

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte CLIFFORD J. DWYER and TIMOTHY ROBINSON

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Appeal No. 2000-1948  
Application No. 08/751,087

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ON BRIEF

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Before COHEN, FRANKFORT and NASE, Administrative Patent Judges.  
NASE, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 2 to 5, 12, 16 and 17. Claims 6 to 11 and 13 to 15 have been objected to as depending from a non-allowed claim. Claim 1 has been canceled.<sup>1</sup>

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<sup>1</sup> In the amendment after final (Paper No. 14, filed July 12, 1999) which was entered by the examiner (see Paper No. 16, mailed August 4, 1999), the appellants canceled claim 1 and amended claim 6. In addition, the appellants set forth amendments to claims 5, 12 and 16, which amendments have not been entered since the proposed words to be changed (i.e., claim 1) do not exist in those claims as those claims were amended by the amendment filed on October 5, 1998 (Paper No. 11).

We REVERSE.

BACKGROUND

The appellants' invention relates to a device for delivering, positioning and releasing, within a body lumen, a self-expandable implant (claims 2 to 5, 12 and 16) and a method for selectively delivering, positioning and releasing, within a body lumen, a self-expandable implant having leading and trailing ends (claim 17). A copy of the claims under appeal is set forth in the appendix to the appellants' brief.

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

Williams et al. 1995 (Williams)	5,391,172	Feb. 21,
Braunschweiler et al. 1996 (Braunschweiler)	5,484,444	Jan. 16,
Lukic et al. 1998 (Lukic)	5,709,703	Jan. 20,
Robinson et al. 1998 (Robinson)	5,733,325	Mar. 31,

Claims 2 to 5, 12, 16 and 17 stand rejected under 35 U.S.C. § 103 as being unpatentable over any of Lukic, or Braunschweiler or Robinson in view of Williams.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejection, we make reference to the final rejection (Paper No. 12, mailed January 7, 1999) and the answer (Paper No. 18, mailed December 2, 1999) for the examiner's complete reasoning in support of the rejection, and to the brief (Paper No. 17, filed September 21, 1999) and reply brief (Paper No. 19, filed February 7, 2000) for the appellants' arguments thereagainst.

#### OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. Upon evaluation of all the evidence before us, it is our conclusion that the evidence adduced by the examiner is insufficient to establish a prima facie case of obviousness

with respect to the claims under appeal. Accordingly, we will not sustain the examiner's rejection of claims 2 to 5, 12, 16 and 17 under 35 U.S.C. § 103. Our reasoning for this determination follows.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is established by presenting evidence that would have led one of ordinary skill in the art to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988) and In re Lintner, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

**Claims 2 to 5, 12 and 16**

We will not sustain the rejection of claims 2 to 5, 12 and 16 under 35 U.S.C. § 103.

Claim 2 reads as follows:

A device for delivering, positioning and releasing, within a body lumen, a self-expandable implant comprising: an elongate tubular sheath for maintaining the implant in a low profile configuration, the sheath having a leading end and a trailing end and being open at its leading end;

a control handle having a body and a movable portion, the movable portion being connected to a trailing portion of the sheath, the movable portion being movable along the body of the handle to effect forward and rearward motion of the sheath with respect to the body of the handle;

an implant retainer engageable with the trailing end of the implant and being disposed to maintain the implant in a fixed position with respect to the body of the handle, the implant retainer being receivable within the sheath whereby the sheath may be moved between a forward, implant-capturing position in which the implant retention device is contained within the sheath and a rearward, implant-release position in which the implant retainer is disposed forwardly beyond the end of the sheath;

the movable portion of the handle being movable between a forward implant-capturing configuration and a rearward implant release configuration, the implant retainer being constructed to engage the implant to enable the leading end of the implant to self-expand as the sheath is moved toward the implant-release position and;

a detent carried by the handle to prevent continuous forward-rearward movement of the movable portion of the handle from the implant capture position to the implant release position.

The references to Lukic, Braunschweiler and Robinson each disclose a device for delivering, positioning and releasing, within a body lumen, a self-expandable implant comprising,

inter alia, an elongate tubular sheath for maintaining the implant in a low profile configuration and an implant retainer engageable with the trailing end of the implant, the implant retainer being receivable within the sheath whereby the sheath may be moved between a forward, implant-capturing position in which the implant retention device is contained within the sheath and a rearward, implant-release position in which the implant retainer is disposed forwardly beyond the end of the sheath; wherein the implant retainer is constructed to engage the implant to enable the leading end of the implant to self-expand as the sheath is moved toward the implant-release position.

