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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* KRISTINE DEBRUYNE, DIRK FIEDLER, THOMAS KAISER,  
BEN KLOECK, DUSAN MILOJEVIC, and JOHN PARKER

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Appeal 2012-002512  
Application 10/536,714  
Technology Center 3700

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Before FRANCISCO C. PRATS, STEPHEN WALSH, and  
ULRIKE W. JENKS, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) from the rejection of claims directed to an implantable tissue stimulating device and a cochlear implant. The Patent Examiner rejected the claims for containing new matter, indefiniteness, anticipation, and obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

Claims 70-75, 77-81, and 83-85 are on appeal. Claims 70 and 84 are illustrative and read as follows:

70. An implantable tissue stimulating device comprising:  
an electrode assembly comprising a lead and an elongate member having its proximal end contiguous with a distal end of the lead, and having one or more electrodes disposed on or in the elongate member; and  
a *slider means for delivery of a bioactive substance* slidably mounted on the lead such the lead extends through the slider means, the slider means configured to receive a bioactive substance and deliver the bioactive substance to a target site in the recipient.

(App. Br. 34, emphasis added.)

84. A cochlear implant comprising:  
a stimulator unit configured to generate electrical stimulation signals;  
an electrode assembly comprising a lead extending from the stimulator unit, and a contiguous elongate member implantable in a recipient's cochlea;  
one or more electrodes disposed on or in the elongate member each configured to deliver the electrical stimulation signals to the cochlea; and  
an annular collar slidably mounted around the lead such that the lead extends through a lumen in the collar, the collar having a *non-porous cavity* therein configured to receive a bioactive substance and an outlet located on an exterior face of the collar through which the bioactive substance can pass from the cavity to a target site in the recipient,  
wherein *the outlet faces the electrode assembly* and forms a boundary of the cavity.

(*Id.* at 36, emphasis added.)

The Examiner rejected the claims as follows:

- I. Claims 84 and 85 under 35 U.S.C. § 112, first paragraph, as containing new matter;

- II. Claim 70<sup>1</sup> under 35 U.S.C. § 112, second paragraph, as indefinite;
- III. Claims 70, 72-75, 78-81, and 83 under 35 U.S.C. § 102(e) as anticipated by Kramm;<sup>2</sup>
- IV. Claims 71 and 77 under 35 U.S.C. § 103(a) as unpatentable over Kramm; and
- V. Claims 72 and 83-85 under 35 U.S.C. § 103(a) as unpatentable over Kramm in view of Kuzma.<sup>3</sup>

I

Claim 84

The Examiner rejected claim 84 because the Examiner was unable to find written description support for a “non-porous cavity,” and for an outlet that “faces the electrode assembly.” (Ans. 2.) Appellants contend that sufficient support for both limitations may be seen in Figure 19. (App. Br. 10-14.) The Examiner argues that Appellants’ points are unpersuasive. (Ans. 10-12.)

The standard to be applied is “whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language.” *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983).

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<sup>1</sup> The statement of rejection does not identify the rejected claim(s). (Final Rej. 3; Ans. 3.) Appellants state that claim 70 was rejected. (App. Br. 8.)

<sup>2</sup> Berthold Kramm et al., US 6,936,040 B2, filed Oct. 29, 2001, issued Aug. 30, 2005.

<sup>3</sup> Janusz A. Kuzma et al., US 6,309,410 B1, issued Oct. 30, 2001.

Applying that standard, we find that the evidence supports Appellants' position, for the reasons provided in the Appeal Brief. The new matter rejection of claim 84 is reversed.

Claim 85

Claim 85 reads, in part, “[t]he cochlear implant of claim 84, wherein the outlet comprises *a valve . . .*” (App. Br. 36, emphasis added.)

The Examiner rejected claim 85 because the Examiner was unable to find written description support for an outlet comprising “a valve.” (Ans. 2.) Appellants contend that description of a valve may be found in at Spec. 32, ll. 10-12.) (App. Br. 15-16.) The Examiner responds that the Specification described a membrane, but a membrane having no moving parts is not a valve. (Ans. 12-13.) Appellants reply that the ordinary meaning of valve is “any device for halting or controlling the flow of a liquid, gas or other material through a passage, pipe, inlet, outlet, etc.,” including a “membranous fold.” (Reply Br. 12, quoting a dictionary.)

The Specification reads, in pertinent part:

The chamber in the collar acts as a reservoir for a bioactive substance. This bioactive substance in the chamber diffuses from the chamber into the implantee through a semi-permeable membrane 270 in the outlet 246. The membrane 270 allows the bioactive substance to leach from the chamber during and/or following implantation to the desired site of action for the bioactive substance.

