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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* MARC HUBREGTSE and JOHAN REMMERSWAAL

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Appeal 2018-005788  
Application 13/488,610  
Technology Center 3700

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Before: JOHN C. KERINS, WILLIAM A. CAPP, and  
BRANDON J. WARNER, *Administrative Patent Judges*.

CAPP, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant<sup>1</sup> seeks our review under 35 U.S.C. § 134(a) of the non-final rejection of claims 1–15 and 18. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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<sup>1</sup> We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42(a). Appellant identifies Ureca B.V. as the real party in interest. Appeal Br. 3.

## THE INVENTION

Appellant's invention is a catheter assembly for passing an occlusion in veins or arteries. Spec. 1–2. Claim 18, reproduced below, is illustrative of the subject matter on appeal.

18. A catheter assembly, comprising:

a hollow catheter having an operative end; and

a loop wire moveably arranged with respect to the hollow catheter to form a cutting loop located forwardly of the operative end of the catheter,

wherein the cutting loop includes a distal cutting edge portion extending from the operative end of the hollow catheter, the distal cutting edge portion being positioned at the distal tip of the cutting loop at a forward most point of the catheter assembly,

wherein the cutting loop includes a first diameter that extends along a longitudinal axis of the hollow catheter and a second diameter that extends perpendicular to the longitudinal axis, the first diameter configured to vary in a direction along the longitudinal axis of the hollow catheter such that the first diameter remains larger than the second diameter, and

wherein the loop wire is supported by the hollow catheter and arranged so that a pushing force from several grams to several hundred grams can be exerted by the cutting loop at the distal cutting edge portion in the direction along the longitudinal axis of the hollow catheter to push aside and cut tissue within a vein or artery in the direction along the longitudinal axis of the hollow catheter when the cutting loop is longitudinally extended.

### THE REJECTIONS

The Examiner relies upon the following as evidence in support of the rejections:

<b>NAME</b>	<b>REFERENCE</b>	<b>DATE</b>
Okada	US 4,643,187	Feb. 17, 1987
Kerin	US 5,716,321	Feb. 10, 1998
Dunham	US 5,797,948	Aug. 25, 1998

The following rejections are before us for review:<sup>2</sup>

1. Claims 1–12, 15, and 18 are rejected under 35 U.S.C. § 112, first paragraph, for failure to comply with the written description requirement.
2. Claim 8 is rejected under 35 U.S.C. § 112, first paragraph, for failure to comply with the enablement requirement.
3. Claims 1–12, 15, and 18 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite.
4. Claims 1–5, 7, 15, and 18 are rejected under 35 U.S.C. § 102(b) as anticipated by Okada.
5. Claims 1–6, 9, 11, 15, and 18 are rejected under 35 U.S.C. § 102(b) as anticipated by Kerin.
6. Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Okada.
7. Claim 10 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Okada and Dunham.
8. Claim 12 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kerin.

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<sup>2</sup> Rejections of claims 13 and 14 have been withdrawn in view of Appellant's election to cancel these claims. Appeal Br. 12.

OPINION

*Indefiniteness of Claims 1–12, 15, and 18*

The Examiner considers that the term “*several*” grams renders independent claims 1 and 18 indefinite. Non-Final Action 4. The Examiner states that it is unclear whether “*several*” includes 2, 3, 4 or even 10. *Id.*

Appellant argues that a person of ordinary skill in the art would understand that “*several*” means more than one. Appeal Br. 14.

In response, the Examiner notes that “*several*” may be defined as “an indefinite number more than two and fewer than many.” Ans. 7.

The PTO can properly reject a claim as indefinite if the claim is ambiguous, vague, incoherent, opaque, or otherwise unclear. *In re Packard*, 751 F.3d 1307, 1311 (Fed. Cir. 2014). The test for definiteness under 35 U.S.C. § 112, is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986) (citations omitted).

Appellant’s Specification teaches:

By using a combination of a rigid catheter and a rigid loop wire material, a separation action can be performed in a forward direction, i.e. in the longitudinal plane of the 20 catheter-loop. Depending on the condition of the patient, the operating force will apply for bypassing an occlusion. Due to calcification, it is possible that a substantial force needs to be exerted by the front side of the loop. In that case, the loop thus chosen must be small in order to make the rigidity of the assembly of loop and catheter as high as possible. The force exerted when passing/ bypassing the occlusion may vary from several grammes and preferably tens of grammes, to several hundred grammes of force. This rigidity is significantly higher than the rigidity required only for introducing a catheter in a vein/artery.

