United States District Court,
D. Delaware.

C.R. BARD, INC,
Plaintiff.
v.
MEDTRONIC, INC,
Defendant.

No. 96-589-SLR

May 7, 1998.

Jack B. Blumenfeld, Morris, Nichols, Arsht & Tunnell, Wilmington, for C R Bard Inc, plaintiffs.

Robert W. Whetzel, Francis DiGiovanni, Richards, Layton & Finger, William J. Marsden, Jr., Fish & Richardson, P.C., Wilmington, for Medtronic, Inc, defendants.

MEMORANDUM ORDER

ROBINSON**, District J.**

I. INTRODUCTION

Plaintiff C.R. Bard, Inc. ("Bard") filed suit against defendant Medtronic, Inc. ("Medtronic") alleging infringement of U .S. Patent No. 5,484,474 (the " '474 patent"). The court has jurisdiction over Bard's patent claims pursuant to 28 U.S.C. s.s. 1331 and 1338(a). Before the court are claim construction issues, presented to the court consistent with Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed.Cir.1995), *aff'd,* 116 S.Ct. 1384 (1996).

II. STANDARD OF REVIEW

The principles of claim interpretation are well established in the law. The exercise begins always with the claim language, which defines the scope of the claim. *See* York Prods., Inc. v. Central Tractor Farm & Family Center, 99 F.3d 1568, 1572 (Fed.Cir.1996). In analyzing claim language, the court must employ "normal rules of syntax," Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F .3d 1547, 1553 (Fed.Cir.1997), for "[a] claim must be read in accordance with the precepts of English grammar." In re Hyatt, 708 F.2d 712, 714 (Fed.Cir.1983). The court must ascribe to any technical term used in a claim "the meaning that it would be given by persons experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning." Hoechst Celanese Corp. v. BP Chemicals Ltd., 78 F.3d 1575, 1578 (Fed.Cir.1996).

In order to give context to the claim language, the court must review as well the specification.

The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication .... As we have repeatedly stated, "[c]laims must be read in view of the specification, of which they are a part." ... The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it. Thus, the specification is always relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.

Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996) (emphasis added).

The last source of intrinsic evidence relevant to claim interpretation is the prosecution history of the patent, if it has been made part of the record.

This history contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims. As such, the record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims.

The claims, specification, and file history ... constitute the public record of the patentee's claim, a record on which the public is entitled to rely. In other words, competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention.

Id. at 1583. In order to further the "fair notice function of the requirement that the patentee distinctly claim the subject matter disclosed in the patent from which he can exclude others temporarily," Athletic Alternatives, Inc. v. Prince Manufacturing, Inc., 73 F.3d 1573, 1581 (Fed.Cir.1996), extrinsic evidence of claim interpretation, such as expert testimony, is improper in most instances. *See, e.g.,* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d at 1583.

III. CLAIM INTERPRETATION

The '474 patent describes a filter to be used, for example,

in extra corporeal circuits for removal of particulate and gaseous matter. Particularly, embodiments of the present invention relate to a disposable arterial blood filter for use in extra corporeal blood flow circuits, such as in a bypass circuit, for filtering out solid or gaseous emboli.

(Col.1, lns.10-14) Bard asserts that Medtronic infringes claims 1, 3-6, 8, 10-13, 15, 16, and 18 of the '474 patent either literally or under the doctrine of equivalents. These claims are apparatus claims and describe "[a] filter for filtering fluids" consisting of, *inter alia,* the following disputed claim elements: (1) "a housing [and/or housing cap] defining a substantially toroidal flow path"; and (2) "a filter element support located within the housing and centrally disposed with respect to the toroidal flow path." (Col. 8, lns. 25-7, 43-5; col. 9, lns. 22, 39-41; col. 10, lns. 18, 34-6, 42-3, 60-2) FN1 Bard maintains that the term "substantially toroidal flow path" means "essentially curved flow path" and that the term "filter element support" does not require that the filter element be supported from the top by a structure descending from the housing cap. (D.I. 77 at 2) Medtronic essentially argues that the claims at issue are limited to the preferred embodiment, that is, a filter consisting of a "doughnut or toroid-shaped housing cover having an indentation in its center" which creates a "doughnut-like curvature [to] provide[ ] a toroidal channel or tunnel through which entering

fluid is guided." (Col.2, lns.37-9, 47-8) Medtronic further urges that "the filter element support limitation requires that the filter element located within the housing be supported from the top by a structure descending from the housing cap." (D.I. 71 at 17) The disputed claim elements shall be addressed *seriatim*.

