

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 16

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte HARRISON M. LAZARUS

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Appeal No. 1998-2095  
Application No. 08/460,311<sup>1</sup>

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ON BRIEF

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Before COHEN, McQUADE and GONZALES, Administrative Patent Judges

GONZALES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal from the examiner's final rejection of claims 30 through 41, which are all of the claims

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<sup>1</sup> Application for patent filed June 2, 1995. According to appellant, this application is a divisional of application no. 08/149,040, filed November 8, 1993, now abandoned.

Appeal No. 1998-2095  
Application No. 08/460,311

remaining in the application.

The invention is directed to a method of implanting an intraluminal vascular graft within a diseased or damaged vessel.

The subject matter before us on appeal is illustrated by reference to claims 30 and 39 which, along with the other claims on appeal, have been reproduced in "Appendix A" attached to the main Brief (Paper No. 12).

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Lazarus 1992	5,104,399	Apr. 14,
Kwan-Gett 29, 1992	5,151,105	Sep.
Barone et al. (Barone) 1994	5,360,443	Nov. 01,

(Filed Jun. 11, 1990)

The following rejections are before us for review:

Claims 30, 31 and 33 through 41 stand rejected under 35 U.S.C. § 103 as being unpatentable over Lazarus in view of Barone; and

Claim 32 stands rejected under 35 U.S.C. § 103 as being

Appeal No. 1998-2095  
Application No. 08/460,311

unpatentable over Lazarus in view of Barone, as applied to claims 30 and 31 above, and further in view of Kwan-Gett.

The full text of the examiner's rejections and the responses to the arguments presented by appellant appear in the final rejection (Paper No. 8, mailed April 29, 1997) and the Answer (Paper No. 13, mailed January 23, 1998), while the complete statement of appellant's arguments can be found in the Main and Reply Briefs (Paper Nos. 12 and 14, filed September 29, 1997 and March 20, 1998, respectively).

#### OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner. As a consequence of our review, we have made the determinations which follow.

#### The rejection of claims 30, 31 and 33-41

We reverse the examiner's rejection of claims 30, 31 and 33 through 41 under 35 U.S.C. § 103.

Appeal No. 1998-2095  
Application No. 08/460,311

In rejecting claims under 35 U.S.C. § 103 the examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993); In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if that burden is met does the burden of coming forward with evidence or argument shift to the applicant. Id. If the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In order to establish the prima facie obviousness of a claimed invention, all the claim limitations

must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 985, 180 USPQ 580, 583 (CCPA 1974).

We begin our review with independent claim 30. We note that claim 30 calls for a method of implanting an intraluminal vascular graft within a diseased or damaged vessel comprising, inter alia,

. . . attaching said intraluminal vascular graft to the

inner wall of said vessel by initiating a non-perforating, inflammatory response between said intraluminal vascular graft and said inner wall of said vessel. . . .

The examiner describes Lazarus as disclosing the invention substantially as claimed, except for the step of attaching the graft to the inner wall of the vessel by initiating a non-perforating, inflammatory response between the graft and the inner wall of the vessel (Answer, pages 4 and 5). Instead, Lazarus teaches attaching the graft to the wall of the lumen with staples or anchoring elements 16, 17 (see col. 3, lines 50-65 and Figure 2). Barone is cited by the examiner for teaching a vascular graft securing means 165 including a thin-walled member 166 having a smooth outer wall surface 169 (Answer, page 5). It is the examiner's position that it would have been obvious to modify the method taught by Lazarus by replacing the vascular

graft of Lazarus with the graft taught by Barone in order "to prevent perforation of the blood vessel" (id.) As to the step of attaching the vascular graft to the inner wall of the

Appeal No. 1998-2095  
Application No. 08/460,311

vessel by initiating an inflammatory response between the vascular graft and the inner wall of the vessel, the examiner asserts that "insertion of any prosthetic device will initiate an inflammatory response and therefore cause attachment" (id.).

Appellant argues that Barone neither teaches nor suggests a configuration of the disclosed securing means to initiate an inflammatory response to facilitate attachment of the graft to the intima or inner wall of the vessel (Brief, page 8). Further, the appellant argues that "while all things implanted in the body may cause an inflammatory response or irritation . . . not all inflammatory responses are of the degree which provides attachment of the device to the surrounding body tissue" (Reply Brief, pages 1 and 2).

Since the examiner has not directed our attention to any particular language in Barone which explicitly supports the position taken by the examiner, we understand the rejection to be based on the examiner's determination that insertion of Barone's intraluminal vascular graft into a vessel will not only initiate

Appeal No. 1998-2095  
Application No. 08/460,311

an inflammatory response between the graft and the inner wall of the vessel, but that the inflammatory response of the inner wall will inherently result in the attachment of the graft to the inner wall of the vessel.

Like the appellant, we do not agree with the examiner's position. We are informed by appellant's specification that the attachment of vascular graft 20 may be accomplished by providing means or material which initiates an inflammatory response in the vessel intima or inner wall (page 22).

Appellant teaches, for example, that the longitudinal and/or circumferential support structures may be constructed of a material, or may be coated with a material, which induces an inflammatory response. According to appellant, such materials may include polylactic acids, polyglycolic acids or polyamino acids. Other materials disclosed as initiating an inflammatory response include cat gut, cellulose and nylon.