Spec. 3–4. Taken in context, a person of ordinary skill in the art would understand that the recital of “several” is intended to be a term of approximation rather than a strict lower limit to the amount of force to be exerted. Such words of approximation are considered to be descriptive terms that are commonly used in patent claims to avoid a strict numerical boundary to the specified parameter. *See, e.g., Anchor Wall Sys. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1311 (Fed. Cir. 2003).

We do not sustain the Examiner’s Section 112 indefiniteness rejection of claims 1–12, 15, and 18.

*Written Description – Claims 1–12, 15, and 18*

The Examiner finds that Appellant’s drawings show a side view of the apparatus, in which a first diameter can be seen, but fails to limit a second diameter along an axis that extends into and out of the figure. Non-Final Action 2–3. Also, the Examiner finds that there is no written description support for the limitation in claim 1 directed to a distal cutting edge portion with a uniform circular cutting edge cross-section. *Id.* at 3.

Appellant asserts that the two recited diameters are used to define an elliptical shape of the loop wire as it projects from the distal end of the catheter. Appeal Br. 9–11.

In response, the Examiner states that the Specification fails to show support for a second diameter with the claimed dimension that extends in the “z” axis, perpendicular to the longitudinal axis. Ans. 6. More particularly, the Examiner states that the Specification is silent as to how much the loop moves away from the longitudinal axis or along the z-axis. *Id.* The Examiner reminds us that the claim language at issue was added by

amendment in an effort to distinguish over prior art that taught a loop that was offset from a central longitudinal axis. *Id.*

In reply, Appellant focuses exclusively on the Examiner's remarks regarding an axis extending into and out of the page. Reply Br. 4. Appellant fails to address the Examiner's findings regarding lack of support in the Specification for diameters that reside within the plane of the ellipse formed by the loop along the "z" axis. *Id.* More importantly, Appellant fails to direct our attention to any portion of the Specification and/or drawings that provides written description support for the claim language at issue. *See generally* Reply Br.

An ellipse may have a major axis and a minor axis that are comprised of diameters that pass through the center of the ellipse. In the instant case, we understand that, in claim 1, the major axis of the ellipse formed by Appellant's loop extends along a longitudinal axis of the hollow catheter, and that the minor axis is perpendicular to the major axis within the plane defined by the ellipse. Claim 1 requires that the first diameter (along the longitudinal axis) of the cutting loop is configured such that it remains larger than the second diameter (along the perpendicular axis) of the loop. Claims App.

Appellant provides Figures 1, 2 and 3a-c with accompanying disclosure in the Specification. According to the Specification, Appellant's catheter assembly consists of a hollow catheter 2 that can be advanced through a vein or artery. Spec. 11, Figs. 1-3c. Attachment 4 is provided at the effective end 5 where loop wire end 9 of loop 8 is attached. *Id.* Loop wire end 3 extends along the length of the catheter past control wheel 7. *Id.* Loop wire end 3 can be moved back and forth and *loop 8 can thereby be*

*made smaller or larger. Id.* As we understand the Specification and accompanying drawings, moving loop wire end 3 back and forth can be accomplished in a manner that would cause the first (longitudinal) diameter to be smaller than the second (perpendicular) diameter. The mere fact that Figures 3a and 3b depict a particular condition of the loop where the longitudinal axis is greater than the perpendicular axis is insufficient to establish that the invention is “configured” so that such lengths remain so relative to each other. Indeed, Figures 1 and 3c suggest that the longitudinal axis may be the shorter of the two. *See* Figs. 1, 3c. We are unable to discern any support in Appellant’s disclosure about “configuring” the assembly so that the first diameter always remains larger than the second diameter. When a written description cannot be found in the Specification, as filed, the only thing the PTO can reasonably be expected to do is to point out its non-existence. *Hyatt v. Dudas*, 492 F.3d 1365, 1377 (Fed. Cir. 2007).

With respect to the uniform, circular cutting edge cross-section issue, Appellant directs our attention to Figures 1–3c as showing distal cutting edge portions of a loop wire. Appeal Br. 11. Appellant alleges that a “wire is generally understood to be an elongated metal circular in cross-section.” *Id.* Therefore, Appellant concludes that “the loop wire which forms the distal cutting edge would have a uniform circular cross-section.” *Id.* Appellant also directs our attention to the Declaration of Dr. Katharine Krol, and represents that Dr. Krol’s testimony establishes that a person of ordinary skill in the art would understand the Specification as disclosing a cutting edge portion of the cutting loop with “a uniform circular cross-section.” *Id.* at 12.

In response, the Examiner observes that it is common for wires to have non-circular cross-sections. Ans. 6 (citing examples).