FN1. More specifically, the disputed claim language is included in independent claims 1, 8, 15, and 16. Claim 1 is reproduced below as illustrative of the other claims:
1. A filter for filtering fluids, comprising:

a housing defining a substantially toroidal flow path and a filter element chamber;

a fluid inlet in fluid flow communication with the substantially toroidal flow path and directed substantially tangential to the fluid flow path; wherein the height of the substantially toroidal flow path rises from the location of the inlet, around the periphery of the housing to a highest point located approximately 180 (deg.) opposite the fluid inlet;

a gas outlet aperture located at the highest point on the substantially toroidal flow path; and in gas flow communication with the substantially toroidal flow path and located approximately 180 (deg.) from the fluid inlet with respect to the substantially toroidal flow path;

a filter element supported within the filter element chamber of the housing;

a filter element support located within the housing and centrally disposed with respect to the torodial flow path; and

a fluid outlet in fluid flow communication with the filter element chamber.

(Col.8, lns.26-48)
A. Substantially Toroidal Flow Path

Starting with the claim language, the element in dispute does not describe the "flow path" as circular or curved, but as "substantially toroidal." The specification is replete with references to "toroidal" in terms of the "housing" and the resulting "flow path," but refers as well to a "curved" flow path:

The doughnut-like curvature provides a toroidal channel or tunnel through which entering fluid is guided.

The toroidal housing cover forms a coil-like tunnel which is enlarged approximately 180 (deg.) from a blood inlet port provided at one end of the toroid-shaped housing cover. This enlarged area defines the highest point on the housing cover. A gas vent is located at the highest point on the toroidal tunnel, at the periphery of the housing cover.

Fluid enters the tangential blood inlet and circulates through the toroidal channel. As the fluid flows about the toroidal channel, gaseous matter is drawn upward by buoyant forces and is allowed to escape through the peripheral gas vent, while the fluid seeps down into a reservoir formed between the inner wall of the housing cover and the outer perimeter of the cylindrical filter element. The gentle swirling action of the entering fluid through the toroidal channel is sufficient to cause the fluid to flow completely about the housing cover and seep down around the sides of the filter element.

(Col.2, lns.47-65) (emphasis added).

The toroidal configuration provides a smooth, curved flow path of maximum radius to minimize or reduce aggressive agitation of the fluid during its flow. Due to the central indentation 22 defined by the toroid-shaped housing cover 14, the curved fluid flow path is radially spaced from the central axis of the housing 12. This allows the radius of curvature of the fluid flow path (and, thus, the length of the path) to be maximized, while containing the path within the housing cover. Maximizing the length of the fluid flow path tends to maximize the time period in which a given volume of fluid flows through the length of the path (for a given flow velocity) and, therefore, maximizes the amount of time in which gas bubbles may be drawn from the fluid.

The curved fluid flow path also tends to gently guide the fluid around the upper periphery of the underlying filter element 16, such that the fluid can flow downward around substantially the entire outer peripheral surface of the filter element and then pass through the filter element from all radial directions with minimal agitation and turbulence. Consequently, the undesired generation of air bubbles is also minimized. This allows the entire filter element to be efficiently used and maximizes the rate at which a given volume of fluid may be passed through the filter element.

Referring to FIGS. 1, 2 and 4, the toroid-shaped housing cover 14 is configured to guide fluid (not shown) in a curved path over the filter housing 12 as it enters the arterial filter 10....

The housing cover 14 has a toroidal, doughnut-like shape. The height of the toroid 34 forming the housing cover 14 rises as it curves about the perimeter of the housing cover 14. As shown in FIGS. 2-4, the highest point of the housing cover 14 is located midway around the toroid curvature, approximately 180 (deg.) from the tangential inlet port 18.

A gas vent cap 20 is located at the perimeter of the housing cover 14, at the highest point on the cover, opposite the inlet port 18. The side view of the arterial filter 10 depicted in FIGS. 2 and 4 show a preferred arrangement of the gas vent 20 disposed on the highest point on the toroidal channel, at the periphery of the housing cover 14. In the preferred embodiment, the gas vent 20 is a one-way valve, such as a female Luer cap, which allows gas to escape but does not permit air or particulate matter to enter.