Where the bioactive substance is carried in or comprises a fluid, the semipermeable membrane 270 allows the fluid to leach or diffuse therethrough.

The membrane 270 can act as a valve means that allows fluid to exit the chamber but prevents, or at least substantially prevents, fluid flow from external the chamber back into the chamber within the body.

(Spec. 32, ll. 1-12.)

We find that the Specification described an outlet with a membrane that can act as a “valve means,” but did not describe an outlet with any other valve. We see no evidence supporting Appellants’ contention that the Specification “disclose[s] a species (the membrane 270) and also discloses the genus (the valve means, or valve) that operates exactly as recited in claim 85.” (App. Br. 15.) When an Applicant claims a genus or class, the Applicant “must describe that class in order to meet the description requirement of the statute.” *In re Lukach*, 442 F.2d 967, 968 (CCPA 1971). Mentioning only a membrane that can act as a valve is not a description of the genus “valve.” Appellants also contend that “by describing a valve means that allows fluid to exit the chamber but prevents fluid flow back into the chamber, Appellants described a valve.” (App. Br. 16.) That may be so, but it remains a description of one kind of valve. Even if it might have been obvious to substitute a valve for the Specification’s membrane, and we do not assume it would have been, “a description that merely renders the invention obvious does not satisfy the [written description] requirement.” *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010). The new matter rejection of claim 85 is affirmed.

## II

### *The Issue*

The Examiner and Appellants agree that claim 70’s “*slider means* for delivery of a bioactive substance” invokes 35 U.S.C. § 112, ¶ 6. (Ans. 3; App. Br. 16.)

The Examiner rejected claim 70 as indefinite because the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. The phrase “slider means” appears to be absent from the original disclosure, and the disclosure also appears to lack any guidance as to precisely which structure or structures constitute the “slider means.”

(Ans. 3.)

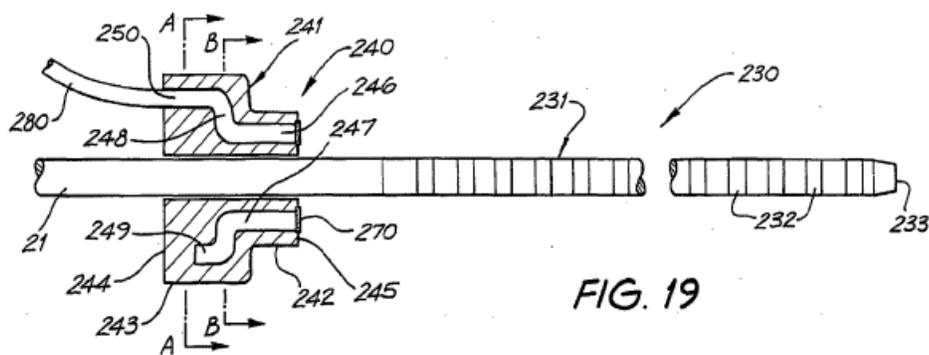
Appellants contend that

an example of a corresponding structure, material or act that performs the function of the slider means for delivery of a bioactive substance may be found on page 30, line 20 to page 31, line 26, and FIGs. 19, 19a and 19b. More specifically, collar 240 is an example of a slider means.

(App. Br. 18, emphasis omitted.)

*Findings of Fact*

1. Appellants’ Figure 19 is reproduced here:



“Fig. 19 is a simplified cross-sectional view of one embodiment of an electrode assembly.” (Spec. 22, ll. 8-9.)

2. The Specification states: “As depicted in Fig. 19, a collar 240 is slidably disposed around the lead 21. The collar 240 is part of a

system for delivering one or more pharmaceutical or bioactive substances to a location just external the cochleostomy of the cochlea.” (Spec. 30, ll. 31-33.)

*Principles of Law*

“[T]he question in the case before us is . . . whether, in utilizing the authority of § 112 ¶ 6 to claim in means-plus-function form, the drafter has adequately described structure, material, or acts which satisfy the claiming requirement of § 112 ¶ 2.” *In re Dossel*, 115 F.3d 942, 946 (Fed. Cir. 1997). “[O]ne construing means-plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure.” *In re Donaldson*, 16 F.3d 1189, 1193 (Fed. Cir. 1994).

“If the specification is not clear as to the structure that the patentee intends to correspond to the claimed function, then the patentee has not paid the price but is attempting to claim in functional terms unbounded by any reference to structure in the specification.” *Medical Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1211 (Fed. Cir. 2003); *see also Biomedino, LLC v. Waters Techs. Corp.*, 490 F.3d 946, 948 (Fed. Cir. 2007) (“[I]n return for generic claiming ability, the applicant must indicate in the specification what structure constitutes the means.”).

