluid flow path as a result of receiving the initial volume of bodily fluid from the patient and substantial pressure equalization

Id. at 13:11–23 (emphasis added). Claim 28, which recites another apparatus with a diverter, depends from claim 21.

Kurin argues that I should construe all the asserted claims that require a “diverter” as “means-plus function” claims under 35 U.S.C. § 112, ¶ 6,¹ because

¹ Paragraph 6 of 35 U.S.C. § 112 was replaced by § 112(f) when the America Invents Act (AIA), Pub.L. No. 112–29, 125 Stat. 284 (2011) took effect on September 16, 2012. Because the provisional application resulting in the #001

the asserted claim limitations describe “diverter” in functional language without reciting sufficient structure to perform the described function. D.I. 59 at 45–46. Magnolia argues that construction of “diverter” is not necessary because its plain and ordinary meaning is apparent. Alternatively, Magnolia asks me to construe the term to mean “a component with an inlet and two outlet branches for directing the flow of fluid.” *Id.* at 40.

1. Legal Standards

Under § 112, ¶ 6 of the Patent Act, “[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”²

The privilege afforded by § 112, ¶ 6 to claim an element as a means to perform a function comes with a price, because the statute requires that functional claims “shall be construed to cover the corresponding structure, material, or acts described in the specification or equivalents thereof.” This requirement effectively imports

patent was filed before that date, I refer to the pre-AIA version of § 112.

² Although § 112, ¶ 6 literally applies only to a claimed “combination,” all inventions are effectively combinations, as “invention itself is the process of combining prior art in a nonobvious manner.” *In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998); *see also Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540 (Fed. Cir. 1983) (“Reference to ‘combination’ patents is . . . meaningless. Virtually all patents are ‘combination patents,’ if by that label one intends to describe patents having claims to inventions formed of a combination of elements. It is difficult to visualize, at least in the mechanical-structural arts, a ‘non-combination’ invention, i.e., an invention consisting of a *single* element. Such inventions, if they exist, are rare indeed.”).

into a claim covered by § 112, ¶ 6 structural limitations from elsewhere in the specification. Thus, patentees who choose to claim their invention in “means-plus-function” language limit the scope of their invention to the structure disclosed in the specification that performs the claimed function. *See Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1347 (Fed. Cir. 2015) (en banc) (“In enacting [§ 112, ¶ 6], Congress struck a balance in allowing patentees to express a claim limitation by reciting a function to be performed rather than by reciting structure for performing that function, while placing specific constraints on how such a limitation is to be construed, namely, by restricting the scope of coverage to only the structure, materials, or acts described in the specification as corresponding to the claimed function and equivalents thereof.”).

Federal Circuit precedent “has long recognized the importance of the presence or absence of the word ‘means’” when determining whether § 112, ¶ 6 applies to a claim limitation. *Id.* If “means” is used in the limitation in question, then there is a rebuttable presumption that § 112, ¶ 6 applies; if “means” is not used in the limitation, then there is a rebuttable presumption that § 112, ¶ 6 does not apply. *Id.* at 1348.

In *Williamson*, however, the Federal Circuit expressly rejected the notion that these presumptions are “strong” and it admonished district courts not to “blindly elevate[] form over substance when evaluating whether a claim limitation

invokes § 112, para. 6.” *Id.* The Court also emphasized in *Williamson* that determining whether § 112, ¶ 6 applies to a claim limitation turns on the language of the claims:

[T]he essential inquiry is not merely the presence or absence of the words “means” but whether the words of *the claim* are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure. When the claim uses the word “means,” our cases have been consistent in looking to the meaning of *the language of the limitation* in assessing whether the presumption is overcome. We have also traditionally held that when a claim term lacks the words “means,” the presumption can be overcome and § 112, para. 6 will apply if the challenger demonstrates that *the claim term* fails to “recite[] sufficiently definite structure” or else recites “function without reciting sufficient structure for performing that structure.”

Id. (emphasis added) (citations omitted) (second set of alterations in original).

This emphasis on looking only at claim language to determine if § 112, ¶ 6 applies to a claim limitation is consistent with the statute’s text, which allows “[a]n element *in a claim*” to “*be expressed* as a means or step.”

If the court determines that § 112, ¶ 6 applies, its next task is to define the scope of the “specified function” that is “expressed” in the claim limitation. After the court determines that definition, it proceeds to identify in the specification “the corresponding structure.” The Federal Circuit has interpreted the “corresponding structure” to mean the minimum structure necessary to perform the recited function. *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1257 (Fed.

Cir. 1999) (holding that § 112, ¶ 6 does not “permit incorporation of structure from the written description beyond that necessary to perform the claimed function.”).