Because the gas vent 20 is located at the highest point on the toroid-shaped housing cover 14, approximately 180 (deg.) opposite the tangential inlet port 18, as the inlet liquid is caused to swirl through the toroidal channel 34, gaseous matter rises, by buoyant forces, to the highest point of the filter and exits through the

gas vent 20. Yet, due to the swirling action, the inlet fluid still retains sufficient momentum to flow through the remaining half of the downwardly sloping toroidal channel to flow steadily and evenly around the perimeter of the toroidal channel of the housing cover 14, before seeping downward into the housing reservoir 32. This feature is discussed in more detail below.

FIG. 4 also illustrates an indentation 22 formed in the center of the toroid-shaped housing cover 14. As discussed in more detail below the indentation 22 serves to stabilize and support the filter element 16 as well as provide clear visibility of the filtered fluid after it passes through the filter element 16 into the central cavity 36 of the filter element 16. The configuration of the housing cover 12 and the indentation 22 comprises an inverted dome cap which, in preferred embodiments, defines a toroidal-shaped fluid flow path.

(Col. 4, lns. 20-67; col. 5, lns 1-23) (emphasis added).

In operation, the toroid-shaped housing cover 14 acts as an air separation chamber. When a fluid, e.g., a priming fluid or blood, enters the tangential inlet port 18 via a tube or other fitting, it flows tangential to the wall of the toroidal channel 34 and through the curved path defined by the channel. The flowing motion creates a gentle swirling action which causes air and other gaseous matter to be separated from the fluid inside the toroidal channel 34. Consequently, in accordance with the principles of buoyancy, the gaseous matter rises and escapes through the peripheral vent cap 20 which is located on the highest point about the toroidal channel 34.

As the gaseous matter is separated from the fluid, the swirling debubbled fluid seeps downward from the periphery of the toroidal tunnel 34, over the potting 30 and the filter element 16, and into the reservoir 32 formed between the inner wall of the housing 12 and the outer perimeter of the filter material 16, as shown in FIG. 4....

(Col. 7, lns 25-42) (emphasis added).

The prosecution history of the '474 patent was included in the record as well. The claims at issue were initially rejected by the Examiner under 35 U.S.C. s. 102 and s. 103 by reason of a certain prior art reference (the "Siposs '135 patent") which showed, according to the Examiner, a "toroidal flow path" "evidenced by the fact that Siposs repeatedly refers to a rotating fluid flow path created in the filter device...." (D.I. 71, Ex. D at 3; Ex. F at 3) Bard responded to such rejection as follows:

Siposs does not appear to have expressly recognized a "toroidal flow path" occurring within the "circular" chamber 54, much less any benefit of enhancing such "toroidal flow path." (Siposs does not appear to mention the term "toroidal.") Siposs teaches a conical cap interior with a central apex defining the highest elevation for channeling gas to the central vent 48. A central indentation in the cap would destroy Siposs' intended operation of congregating gas in the center of the chamber.... Thus, Siposs provides no suggestion of (and teaches away from) a central indentation and a laterally offset gas vent as claimed....

According to Siposs, fluid enters a circular chamber tangentially so as to create a rotation of the fluid about the circular chamber to separate gas therefrom. As the fluid rotates around the circular chamber, the lighter gas bubbles purportedly "congregate in the center of the chamber" .... Thus, Siposs' device purportedly operates under principles of centrifugal force, wherein the rotation of the fluid within the circular chamber causes the heavier fluid to flow near the peripheral wall of the chamber, while lighter gas bubbles

congregate toward the center of the chamber.

(D.I. 71, Ex. E at 13, 16) (emphasis in original).

The '474 claims eventually were allowed as presently written after an unrecorded telephone interview. The Examiner apparently concluded that the independent claims would be distinguished from the art of record if amended to include limitations of various dependent claims. For example, claim 25 (now claim 1) was amended as follows (underlined language indicates added language):

1. (TWICE AMENDED) A filter for filtering fluids, comprising:

a housing defining a substantially toroidal flow path and a filter element chamber;

a fluid inlet in fluid flow communication with the substantially toroidal flow path and directed substantially tangential to the fluid flow path; *wherein the height of the substantially toroidal flow path rises from the location of the inlet, around the periphery of the housing to a highest point located approximately 180 (deg.) opposite the fluid inlet;*

a gas outlet aperture *located at the highest point on the substantially toroidal flow path; and* in gas flow communication with the substantially toroidal flow path and located approximately 180 (deg.) from the fluid inlet with respect to the substantially toroidal flow path;

a filter element supported within the filter element chamber of the housing; [and]

a filter element support located within the housing and centrally disposed with respect to the toroidal flow path; and

a fluid outlet in fluid flow communication with the filter element chamber.