*Analysis*

We agree with the Examiner and Appellants that the disputed limitation in claim 70 invokes the means-plus-function provision of 112, ¶6.

Claim 70 states that its slider means is “for delivery of a bioactive substance” and it is “slidably mounted on the lead such the lead extends through the slider means.” The Specification states that collar 240, as depicted in Figure 19, is “part of a system for delivering one or more . . . bioactive substances,” and it is “slidably disposed around the lead 21.” (FF 2.) We agree with Appellants that collar 240 is a slider means as defined in claim 70.

Appellants have argued that collar 240 is “an example” of a slider means, but the Examiner appears to argue that because no other examples are described, no equivalents are described, and claim 70 is indefinite. While we agree with the Examiner that collar 240 is the only means described, and no other examples are described, those facts do not make the claim indefinite. A means clause does not cover every means for performing the specified function; it may properly cover only one means and its equivalents. *See, e.g., Nomos Corp. v. Brainlab USA, Inc.*, 357 F.3d 1364, 1368 (Fed. Cir. 2004) (“In this case, only one embodiment is described in the '026 patent, therefore, the corresponding structure is limited to this embodiment and its equivalents.”). Notwithstanding Appellants’ argument that collar 240 should be treated as “an example,” sliding collar 240 is the only embodiment described. Therefore, claim 70 covers only a sliding collar, and its equivalents.

To the extent the rejection rests on a lack of description for equivalents of the sliding collar, that concern is misplaced. “The specification need not describe the equivalents of the structures, material, or acts corresponding to the means-(or step-) plus-function claim element.” MANUAL OF PATENT EXAMINING PROCEDURE (MPEP) § 2184, citing *In re*

*Noll*, 545F.2d 141, 149-50 (CCPA 1976). Instead, the features of a potentially infringing, or potentially anticipating, device are assessed to determine if it is an equivalent. *See* MPEP § 2183.

The indefiniteness rejection of claim 70 is reversed.

### III

#### *The Issue*

The Examiner's position is that Kramm described the claimed device including "a slider means for delivery of a bioactive substance mounted around the lead such that the lead extends through a lumen in the collar (Fig. 6; element 48, 42, and 56), the collar having a chamber therein (56) configured to receive a bioactive substance (col. 6, lines 45-50) and deliver the bioactive substance to a target in the recipient." (Ans. 4.) "The Examiner is considering Kramm's element 48 and distal portions of 42 and 56 to be equivalent to the claimed 'slider means' because it slides with respect to the lead and functions to deliver bioactive substances to a target site in a recipient." (*Id.* at 4-5.)

Appellants contend that the Examiner has not shown that Kramm's slider means for delivery of a bioactive substance is an equivalent to Appellants' collar 240, shown in Appellants' Figure 19. (App. Br. 20-21.) In Appellants' view, the rejection relies on a finding that Kramm's device performs the same function, but the rejection fails to do the structural analysis to show that Kramm's slider means is equivalent to Appellants' slider means. (*Id.* at 21-23, citing MPEP §§ 2181, 2182.) Appellants present a structural analysis purportedly demonstrating that Kramm's slider means is not equivalent to Appellants' slider means at least because

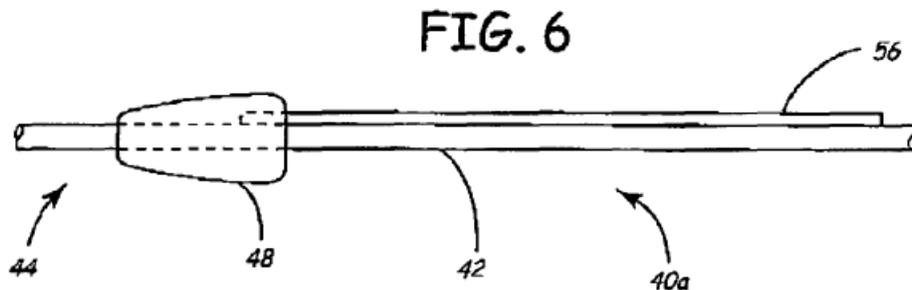
Kramm's distribution device 48 does not slide along element 42, among other reasons. (*Id.* at 24-25.)

The issues are:

- a) whether the rejection demonstrated that the device shown in Kramm's Figure 6 performs the identical function as Appellants' sliding means;
- b) whether the rejection demonstrated that the device shown in Kramm's Figure 6 is insubstantially different with respect to structure from Appellants' collar 240 shown in Appellants' Figure 19; and if not,
- c) whether the rejection demonstrated that the two structures perform the identical function, in substantially the same way, with substantially the same result.

