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Row 1: 14/714,488, 05/18/2015, Steven Zaver, H-KN-02072US01, 5205
Row 2: 77218, 7590, 09/17/2019, Medtronic Vascular - APV Division, c/o IP Legal Department, 3576 Unocal Place, Santa Rosa, CA 95403
Row 3: EXAMINER ORKIN, ALEXANDER J
Row 4: ART UNIT 3771, PAPER NUMBER
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rs.patents.five@medtronic.com

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* STEVEN ZAVER, SENGKHAM SIRIVONG,  
CHRISTOPHER QUINN, EARL SLEE, and LINDA ANDERSON

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Appeal 2017-010761  
Application 14/714,488  
Technology Center 3700

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Before ERIC B. GRIMES, JEFFREY N. FREDMAN, and  
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant<sup>1</sup> appeals from the Examiner's decision to reject claims 21–34 on obviousness grounds. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

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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. Appellant identifies the real party in interest as Medtronic plc of Dublin, Ireland, which is the parent entity of the assignee of record, Covidien LP. (Appeal Br. 3.)

## STATEMENT OF THE CASE

### *Background*

“The present invention relates to embolic protection systems, and, more particularly, to embolic protection systems for use in blood vessels.” (Spec. ¶ 2.) “Embolic protection devices can remove emboli from the bloodstream by filtering debris from blood, by occluding blood flow followed by aspiration of debris, or can cause blood flow reversal to effect removal of debris.” (*Id.* ¶ 4.) However, “[d]ifficulties can arise where embolic protection devices are not properly deployed within the anatomy,” and also “when recovering an embolic protection device.” (*Id.* ¶¶ 5–6.) “Accordingly, a need exists for an embolic protection device having improved radiopacity that is inexpensive, durable, provides visibility to the appropriate regions of the device, and which uses technology that does not compromise the performance of the device.” (*Id.* ¶ 8.)

### *The Claims*

Claims 21–34 are on appeal. Independent claim 21 is representative, and reads as follows:

21. A device comprising:
  - a filter element comprising a mesh including a filament, the filter element being configured to expand from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained, wherein the filter element defines a cavity including a proximal facing opening in the expanded configuration;
  - a bead of radiopaque material attached to the filament of the mesh;
  - an elongate support member;
  - a proximal marker disposed on the elongate support member and slideable with respect to the elongate support member; and

a distal marker disposed on the elongate support member and slideable with respect to the elongate support member, wherein the mesh of the filter is attached to the proximal and distal markers,

wherein the elongate support member comprises a stop between the proximal and distal markers that limits the movement of proximal and distal markers.

*The Issues*

The Examiner rejected the claims as follows:

Claims 21–34 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Clubb<sup>2</sup> and Goicoechea.<sup>3</sup> The Examiner additionally relies upon Linder<sup>4</sup> and Brady<sup>5</sup> as evidentiary references in support of the rejection.

FINDINGS OF FACT

- FF1. Clubb teaches a device for filtering emboli having a mesh filter element being expandable from a collapsed configuration when restrained to an expanded configuration when unrestrained having a proximal, distal, and central portion creating a proximal facing cavity having a perimeter, an elongate support member, and a radiopaque band attached to the mesh. (Clubb, Abstract, ¶¶ 29, 63.)
- FF2. Clubb teaches that the material used for the filter mesh may be a nickel-titanium alloy (“nitinol”). (*Id.* ¶¶ 34, 36.)
- FF3. Clubb teaches that “[t]he material comprising the filter is preferably at least partially radiopaque,” and “[t]his material

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<sup>2</sup> Clubb et al., US 2004/0153118 A1, published Aug. 5, 2004.

<sup>3</sup> Goicoechea et al., US 6,165,213, issued Dec. 26, 2000.

<sup>4</sup> Linder et al., US 2005/0096692 A1, published May 5, 2005.

<sup>5</sup> Brady et al., US 2006/0241681 A1, published Oct. 26, 2006.

can be made radiopaque by plating, or by using core wires, tracer wires, or fillers that have good X-ray absorption characteristics compared to the human body.” (*Id.* ¶ 37.)

FF4. As shown in Fig. 4(a), Goicoechea teaches an endoluminal prosthesis wherein “a radiopaque marker may typically comprise a gold or platinum wire 17 crimped onto an end of stent 16. Alternatively, the radiopaque marker may be a tube 17a disposed around a length of wire on the stent, also as shown in FIG. 4(a).” (Goicoechea, 10:53–57, Fig. 4(a).)

FF5. Linder teaches an embolic protection device with a filter assembly wherein:

[b]ands 120 of a radiopaque material can be added to at least one of struts 116 of filter basket 112. The bands, 120, may be made from cut tubing of a radiopaque material, or optionally be made from a section of helically wound coil of a radiopaque material.

Optionally, a band 124 of radiopaque material, similar to band 120, can also be added at the proximal junction of filter basket 112 and guide member 102. This band 124 can optionally surround at least a portion of body 122 and can be encapsulated in an adhesive filet to provide a smooth transition in outer diameters. The radiopaque substances can include, but not limited to, barium sulphate, bismuth subcarbonate, titanium dioxide, combinations thereof, or other radiopaque substances.

(Linder ¶ 53.)

FF6. Brady teaches a support frame for an embolic protection device that includes a radiopaque core wherein “[i]deally the radiopaque core is provided as a core embedded within at least one support element.” The radiopaque core may be in powder form or liquid form, and/or include a radiopaque element that comprises a wire, and be made of mercury, gold, or platinum. (Brady ¶¶ 110–112.)