(D.I. 71, Ex. I at 1-2) Consistent with Bard's summary reproduced below, it appears as though the focus of the review process was on the location of the gas outlet, not on the significance of a "toroidal flow path."

It is respectfully submitted that a filter having the combination of a toroidal flow path, a fluid inlet tangentially directed with respect to the toroidal flow path, and a gas outlet as defined in the above-noted claims is neither described nor suggested by the prior art of record. Siposs describes a filter having a centrally located gas outlet and provides no disclosure or suggestion of the above-referenced combination of features, including a gas outlet located 180 (deg.) from the fluid inlet ... directly above the toroidal flow path ... or laterally offset with respect to a central portion of the housing cap....

(D.I. 71, Ex. I at 10)

As far as the court can discern from the record, the phrase "substantially toroidal flow path" means either a circular flow path (as asserted by Bard) or a flow path defined by a toroidal structure (as asserted by Medtronic).FN2 Based on the principle that every word in a claim should be given its ordinary meaning, and fully cognizant of the proscription against limiting claims by what is disclosed in a preferred embodiment, the court concludes that Medtronic's construction is the proper one. The definition of a toroid encompasses two features: (1) a closed curve; (2) rotating about, but not intersecting or containing, an axis

in its own plane. *Webster's Third New Int'l Dictionary* 2412 (1971). *Accord* Adelphon, Inc. v. DiRico, No. CA 3-91-2551-T, 1992 WL 281395, at 3 n. 1 (M.D.Tex. Mar. 26, 1992) Bard's contention that the phrase "substantially toroidal" means only "circular" essentially allows a nontechnical word ("substantially") to negate the meaning of a technical word ("toroidal"). The court considers such an interpretation to be inappropriate.

FN2. It appears from the specification and, particularly, from figures 1, 2, and 4, that the "toroidal channel" of the preferred embodiment is not a closed curve (it is flat at the bottom) and, therefore, is a "substantially toroidal" structure.

The above construction is supported by and consistent with the intrinsic evidence of record. Looking at the claim language in light of the specification and the prosecution history, the '474 patent is distinguished from the prior art because its housing "define[s] FN3 a substantially toroidal flow path." As recognized in the prosecution history, prior art devices which employed a tangential entry into a cylindrical chamber achieved, to some extent, a circular flow path. Such a flow path, albeit circular, is not bounded by a "closed curve" but, rather, by a cylindrical wall. Neither does such a flow path rotate about, but not intersect, a discernable axis. (See, for instance, D.I. 71, Ex. E at 13, 16) Accordingly, the claim language-"substantially toroidal flow path"-is construed to mean a fluid path defined by a toroidal (or substantially toroidal) structure.

FN3. To define means: "to mark the limits of: determine with precision or exhibit clearly the boundaries of." *Webster's Third New Int'l Dictionary* 592 (1971).

B. Filter element support

Claims 1, 3-6, 8, 10-13, 15, 16, and 18 require that the claimed device have a "filter element support" which is "located within the housing and centrally disposed with respect to the substantially toroidal flow path." The term "filter element" is defined in claims 4 and 11 as follows:

[T]he filter element comprises:

a layer of highly porous material and a layer of fine, porous filter material adjacent the highly porous material to form a layered filter sheet, the layered filter sheet being pleated into a substantially cylindrical configuration.

(Col. 8, lns. 53-59; col. 9, lns. 49-55)

This definition is consistent with the language of the specification:

In the preferred embodiment, the filter element 16 is formed of multiple layers of filter material. The filter material 16 includes a sheet of webbed netting material layered adjacent a thin, finely-pored filtered fabric. The webbed, netting layer comprises the inner layer of the plea[t]ed sheet. The smooth, finely-pored filter fabric comprises the outer filter screen. The smooth finish of the outer filter screen obviates the need for harsh, rigorous and prolonged agitation which would otherwise be required to dislodge bubbles trapped in a large-pored material, such as the netting screen, during a priming process or during actual filtration use.