2. Analysis

Claim 1 recites a “diverter configured to transition from the first operating mode to the second operating mode.” Claim 21, from which claim 28 depends, recites a “diverter configured to divert the flow of bodily fluid to the second fluid flow path.” Neither limitation uses the word “means” and therefore there is a rebuttable presumption that § 112, ¶ 6 does not apply. I find, however, that the presumption is overcome because both limitations express a means to perform a function and the claims in which they reside do not recite structure sufficient to perform that function. In both cases, the function is to divert (or direct) fluid flow from one fluid flow path to a second fluid flow path.

It is true, as Magnolia argues, that the claims recite some structure for the diverter. In claim 1, that structure is “an inlet, a first outlet in fluid communication with the reservoir, and a second outlet.” In claim 21, the recited structure consists of “an inlet, an outlet, and a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient.” But these recited structures—even considered in the aggregate—are insufficient to perform the diverting function expressed in the claim limitations. As Magnolia conceded in its briefing, “[a] diverter, quite simply, facilitates diversion.” D.I. 59 at 41. But inlets, outlets, and

reservoirs do not by themselves or collectively change or divert the direction of a fluid's flow. In short, the claim language does not disclose a structure that could accomplish the diversion of a fluid's flow from one path to another path.

Accordingly, the presumption that § 112, ¶ 6 does not apply in this case is rebutted.

That leaves for resolution what is the corresponding structure in the specification that performs the claimed diversion. Before the hearing, Kurin had insisted that the corresponding structure consisted of four figures and 101 lines of text in the #001 patent's written description. *Id.* at 40–41. But in its post-hearing letter submission, Kurin says it “is sensitive to Magnolia’s concern about including more text from the specification than [is] necessary” and that it now proposes “[a]s a compromise” that the corresponding structure be defined as “[a] switchable valve as shown in Figures 6A/B or flow-control blocks as shown in in Figures 7A/B of the [#]001 patent.” D.I. 73 at 2.

Magnolia did not bother to propose before the hearing a corresponding structure. It proposes in its post-hearing letter the following corresponding structure:

The structures already recited in the claim (i.e., inlet, first outlet, and [claim 1: second outlet; claim 21: reservoir]) and either: (i) a switchable valve, or (ii) flow control blocks.

D.I. 71 at 1 (alterations in original).

Kurin cries foul at Magnolia’s inclusion of claim elements in its proposed corresponding structure. It argues that “[b]ecause the relevant structure is the one disclosed in the specification, Magnolia’s attempt to incorporate additional elements from the claims is improper.” D.I. 73 at 2 (underline in original). The implicit premise of this argument is that a patent’s specification does not include the patent’s claims.

Though that premise is commonplace in patent case law and in patent lawyers’ speech and writings, it cannot be squared with the explicit terms of § 112. Section 112 is titled “Specification,” and § 112, ¶ 2 provides that “[t]he specification shall conclude with one or more claims” This language makes clear that the specification includes the claims asserted in the patent, and the Federal Circuit has expressly so held. As the Court stated in its seminal *Markman* decision, “[c]laims must be read in view of the specification, *of which they are a part.*” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc) (emphasis added), *aff’d*, 517 U.S. 370 (1996).

I recognize that, like Kurin here, the Federal Circuit and other courts frequently use “specification” to mean everything in the patent *other than* the claims.³ Indeed, in *Markman* itself, the Federal Circuit treated the specification as

³ See, e.g., *Williamson*, 792 F.3d at 1352–1354; *TEK Glob., S.R.L. v. Sealant Sys. Int’l, Inc.*, 920 F.3d 777, 786 (Fed. Cir. 2019); *Advanced Ground Info. Sys., Inc. v. Life360, Inc.*, 830 F.3d 1341, 1349 (Fed. Cir. 2016); *Quanergy Sys., Inc. v.*

something separate from the claims when it stated that “[t]o ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history.” But the first canon of statutory interpretation is that “courts must presume that a legislature says in a statute what it means and means in a statute what it says there.” *Connecticut Nat. Bank v. Germain*, 503 U.S. 249, 253–54 (1992). Congress spoke unambiguously when it decreed in § 112, ¶ 2 that “[t]he specification shall conclude with one or more claims.” For that reason, I believe the statement in *Markman* that the claims “are a part” of the specification is binding precedent that trumps any suggestion in other Federal Circuit case law that the specification does not include the claims.

