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USGI Medical, Inc. 1140 Calle Cordillera San Clemente, CA 92673			EXAMINER KASZTEJNA, MATTHEW JOHN	
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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* VAHID SAADAT, DESMOND BIRKETT, CHRIS ROTHE,  
and TRACY MAAHS

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Appeal 2011-006676  
Application 10/824,936  
Technology Center 3700

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Before ERICA A. FRANKLIN, JACQUELINE WRIGHT BONILLA, and  
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an apparatus for obtaining endoluminal access. The Examiner has rejected the claims as anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 1, 2, 5-9, 19, 23, 24, 26, 27, 29-33, 36-38, 40-43 and 65-77 are on appeal. Independent claims 1, 31 and 65 are representative and read as follows (emphasis added):

1. Apparatus for obtaining endoluminal access, the apparatus comprising:

an elongate body having a working axis and a distal region, the elongate body configured for insertion within a body lumen and comprising a plurality of links and at least one tensioning wire whereby said elongate body has a first, substantially flexible state and a second, substantially rigid state;

*at least two working lumens extending through the elongate body;*

at least one articulating element disposed near or at the distal region of the elongate body and pivotally connected to the elongate body near or at its distal region by a linkage member pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body,

wherein the articulating element articulates from an in-line position to an off-axis position relative to the working axis of the elongate body, and

wherein a distal opening of at least one of the working lumens is substantially covered by the articulating element in the in-line position and is substantially uncovered by the articulating element in the off-axis position.

31. A method for obtaining endoluminal access, the method comprising:

advancing an elongate body having at least one articulatable element disposed near or at a distal region thereof into a body lumen;

moving the articulatable element from a position in-line with or adjacent to a working axis of the elongate body to a position out-of-line with the working axis, thereby at least

substantially exposing a distal opening of a working lumen provided in the elongate body; and

*passing a diagnostic or therapeutic tool through the working lumen while the articulatable element is maintained in the out-of-line position.*

65. Apparatus for obtaining endoluminal access, the apparatus comprising:

a substantially flexible elongate body having a working axis and a distal region, the elongate body configured for insertion within a body lumen;

*at least two working lumens extending through the elongate body;*

at least one articulating element disposed near or at the distal region of the elongate body and pivotally connected to the elongate body near or at its distal region by a linkage member pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body,

wherein the at least one articulating element articulates from an in-line position to an off-axis position relative to the working axis of the elongate body, and

wherein a distal opening of at least one of the working lumens is substantially covered by the at least one articulating element in the in-line position and is substantially uncovered by the at least one articulating element in the off-axis position.

The claims stand rejected as follows:

- Claims 31-33, 36-38, 40-43, and 65-77 are patentable under 35 U.S.C. § 102(e) over Khalili.<sup>1</sup>
- Claims 1-2, 5-9, 19, 23-24, 26-27 and 29-30 are patentable under 35 U.S.C. § 103(a) over the combination of Khalili and Zehel.<sup>2</sup>

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<sup>1</sup> Khalili et al., US 2005/0096502, published May 5, 2005.

<sup>2</sup> Zehel et al., US 5,251,611, issued Oct. 12, 1993.

*Issue*

The same issue is dispositive for all of the rejections. The Examiner finds that Khalili discloses the disputed element of a “working lumen,” where “the term ‘working lumen’, may be interpreted as being a fixed camera, as the CCD itself is a ‘working’ element that is provided within a lumen” (Ans. 11, citing Figure 13B, element 330, of Khalili).

Appellants contend as follows:

The recitation in each of the claims of “a working lumen”... refers to an open space(s), channel(s), or conduit(s) to be used for passage of diagnostic or therapeutic tools therethrough. This interpretation is supported by Appellants’ specification, which consistently uses the terms to refer to such a structure. (See, e.g., ¶ 0002: “The elongate body may also include *a working lumen to facilitate passage of diagnostic or therapeutic tools therethrough*, or for injection of fluids or to draw suction.”

...

[E]ven if a subassembly of the Khalili device included at one time (e.g., during assembly) a conduit or channel that would constitute a “working lumen,” the body of the camera 330 is installed in the conduit or channel, and there is therefore no longer a “working lumen” as claimed.

(App. Br. 13 and 14.)

The issue presented is: Does the evidence of record support the Examiner’s findings that Khalili discloses “at least two working lumens” or “passing a diagnostic or therapeutic tool through the working lumen” as required by the claims?

*Findings of Fact*

The following findings of fact (“FF”) are supported by a preponderance of the evidence of record.

FF1. The Specification discloses as follows: “The elongate body may also include a working lumen to facilitate passage of diagnostic or therapeutic tools therethrough, or for injection of fluids or to draw suction” (Specification 1, ¶ [0002]).

FF2. Khalili discloses robotic surgical device where “a camera **330** may be provided at the interface region where the leaflets connect to the body of the device” (Khalili 8, ¶ [0079]).

*Principles of Law*

“[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification.” *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000). However, a claim element cannot be interpreted so broadly so as to read the limitation out of the claim. *See Texas Instr. Inc. v. United States Int’l Trade Comm’n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (Claim language cannot be mere surplusage. An express limitation cannot be read out of the claim). Further, claim terms are not interpreted in a vacuum, devoid of the context of the claim as a whole.

*Analysis*

We agree with Appellants. The evidence of record fails to establish that a “working” camera fixed within the interior of a device assembly (FF2) would have been understood by a person of ordinary skill in the art to be a “working lumen” (*see, e.g.*, Ans. 11). Rather, a broadest reasonable interpretation of the phrase “working lumen” in light of the Specification is consistent with the Appellants’ view that a “working lumen” is a lumen capable of facilitating the passage of tools (FF1; *see also*, App. Br. 13). An occupied channel or cavity would not be capable of this function.

Furthermore, independent claim 31 defines a method for obtaining endoluminal access requiring “passing a diagnostic or therapeutic tool through the working lumen.” We find that the Examiner’s claim interpretation reads this element out of the claim (*see, e.g.*, Ans. 11). The Examiner has not established that a skilled worker would have recognized that Khalili discloses a method for obtaining endoluminal access requiring *passing a diagnostic or therapeutic tool through the working lumen* as required by claim 31. For example, the Examiner has not adequately explained how disclosing the robot arm(s) as shown in Figures 15 and 16 in Khalili describes a step of passing a tool through a working lumen (Ans. 5, 12-13; *see also* Khalili [0082]-[0083]).

Regarding claim 65, as Appellants point out, “camera 330” in Khalili’s apparatus is not a “working lumen” as recited in independent claims (App. Br. 14). The Examiner therefore fails to establish by a preponderance of the evidence that this reference describes or suggests “at least two working lumens” by referring to “330, 332” in Khalili (Ans. 4). The Examiner has not established that a skilled worker would have recognized that Khalili discloses an apparatus having *at least two working lumens* as required by claim 65. Khalili fails to anticipate claims 31, 65 and dependent claims thereto.

The rejection for obviousness relies on the Examiner’s same findings that Khalili discloses *at least two working lumens* (Ans. 7-8), and therefore suffers from the same deficiency. The Examiner fails to establish by a preponderance of the evidence that this reference describes or suggests “at

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least two working lumens” as required in independent claim 1 and dependent claims thereto.

**SUMMARY**

We reverse all of the rejections on appeal.

**REVERSED**

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