*Further Findings of Fact*

3. Kramm's Figure 6 is reproduced here:



“FIG. 6 schematically illustrates an alternate embodiment guide catheter.” (Kramm, col. 3, ll. 39-40.)

4. Kramm explained the relation between tubular body 42, shown in Figure 6, and the lead, not shown in Fig. 6:

an exemplary guide catheter **40** includes a flexible tubular body **42** having a distal end **44** and a proximal end **46**. A distributor **48** is

mounted on the distal end **44** of the flexible tubular body **42**, and a hub **50** is mounted on the proximal end **46** of the flexible tubular body **42**. The axial lumen **52** of the tubular body **42** provides a passageway for a lead (e.g., an electrical lead) to be directed out of the distal end **44** of the catheter **40**.

(*Id.* at col. 5, ll. 32-39.)

5. Kramm described the Figure 6 embodiment as follows:

FIG. 6 presents an alternate embodiment of a catheter device **40a** having a flexible tubular body **42** and a distribution device **48** located approximate the distal end **44** of the device **40a**. A secondary passageway **56** connects to the distribution device **48** and enables vasodilating agents to be transported to the distribution device **48**. The distribution device **48** may comprise a porous material that dissipates the vasodilating agents in a substantially controlled manner. The distribution device **48** can typically dispense the vasodilating agents in a more uniform pattern than dispensing without the use of a distribution device **48**.

(*Id.* at col. 6, ll. 40-50.)

### *Principles of Law*

In order for an accused structure to literally meet a section 112, paragraph 6 means-plus-function limitation, the accused structure must either be the same as the disclosed structure or be a section 112, paragraph 6 “equivalent,” i.e., (1) perform the identical function and (2) be otherwise insubstantially different with respect to structure. . . . two structures may be “equivalent” for purposes of section 112, paragraph 6 if they perform the identical function, in substantially the same way, with substantially the same result.

*Kemco Sales, Inc. v. Control Papers Co., Inc.*, 208 F.3d 1352, 1364 (Fed. Cir. 2000) (citations omitted). A conclusion of equivalence may also be supported if (i) a person of ordinary skill in the art would have recognized the interchangeability of the element shown in the prior art for the

corresponding element disclosed in the specification, or (ii) there are insubstantial differences between the prior art element and the corresponding element disclosed in the specification. MPEP § 2183 (citing cases).

*Analysis*

a) The device shown in Kramm's Figure 6 dispenses vasodilating agents. (FF 5.) Claim 70 requires the slider means to be configured to receive a bioactive substance and deliver the bioactive substance to a target site in the recipient. Because Kramm's sliding device receives and delivers a bioactive substance, we find that it performs the identical function Appellants' sliding means performs.

b) The rejection did not address whether the sliding distribution device comprising Kramm's elements 48, 42, and 56 is insubstantially different in structure from Appellants' collar 240. The Examiner responded to arguments on this point as follows:

The argument that element 48 'is not the same as the structure depicted in Fig. 19' again highlights the vagueness of the 'slider means' element because the examiner cannot address this argument due to the inability to determine exactly what limitations Appellant would like the examiner to import into the claim.

(Ans. 15.) We do not find this response reasonable because (i) claim 70 is not vague as to the slider means, as explained in section II above; (ii) the structure that corresponds to the slider means is collar 240; and (iii) there is no need to import limitations into the claim.

Given the apparent structural differences between Kramm's Figure 6 embodiment and Appellants' sliding collar (see FF 1 and 3), we find that the rejection did not carry its initial burden of proof to show that Kramm's

sliding distribution device is insubstantially different from Appellants' sliding collar. *See* MPEP § 2182 (“an examiner carries the initial burden of proof for showing that the prior art structure . . . is the same as or equivalent to the structure . . . described in the specification which has been identified as corresponding to the claimed means”). *See also* MPEP § 2183.

c) The rejection made no findings on whether the two structures perform the identical function in substantially the same way, with substantially the same result. Accordingly, the rejection also failed to carry its initial burden of proof to show that Kramm's device performs in substantially the same way. *See* MPEP § 2182. *See also* MPEP § 2183.

Summarizing, although we agree that Kramm's sliding distribution device performs the same function as Appellants' sliding collar, we find that the rejection must be reversed because it failed to show that there are only insubstantial structural differences between the two devices, or if there are substantial structural differences, that the devices act in substantially the same way.