Williams discloses a stent delivery catheter handle for providing relative motion between the outer sheath of a stent delivery catheter and an underlying catheter, via a thumbswitch, to enable the outer sheath to withdraw from over the underlying catheter and expose a vascular prosthesis. Figures 1-5 of Williams show a retractable sleeve stent delivery handle. A retractable sheath 10 of a stent delivery catheter 20 is received by the distal nosepiece 25 of a

slidable flush port and plunger assembly 30. The flush port and plunger assembly, as well as the entire handle, are generally coaxially disposed about the underlying catheter that they surround. As can be seen in Figure 5, retractable sheath 10 overlies the outer lumen 35 of the catheter. The retractable sheath 10 serves to protect an intravascular prosthesis or stent 40 that is disposed between the retractable sheath 10 and the outer lumen 35, on balloon portion 45. The retractable sheath 10 covers the stent during transport of the stent through the vasculature by the catheter. The sheath 10 is withdrawn from over the stent, to expose the stent, by the stent delivery handle and thereafter the stent is expanded to engage the vasculature and the catheter is withdrawn.

Williams' stent delivery handle has a housing body 50 made of a top half 60 and a bottom half 70, with each half made to fit into the other half. Bottom half 70 is provided with a finger grip 80, while top half 60 is provided with a thumb switch track that is formed by slot 90 along which a thumbswitch 100 reciprocates. The underside of slot 90

includes a pair of semicircular recesses 105, 110, situated towards the distal end 115 and proximal end 120 of the catheter handle tool, respectively, with the recesses engaged by laterally projecting semicircular locking arms 303, 306 on the thumbswitch 100. The locking arms serve to retain the thumbswitch along the slot at the recesses.

The plunger and flush port assembly of Williams includes a reciprocating plunger 180 having a distal end 185 that is attached to a sliding flush port assembly 190. The flush port assembly 190 is attached to the outermost retractable sheath 10. The sheath 10 is moved relative to the underlying stent delivery catheter 20, in order to expose the underlying stent at the distal end of the catheter. The flush port assembly 190 is attached to the thumbswitch 100, via posts 172, 174. Reciprocating the thumbswitch along the track formed by slot 90 will also reciprocate the sliding flush port assembly along the slot, and therefore create relative motion between the retractable sheath 10 and the underlying stent delivery catheter 20 to retract sheath 10 from catheter 20.

Figures 1 and 4 of Williams show a cross-sectional view of the thumbswitch 100 and thumbswitch pushbutton locking mechanism. The thumbswitch has a distal thumb grip portion 280, a proximal thumb grip portion 285, and vertical posts 172, 174, that connect the thumb grip portion with the flush port and plunger assembly 30. The thumbswitch includes a pushbutton locking mechanism having a pushbutton 295 connected to a cap shaped member 300. The sleeve retraction thumbswitch is locked into place on the catheter handle by having cap shaped member 300 engage spaced semicircular recesses 105, 110, via laterally projecting semicircular arms 303, 306. The spaced recesses are located on the underside of the housing top half 60, along the underside of slot 90, and are locations where the thumbswitch may be locked to fix the retraction of sleeve 10. Williams teaches (column 4, lines 35-37) that "[t]he recesses may be spaced at a plurality of locations, to give a plurality of stops." The cap shaped locking member 300 and pushbutton 295 are spring biased upwards with respect to the plunger and flush port assembly 190 by a spring 315, that continuously forces the cap shaped locking member against the underside of

slot 90 in the upper portion 60 of housing 50. Williams also teaches (column 4, lines 43-55) that

While in the preferred embodiment a spring biased pushbutton locking device is shown to lock the thumbswitch in a fixed position along said thumbswitch slot, it is envisioned that any other equivalent means can be used to lock the thumbswitch, including dispensing with the pushbutton assembly shown and providing tabs along the slot to frictionally engage posts 172, 174. The specific embodiment of the present invention has been described above in connection with a specialized catheter designed to deliver stents, however, it is within the scope of the present invention that the present invention may be used with any type of catheter or any other medical instrument.

After the scope and content of the prior art are determined, the differences between the prior art and the claims at issue are to be ascertained. Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966).

Based on our analysis and review of each of the references to Lukic, Braunschweiler and Robinson, it is our opinion that the differences include (1) a control handle having a body and a movable portion, the movable portion being connected to a trailing portion of the sheath, the movable portion being movable along the body of the handle to effect

forward and rearward motion of the sheath with respect to the body of the handle; and (2) a detent carried by the handle to prevent continuous forward-rearward movement of the movable portion of the handle from the implant capture position to the implant release position.

With regard to these differences, the examiner determined (final rejection, p. 2) that it would have been obvious to one having ordinary skill in the art at the time of the invention to place the control handle of Williams on any of the three base references (i.e., Lukic, Braunschweiler and Robinson), as simply a matter of an obvious design choice as to this type of means to actuate the release of the stent.