Barone, on the other hand, teaches that the graft or tube 160 is made of a material compatible with the patient's body, e. g., DACRON®, TEFLON® or TEFLON® coated DACRON® and porous polyurethane (col. 6, lines 55-66) and that the tube 160 or securing means 165 may have a coating of biologically inert

Appeal No. 1998-2095  
Application No. 08/460,311

material, e. g., TEFLON® or

porous polyurethane (col. 7, lines 16-19). Further, Barone teaches that "the thin-walled member 166 is forced radially outwardly into contact with the aorta 152 to remain secured thereto" (id. at 46-48). Given that Barone fails to teach or suggest any of the inflammation-inducing materials taught in appellant's specification and teaches that the tube 160 is attached to the aorta by forcing the thin-walled member 166 radially outwardly into contact with the aorta, we find the examiner's apparent position that the inflammatory response of the inner wall of the vessel to Barone's tube 160 or securing means 165 will inherently result in the attachment of the graft to the inner wall of the vessel to be speculative and unsupportable.

It is well settled that inherency may not be established by probabilities or possibilities, but must instead be "the natural result flowing from the operation as taught." See In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). In the present case, the examiner has not explained how the Barone reference provides factual basis to establish that the

Appeal No. 1998-2095  
Application No. 08/460,311

natural result flowing from following the teachings of Barone would be an

inflammatory response between the intraluminal graft and the

inner wall of the diseased or damaged vessel sufficient to result in the attachment of the graft to the inner wall of the vessel as claimed by appellant. Accordingly, since all the limitations of appellant's claim 30 are not found in the applied prior art or obvious therefrom, it follows that the examiner's rejection of claim 30 under 35 U.S.C. § 103 will not be sustained.

Claims 31 and 33 through 38 are dependent on claim 30 and, therefore, contain all of the limitations of that claim. Therefore, we will also not sustain the standing 35 U.S.C. § 103 rejection of claims 31 and 33 through 38.

Turning next to independent claim 39, we note that claim 39 calls for a method of implanting an intraluminal vascular graft within a diseased or damaged vessel which is bifurcated along its length and does not call for the step of attaching the intraluminal vascular graft to the inner wall of said vessel by initiating a non-perforating, inflammatory response

between the graft and the inner wall of said vessel. Instead, claim 39 calls for

. . . compressing an intraluminal vascular graft structure to provide a reduced circumferential dimension sized to be receivable within said transportation structure, said intraluminal vascular graft structure comprising a tubular body having an expandable frame structure including a circumferential support structure positioned to contact and

span the bifurcation of a bifurcated vessel . . . and supporting said intraluminal vascular graft structure within said bifurcated vessel by positioning said circumferential support structure at the bifurcation of the bifurcated vessel to be supported by the bifurcation.  
. . .

Appellant argues that "[a] method of supporting a vascular graft on the cusp of a bifurcated vessel by use of a circumferential support is not disclosed by either Lazarus '399 or Barone, et al." (Brief, page 9). The examiner's position is that the language "vascular graft structure comprising a tubular body having an expandable frame structure including a circumferential support structure positioned to contact and span the bifurcation of a bifurcated vessel" is unclear and can be construed to mean that it is the vascular graft, not the circumferential support structure, which is

Appeal No. 1998-2095  
Application No. 08/460,311

intended to contact the bifurcation and that Barone shows, in Figure 4, a vascular graft contacting the bifurcation (Answer, pages 7 and 8).

We do not agree. Appellant's Figure 11 illustrates a preferred embodiment of an intraluminal vascular graft for repairing bifurcated vessels. With regard to this particular embodiment, page 24 of the specification informs us that when the vascular graft 20 is deployed in a bifurcating vessel, "the expandible caudal ring 35 is seated upon and supported by the bifurcation of the vessel, otherwise referred to as the crotch 98 of the bifurcation." Thus, based on the underlying specification, we understand the claim language referred to by the examiner as being unclear, unambiguous and as actually requiring that the circumferential support structure, not the vascular graft, be capable of being positioned to contact and span the bifurcation. Furthermore, this interpretation is consistent with the step of "supporting said intraluminal vascular graft structure within said bifurcated vessel, by

Appeal No. 1998-2095  
Application No. 08/460,311

positioning said circumferential support structure at the bifurcation of the bifurcated vessel to be supported by the bifurcation" (emphasis added) recited in claim 39. In addition, in order to be "supported by the bifurcation," the circumferential support structure must be seated upon the bifurcation of the vessel, again consistent with the underlying specification. We find no corresponding teaching or suggestion in Barone. In Figure 4, Barone does not show the thin-walled member 166 (which corresponds to the claimed circumferential support structure) seated upon or supported by the crotch of the bifurcation.

Since all the limitations of claim 39 would not have been taught or suggested by the combined disclosures of Lazarus and Barone, it follows that the examiner has not established the prima facie obviousness of the invention set forth in claim 39. See In re Royka, supra. Thus, the examiner's rejection of claim 39 under 35 U.S.C. § 103 will not be sustained.

Claims 40 and 41 are dependent on claim 39 and contain all of the limitations of that claim. Therefore, we will also

Appeal No. 1998-2095  
Application No. 08/460,311

not sustain the standing 35 U.S.C. § 103 rejection of claims  
40 and 41.

The rejection of claim 32

Claim 32 is dependent on claim 31, which, in turn, is dependent on claim 30. Our review of the Kwan-Gett reference, which is used in combination with Lazarus and Barone in the rejection of claim 32, indicates to us that this reference does not supply the deficiencies in the combined teachings of Lazarus and Barone noted above with regard to claim 30 on appeal. Accordingly, the examiner's rejection of claim 32 under 35 U.S.C. § 103 will not be sustained.

In summary, all of the examiner's rejections of claims 30 through 41 are reversed.

REVERSED

Appeal No. 1998-2095  
Application No. 08/460,311

IRWIN CHARLES COHEN	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
JOHN P. McQUADE	)	APPEALS AND
Administrative Patent Judge	)	INTERFERENCES
	)	
	)	
	)	
JOHN F. GONZALES	)	
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Appeal No. 1998-2095  
Application No. 08/460,311

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