FF7. Brady further teaches that the device may include filaments with a radiopaque core embedded therein, and also a jacket around the filaments made at least partially of a radiopaque material. (*Id.* ¶¶ 130–131.)

#### PRINCIPLES OF LAW

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness” . . . however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

*KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (citation omitted).

#### ANALYSIS

*Rejection Based on Clubb and Goicoechea, as evidenced by Linder and Brady*

With respect to claims 21–29, 32, and 33, the Examiner finds that Clubb discloses a device satisfying most of the claim elements with the exception that Clubb “is silent about the radiopaque bead attached to the filament of the mesh.” Final Act. 3. The Examiner, however, relies upon Clubb’s disclosure that the filter can be radiopaque. *Id.* The Examiner further relies upon Goicoechea as teaching a similar device with a radiopaque element in the form of a plurality of beads defining a through hole into which the filament extends, wherein the bead is mechanically crimped onto the filament or formed over the filament. *Id.* (citing Goicoechea, Fig. 4(a), 10:50–60). The Examiner further contends that Goicoechea teaches that the bead comprises a tubular marker band, and

comprises a platinum alloy. *Id.* Based on these teachings, the Examiner asserts that “[i]t would have been obvious to one of ordinary skill [in] the art at the time of the invention to substitute the bead of Goicoechea with the device (radiopaque mechanism) of Clubb in order for using an alternative mechanism to monitor the device during delivery.” *Id.* at 3–4.

With respect to claim 30, the Examiner contends that Clubb teaches the bead is integral with the braided filament. *Id.* at 4 (citing Clubb ¶ 37). With respect to claim 31, the Examiner contends that Clubb discloses the mesh comprises a polymer film defining holes and the filament is applied to the polymer film. *Id.* (citing Clubb ¶¶ 4, 36). With respect to claim 34, the Examiner contends that Clubb discloses that the plurality of elements are metal filaments. *Id.* (citing Clubb ¶ 36).

Appellant makes several arguments as to why the Examiner failed to make a prima facie case of obviousness. Although Appellant has presented arguments under different groupings of the claims, we focus our analysis on claims 21 and 32 as our analysis for these independent claims applies to all the claims on appeal. In particular, we are persuaded that the Examiner has failed to establish that one of ordinary skill in the art would have found it obvious to substitute the radiopaque mechanism taught by Clubb with the radiopaque marker taught by Goicoechea in order to arrive at the claimed bead of radiopaque material attached to the filament of the mesh.<sup>6</sup> *See* Appeal Br. 7–9.

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<sup>6</sup> In a prior appeal in the parent application, we were persuaded by Appellant’s argument that “‘because Clubb discloses a filter that is made from a radiopaque material, there would have been no apparent reason, absent access to Appellant’s disclosure, to modify the filter to include an additional radiopaque element.’” *See Ex Parte Zaver*, Appeal No. 2012-

Under the Manual of Patent Examining Procedure (“MPEP”), one exemplary rationale that may support a conclusion of obviousness is the “[s]imple substitution of one known element for another to obtain predictable results.” *See* MPEP §§ 2141, 2143. In this case, however, the Examiner has not shown that one of ordinary skill in the art would have considered the substitution of the at least partially radiopaque material of Clubb’s filter with the radiopaque marker taught by Goicoechea to be a “[s]imple substitution” that would lead to “predictable results,” or that the different means to achieve radiopacity taught by the references would have been considered equivalent in the art. Nor has the Examiner pointed to any particular advantage to be gained by using Goicoechea’s radiopaque markers in lieu of, or in addition to, Clubb’s partially radiopaque filter material. The Examiner’s stated reason for making the substitution, in order to “us[e] an alternative mechanism to monitor the device during delivery,” is merely conclusory, and does not provide the requisite articulated reasoning with rational underpinning to support the legal conclusion of obviousness.

We have also considered the Examiner’s reliance on the teachings of Linder and Brady. The Examiner cites these references as allegedly showing that the radiopaque mechanisms of Clubb and Goicoechea are “similar or known” substitutions. Ans. 3. Linder teaches that radiopaque bands 120, 124 that are similar to Goicoechea’s radiopaque tubes may be positioned at different parts of a filter assembly. FF5. Brady teaches that a

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005308, 2014 WL 6807802, at \*1 (PTAB Dec. 2, 2014). Unlike in the prior appeal, however, we recognize that the Examiner relies upon a *substitution* rationale rather than a rationale to modify Clubb’s filter to include an *additional* radiopaque element.

radiopaque core or radiopaque elements in the form of a wire or a jacket may be used in an embolic protection device. FF6. However, neither reference suggests that the use of the radiopaque mechanisms taught therein would have been considered a similar or known substitution for a mechanism in which the filter material itself is made of at least a partially radiopaque material, as taught in Clubb. Nor does either reference identify any other advantage in using beads as the radiopaque material.

Accordingly, we are persuaded that the Examiner has not made a prima facie case of obviousness for any of claims on appeal, which all require at least one bead of radiopaque material attached to the filament of the mesh.

#### CONCLUSION

We reverse the rejection of claims 21–34 under 35 U.S.C. § 103(a) as being unpatentable over the combination Clubb and Goicoechea, as evidenced by Linder and Brady.

<b>Claims Rejected</b>	<b>Basis</b>	<b>Affirmed</b>	<b>Reversed</b>
21–34	§ 103 Clubb, Goicoechea, Linder, Brady		21–34

REVERSED