(Col.5, lns.43-54) The specification describes the filter element as being substantially cylindrical in shape and located concentric with the central longitudinal axis of the housing:

The cylindrical filter element 16 is contained inside a filter element chamber defined by the cylindrical housing 12. The filter element 16 rests on the housing bottom 26 and extends approximately to the housing lip 24, where the filter housing 12 meets the housing cover 14. The filter element 16 is concentric with the central longitudinal axis of the housing such that the central cavity of the cylindrical filter element 16 encircles the fluid outlet port 28 located at the center of the bottom 26 of the housing 12.

(Col. 5, lns 24-32)

The term "support" should be given its ordinary meaning: "To bear the weight of, esp[ecially] from below; To hold in position so as to keep from falling, sinking, or slipping." (D.I.77, Ex. G) The language in the specification of the '474 patent is consistent with the dictionary definition of "support."

Unlike certain conventional arterial filters which require a central support shaft or core for supporting a filter element, the upper and lower potting configurations 30 of the illustrated embodiment provide[ ] secure retention of the pleated cylindrical filter media, obviating the need for an additional support structure.

(Col. 6, lns 59-64)

The prosecution history includes the following relevant information. As noted above, the Examiner initially rejected all of the claims, citing the Siposs '135 patent. In response to the Examiner's rejection, Bard argued that its claims were patentable over the Siposs patent. Among other arguments, Bard stated:

Siposs employs a center cone 26 extending upward from the *bottom* of the filtered chamber to hold the end plates 34 and 28. The filter element is, therefore, fully supported by the center cone 26 and need not be supported by the central indentation in the cap. Thus, Siposs provides no suggestion or motivation for providing a central indentation, much less enhancing a filter element support with a central indentation, as suggested by the Examiner.

(D.I. 71, Ex. E at 13) (emphasis in original). In an Office Action dated January 11, 1995, the Examiner stated that having fully considered Bard's arguments he was again rejecting all claims in the continuation application. The Examiner did indicate that claims 25, 42, and 33 would be patentable if amended to include additional limitations. At that point, Bard's patent lawyer held an interview with the Examiner. The Examiner's Interview Summary Record states:

No agreements. Examiner did however indicate that he would reconsider rejection and claim 25 would be allowable if amended to include limitations in claims 26 and 27 and filter element support means centrally located in the toroidal flow path.

(D.I. 71, Ex. G at 1) Medtronic argues that the phrase a "filter element support means centrally located in the toroidal flow path" limitation was substituted for "a central indentation, centrally located with respect to the substantially toroidal flow path" limitation. According to Medtronic, the new language describes the limitation functionally as opposed to structurally, an interpretation consistent with the specification which describes one function of the central indentation as such:

The indentation is coupled to the top of the cylindrical filter element to support and hold the filter element in place within the filter housing, ...

(Col. 2, lns 39-41)

There is no dispute that the central indentation described in the preferred embodiment "enhances" the filter element support, as evidenced by the prosecution history. Neither the specification nor the claim language require that the filter element be supported by such a structure, however. Indeed, the specification expressly provides that the upper and lower potting alone provide secure retention of the filter element. (Col.6, lns.59-64) Thus, it is appropriate and consistent with the specification to interpret the "filter element support" to include the upper and lower potting material, but not support from the top by a structure descending from the housing cap.FN4

FN4. This interpretation is also consistent with the legal principle that claims should not be limited by what is disclosed in the preferred embodiment. *See, e.g.,* Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopedics, Inc., 976 F.2d 1559, 1566 (Fed.Cir.1992) ("In defining the meaning of key terms in a claim, reference may be had to the specification, the prosecution history, prior art and other claims .... This is not, however, to be confused with reading into a claim a limitation appearing in the specification but not in the claim."); Intervet America, Inc. v. Kee-Vet Lab, Inc., 887 F.2d 1050, 1053 (Fed.Cir.1989) ("[L]imitations appearing in the specification will not be read into the claims, and ... interpreting what is meant by a word in a claim 'is not to be confused with adding an extraneous limitation appearing in the specification, which is improper." '); Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 855, 865 (Fed.Cir.1988) ("[R]eferences to a preferred embodiment, such as those often present in a specification, are not claim limitations.")

THEREFORE, at Wilmington this 7th day of May, 1998;

IT IS ORDERED that:

1. The claim language, "substantially toroidal flow path," is construed to mean a fluid path defined by a toroidal

2. The claim language, "the filter element support," is construed to include the upper and lower potting material, but not support from the top by a structure descending from the housing cap.

D.Del.,1998.
C.R. Bard, Inc. v. Medtronic, Inc.

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