In the briefs before us in this appeal, the appellants do not contest the obviousness of combining Williams' control handle with the device of either Lukic, Braunschweiler or Robinson; however, the appellants do argue that the resulting structure does not arrive at the subject matter of claim 2. We agree. In that regard, it is our determination that the combined teachings of the applied prior art would not have

taught or suggested at the time the invention was made to a person having ordinary skill in the art a detent carried by the handle to prevent continuous forward-rearward movement of the movable portion of the handle from the implant capture position to the implant release position.

In our view, when the control handle of Williams is combined with either Lukic's, Braunschweiler's or Robinson's device for delivering, positioning and releasing, within a body lumen, a self-expandable implant, the semicircular recesses 105, 110 taught by Williams would be located at the implant release position and the implant capture position, respectively. Thus, the semicircular recesses 105, 110 are not readable on the claimed "detent" since they would not prevent continuous forward-rearward movement of the movable portion of the handle from the implant capture position to the implant release position.

Additionally, it is our view that the combined teachings of Robinson and Williams would have made it obvious at the time the invention was made to a person having ordinary skill

in the art to have included a further set of semicircular recesses intermediate the semicircular recesses 105, 110 to permit fluoroscopic visualization methods to be used to determine if Robinson's implant is being positioned as desired.<sup>2</sup> However, even this modification does not arrive at the claimed subject matter. In this regard, while such intermediate recesses would constitute a detent carried by the handle that **could** prevent continuous forward-rearward movement of the movable portion of the handle from the implant capture position to the implant release position as set forth by the examiner (answer, pp. 4-5), it is equally true that such intermediate recesses would not prevent continuous forward-rearward movement of the movable portion of the handle from the implant capture position to the implant release position if the pushbutton 295 is continuously pressed downwardly during such movement. In our view, the recitation in claim 2 that the detent prevents continuous forward-rearward movement of the movable portion of the handle from the implant capture position to the implant release position means that the

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<sup>2</sup> Note column 10 of Robinson and column 4 of Williams.

movable portion of the handle in moving from the implant capture position to the implant release position will always engage a detent carried by the handle to prevent continuous forward-rearward movement of the movable portion of the handle from the implant capture position to the implant release position. This is not true of the intermediate recesses that are suggested by the combined teachings of Robinson and Williams.

For the reasons set forth above, the decision of the examiner to reject claim 2, and claims 3 to 5, 12 and 16 dependent thereon, under 35 U.S.C. § 103 is reversed.

**Claim 17**

We will not sustain the rejection of claim 17 under 35 U.S.C. § 103.

Claim 17 reads as follows:

A method for selectively delivering, positioning and releasing, within a body lumen, a self-expandable implant having leading and trailing ends comprising:  
providing an elongate tubular sheath for maintaining the implant in a low profile configuration, the sheath

having a leading end and a trailing end and being open at its leading end to receive the implant, an implant retainer engageable with the trailing end of the implant to retain the trailing end of the implant in a fixed position while enabling the sheath to be withdrawn rearwardly relative to the implant retainer and implant, the method further comprising:

inserting the sheath and implant retainer together with the implant contained within the sheath, into the body lumen and advancing them as a unit to a location in the body lumen;

providing a detent to prevent direct continuous movement of the sheath from a capture position to a release position;

withdrawing the sheath to the detent between the captured and release positions while exposing the leading end of the implant to enable the leading end of the implant to self-expand;

while in the detent configuration, determining whether the implant is in a desired position and orientation; and thereafter selectively (1) moving the detent to permit the sheath to be withdrawn to a release position or (2) without shifting the detent, returning the sheath to the capture position.

As in the rejection of claim 2, the appellants do not contest the obviousness of combining Williams' control handle with the device of either Lukic, Braunschweiler or Robinson; however, the appellants do argue that the resulting method does not arrive at the subject matter of claim 17. We agree. For the same reasons as provided in our discussion above with regard to claim 2, it is our determination that the combined

teachings of the applied prior art would not have taught or suggested the step of providing a detent to prevent continuous movement of the sheath from a capture position to a release position. Accordingly, the decision of the examiner to reject claim 17 under 35 U.S.C. § 103 is reversed.

CONCLUSION

To summarize, the decision of the examiner to reject claims 2 to 5, 12, 16 and 17 under 35 U.S.C. § 103 is reversed.

REVERSED

IRWIN CHARLES COHEN	)	
Administrative Patent Judge	)	
	)	
	)	
	)	
	)	BOARD OF PATENT
CHARLES E. FRANKFORT	)	APPEALS
Administrative Patent Judge	)	AND
	)	INTERFERENCES
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	)	
JEFFREY V. NASE	)	
Administrative Patent Judge	)	

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