In reply, Appellant states that its position is not that a wire always has a “uniform circular cross-section,” but that one of ordinary skill in the art would understand that Appellant’s loop wire has a “uniform circular cross-section.” Reply Br. 5. Appellant argues that the Examiner fails to rebut Dr. Krol’s testimony to that effect. *Id.* Appellant, once again, represents that Dr. Krol’s testimony establishes that person of ordinary skill in the art would understand that the Specification teaches a uniform circular cross-section and does so “precisely.” *Id.*

Appellant’s arguments are not persuasive. We agree with the Examiner that not all wires have a circular cross-section and we further agree with the Examiner that the Specification provides no written description for the recited circular cross-section limitation. Ans. 6–7. Dr. Krol testifies that that Appellant’s device uses a cutting loop with a cutting edge portion that has a uniform circular cross-section that cuts tissue when advanced forwardly. *See* Krol Decl. ¶ 11. Dr. Krol’s testimony appears to be based on testing a physical embodiment of a device provided by Appellant and is otherwise devoid of any analysis whereby a person of ordinary skill in the art would “understand” that Appellant’s Specification demonstrates possession of a cutting wire with a uniform circular cross-section. Dr. Krol’s testimony falls short of demonstrating written description support for the circular cross-section limitation in claim 1.

We sustain the Examiner’s Section 112 written description rejection of claims 1–12, 15, and 18.

*Enablement of Claim 8*

The Examiner rejects claim 8 as non-enabled because it recites the lower end of a range only. Non-Final Action 3.

Appellant argues that there is no *per se* prohibition on claiming open-ended ranges. Appeal Br. 12. Appellant argues that an upper limit is implicitly directed by the effective operation distance of the catheter assembly itself. *Id.* at 13.

In response, the Examiner notes that the upper limit of the claimed range is open-ended and that the Specification never explains how its scale gradation would work if the control wheel were turned more than once to accommodate a large range. Ans. 7. The Examiner never addresses Appellant's argument that an upper limit to the range is implied by the size of the catheter assembly itself. *See generally* Ans.

It is well settled that open-ended claims are not inherently improper. *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1376 (Fed. Cir. 2007). They may be supported if there is an inherent, albeit not precisely known, upper limit and the Specification enables one of skill in the art to approach that limit. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1572 (Fed. Cir. 1991). Here, the Examiner does not adequately address Appellant's contention that there is an inherent upper limit imposed by the size of the catheter assembly.

We do not sustain the Examiner's non-enablement rejection of claim 8.

*Prior Art Rejections*

The Examiner's prior art rejections are predicated on findings of fact that each of Okada and Kerin disclose a "cutting loop" as claimed in

independent claims 1 and 18, the only independent claims presented on appeal. Final Action 4–8. Appellant disputes such findings and is correct to do so.

Okada is directed to a high-frequency incising and excising instrument. Okada, Abstract. In operation, Okada's loop 16 is hooked around a polyp (or the like) to be excised, after which the loop is constricted until it tight binds the neck of the polyp and then high-frequency current is applied to the wire and polyp is burned away. Okada, col. 5, l. 37 – col. 6, l. 7. There is no evidentiary support for the Examiner's finding that Okada has a cutting loop that is arranged to cut tissue at a distal edge portion of a cutting loop.

Similarly, Kerin discloses an apparatus for imaging a narrow body lumen. Kerin, Abstract. To facilitate imaging, Kerin provides a structure disposed distal to an optical viewing scope. *Id.* Such structure, which could take the form of a cage or a wire loop guide, creates controllable separation between body lumen tissue and the lens of the optical viewing scope to prevent while-conditions. *Id.* col. 2, l. 60 – col. 4, l. 8. As with the grounds of rejection involving Okada, there is no evidentiary support for the Examiner's finding that Kerin has a cutting loop that is arranged to cut tissue at a distal edge portion of a cutting loop.

The erroneous findings of fact detailed in the preceding two paragraphs taint all of the various grounds of rejection over both of the independent claims and all of the dependent claims that depend therefrom, including the Section 103 rejection of claim 10 as Dunham does not cure such deficiency. Accordingly, we do not sustain any of the Examiner's grounds of rejection over the prior art.

CONCLUSION

In summary:

<b>Claims Rejected</b>	<b>§</b>	<b>Reference(s)/Basis</b>	<b>Aff'd</b>	<b>Rev'd</b>
1-12, 15, 18	112	Written Description	1-12, 15, 18	
8	112	Enablement		8
1-12, 15, 18	112	Indefiniteness		1-12, 15, 18
1-5, 7, 15, 18	102	Okada		1-5, 7, 15, 18
1-6, 9, 11, 15, 18		Kerin		1-6, 9, 11, 15, 18
8	103	Okada		8
10	103	Okada, Dunham		10
12	103	Kerin		12
<b>Overall Outcome</b>			1-12, 15, 18	

AFFIRMED