I therefore reject Kurin’s assertion that it is inappropriate to consider structural elements recited in the #001 patent’s claims in determining the

Velodyne Lidar, Inc., 2017 WL 4410174, at *9 (N.D. Cal. Oct. 4, 2017); *Cypress Lake Software, Inc. v. Samsung Elecs. Am., Inc.*, 382 F. Supp. 3d 586, 616 (E.D. Tex. 2019), *reconsideration denied*, 2019 WL 4935280 (E.D. Tex. Aug. 23, 2019); *Maxell Ltd. v. Huawei Device USA Inc.*, 297 F. Supp. 3d 668, 696 (E.D. Tex. 2018). The irony that courts use “specification” inconsistently when construing patent claims is not lost on me. It is after all a fundamental teaching of patent law that “a claim term should be construed consistently with its appearance in other places in the same claim or in other claims of the same patent.” *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001). *See also Phonometrics, Inc. v. N. Telecom Inc.*, 133 F.3d 1459, 1465 (Fed. Cir. 1998) (“A word or phrase used consistently throughout a claim should be interpreted consistently.”). In the typical patent case, the fact that the court and counsel use “specification” to mean two different things is of no moment. But in this case, deciding the merits of the parties’ competing corresponding structure proposals turns on the meaning of “specification” in § 112, ¶ 6.

corresponding structure for diverter. I agree that Magnolia's proposed definition is inappropriate, but for a different reason: Magnolia asks me to adopt two different structures for "diverter," depending on the claim in which the term appears.

Specifically, it asks me to construe "diverter" to consist of a first outlet, a second outlet, and either a switchable valve or flow-control blocks for purposes of claim 1; but to construe it as an inlet, a first outlet, a reservoir, and either a switchable valve or flow-control blocks for purposes of claims 21 and 28. A claim term, however, "should be construed consistently with its appearance in other places in the same claim or in other claims of the same patent." *See Rexnord*, 274 F.3d at 1342.

I will instead construe the corresponding structure for "diverter" to consist of the structural elements of a diverter that are recited in both claims 1 and 21—i.e., an inlet and outlets—and at least one of the two "diversion mechanisms" disclosed in the patent's written description—a switchable valve and flow-control blocks. Figures 6A and 6B in the written description show a switchable valve "that pivots about a pivot point positioned at the junction" of "input tubing" (i.e., an inlet) and two "output tubing[s]" (i.e., outlets). #001 patent at 7:52–54 and Figures 6A and 6B. The figures and accompanying text disclose that that the valve can be moved (i.e., switched) from one position to a second position to "create[] a seal disallowing the flow" of fluid from the input tubing into one output tubing and thereby diverting the flow into the other output tubing. *Id.* at 7:60 and Figures 6A

and 6B. Figures 7A and 7B show an “input flow-control block” and a “slidably-mounted output flow-control block” positioned between sterile input tubing (i.e., an inlet) and two sterile output tubings (i.e. outlets). *See id.* at 8:29–59 and Figures 7A and 7B. These figures and the accompanying text disclose that the flow-control blocks can be slid from a first position that allows the flow of fluid from the sterile input tubing to a “pre-sample reservoir” “via the first sterile output tubing” to a second position that diverts that flow from the sterile input tubing to “one or more sample vessels” “via the second sterile output tubing.” *Id.* at 8:58–9:9 and Figures 7A and 7B. An inlet, at least two outlets, and either a switchable valve or fluid control blocks are the minimum structural elements disclosed in the specification that are necessary to achieve diversion of the fluid flow.

Accordingly, I find that they constitute the corresponding structure for the diversion function expressed in claims 1 and 21 of the #001 patent.

B. “Housing”

The second remaining issue concerns my oral rulings with respect to the term “housing.” During the hearing, I stated that “I’m going to construe housing to mean a casing that encloses one or more components.” Tr. of Apr. 15, 2020 Hr’g at 38:12–13. Kurin insists that this statement constituted the totality of my construction of the term. But, as Magnolia notes, I also made clear at the hearing that this definition of “housing” could be met as long as the structure in question

“[a]t some point” encased at least “part of [a] component.” Tr. at 36:18–37:1. As I stated at the hearing: “There has got to be something inside [the casing], whether it’s part of a component, whether it is an entire component. It can’t just be empty air. Otherwise, it’s not housing anything.” Tr. at 36:18–21.

So that there is no doubt going forward, I hereby construe “housing” to mean “a casing that at some point in time encloses at least a portion of one or more components.”

C. Conclusion

For the reasons stated above, I will construe “diverter” as a means-plus-function term with a corresponding structure that consists of an inlet, at least two outlets, and either a switchable valve or flow-control blocks. I will construe “housing” to mean “a casing that at some point in time encloses at least a portion of one or more components.”

The Court will issue an Order consistent with this Memorandum Opinion.