#### IV

The Examiner rejected claims 71 and 77 under 35 U.S.C. § 103(a) as unpatentable over Kramm, on the basis that the only difference between Kramm's device and the claimed device is the claimed “stop.” (Ans. 7-8.) We reverse this rejection because the obviousness rejection does not account for the “slider means” element. *See* section III, above.

#### V

*The Issues*

The Examiner found that Kramm disclosed features defined by claims 72 and 83-85, including “an annular collar (elements 42, 48, and 56) mounted on the lead and having a non-porous cavity (lumen of 56) therein and an outlet located on an exterior face of the collar through which the bioactive substance can pass (48), wherein the outlet faces the electrode assembly (the inner and distal surfaces of 48 face the electrode assembly in a radially-inward direction and in a distal direction) and forms a boundary of the cavity (the distal boundary at the distal end of 56’s lumen -- see Fig. 6).” (Ans. 6.) However, “Kramm does not explicitly disclose that the lead is implantable in a cochlea/middle ear, the collar dimensioned to slide along the lead in the middle ear, or that the system is a cochlear implant.” (*Id.* at 6-7.) The Examiner found that Kuzma described “a similar cochlear drug delivery/electrical stimulation system implantable in a cochlea middle ear, the drug delivery device dimensioned to slide along the lead in the middle ear (Figs. 2a and 2b),” and concluded that it would have been obvious to size Kramm’s device to fit the middle ear. (*Id.* at 7.)

Appellants contend that the prior art does not “teach or render obvious each and every limitation of Appellants’ claim 84.” (App. Br. 26.) Specifically, Appellants contend (i) the person of ordinary skill in the art would not have considered Kramm’s elements 42, 48, and 56 to be an annular collar (*id.* at 28); (ii) Kramm does not teach that element 56 forms a non-porous cavity in porous element 48 (*id.* at 29); and (iii) Kramm does not teach an outlet facing the electrode assembly and located on the exterior face of the collar (*id.* at 30).

According to Kramm, element 42 has a tubular body, through which the electrical lead passes. (FF 4.)

*Further Findings of Fact*

6. Ordinary meanings of “collar” include:

5. Any of various ringlike devices used to limit, guide, or secure a machine part.<sup>4</sup>

5. (Engineering / Mechanical Engineering) a section of a shaft or rod having a locally increased diameter to provide a bearing seat or a locating ring.<sup>5</sup>

*Analysis*

Before considering Appellants’ points, we reverse the rejection of claims 72 and 83 because it does not account for the “slider means” element defined in those claims. *See* section III, above.

In an Advisory Action dated April 1, 2011, the Examiner advised Appellants that the obviousness rejection of claim 85 was withdrawn. The Examiner’s Answer reinstated the rejection. We treat the obviousness rejection of claim 85 as before us for review.

Appellants contend that the scope of “collar” should be the broadest reasonable interpretation in light of the specification as it would be understood by one of ordinary skill in the art. (App. Br. 28.) We find the way in which the Specification uses “collar” is consistent with the ordinary

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<sup>4</sup> *The American Heritage® Dictionary of the English Language*, 4<sup>th</sup> ed., ©2000 by Houghton Mifflin Company. Updated in 2009. Published by Houghton Mifflin Company.

<sup>5</sup> *Collins English Dictionary – Complete and Unabridged* © HarperCollins Publishers 1991, 1994, 1998, 2000, 2003.

meaning of collar as a ring-like device. (*See* FF 1, 2, and 6.) The Examiner's argument is: "Taken as a cross-section, element 42 completely surrounds the lead in an encircling, band-like manner." (Ans. 16.) We cannot agree that a person of ordinary skill in the art would consider the tubular body of Kramm's element 42 to be a collar merely because it might appear band-like in cross-section. However, element 42 might appear in different views, its tubular shape does not correspond to the ordinary meaning of collar. The obviousness rejection of claims 84 and 85 is reversed.

#### SUMMARY

We reverse the rejection of claim 84 under 35 U.S.C. § 112, first paragraph.

We affirm the rejection of claim 85 under 35 U.S.C. § 112, first paragraph.

We reverse the rejection of claim 70 under 35 U.S.C. § 112, second paragraph.

We reverse the rejection of claims 70, 72-75, 78-81, and 83 under 35 U.S.C. § 102(e) as anticipated by Kramm.

We reverse the rejection of claims 71 and 77 under 35 U.S.C. § 103(a) as unpatentable over Kramm.

We reverse the rejection of claims 72 and 83 under 35 U.S.C. § 103(a) as unpatentable over Kramm in view of Kuzma.

We reverse the rejection of claims 84 and 85 under 35 U.S.C. § 103(a) as unpatentable over Kramm in view of Kuzma.

Appeal 2012-002512  
Application 10/536,714

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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