

The opinion in support of the decision being entered today  
is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* DONALD T. SHANNON

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Appeal 2007-1998  
Application 09/997,829  
Technology Center 3700

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Decided: August 1, 2007

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Before TONI R. SCHEINER, DONALD E. ADAMS, and  
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 103-119, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

## INTRODUCTION

The claims are directed to an implantable drug eluting device. Claim 103 is illustrative:

103. An implantable drug eluting device that has a compressed undeployed diameter and an expanded deployed diameter, the device comprising:

a radially expandable stent comprising a generally cylindrical wall surface and having a hollow bore extending longitudinally therethrough, wherein the generally cylindrical wall surface comprises a plurality of lateral openings in the wall surface;

a coating comprising a polymer and a therapeutic substance disposed on the wall surface of the stent; and

a tubular outer layer comprising expanded, sintered PTFE tape wound about the outer surface of said stent.

The Examiner relies on the following prior art references to show unpatentability:

Choi	US 4,131,648	Dec. 26, 1978
Myers	US 5,700,285	Dec. 23, 1997
Banas	US 5,749,880	May 12, 1998
Wijay	US 6,053,940	Apr. 25, 2000
Becker	US 6,117,165	Sept. 12, 2000
Michal	US 6,287,285 B1	Sept. 11, 2001

The rejections as presented by the Examiner are as follows:

1. Claims 103-105, 107, and 113-117 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Myer and Choi.

2. Claim 106 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Myer, Choi and Michal.
3. Claims 108-111 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Myer, Choi, and Wijay.
4. Claims 108-110 and 112 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Myer, Choi and Becker.
5. Claims 118 and 119 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Myer, Choi, and Banas.

We reverse.

#### DISCUSSION

Claims 103-105, 107, and 113-117 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Myer and Choi.

Claim 103 is drawn to an implantable drug eluting device. Claims 104, 105, 107, and 113-117 depend directly or indirectly from claim 103. The device of claim 103 has a compressed undeployed diameter and an expanded deployed diameter. The device comprises three elements:

1. a radially expandable stent comprising a generally cylindrical wall surface and having a hollow bore extending longitudinally therethrough, wherein the generally cylindrical wall surface comprises a plurality of lateral openings in the wall surface;
2. a coating comprising a polymer and a therapeutic substance disposed on the wall surface of the stent; and
3. a tubular outer layer comprising expanded, sintered PTFE tape wound about the outer surface of said stent.

The Examiner finds that Myers teaches a stent having a plurality of lateral openings and at least one overlapping PTFE tape layer on the surface of the stent (Answer 4). The Examiner recognizes, however, that Myers “fail[s] to disclose a polymer incorporated with a therapeutic substance disposed on the surface of the stent” (Answer 4-5). The Examiner relies on Choi to make up for this deficiency in Myers.

According to the Examiner, Choi teaches an erodible polymer coating that comprises a therapeutic agent (Answer 5). In addition, the Examiner finds that Choi “teaches that implantable tubular devices can be coated or layered with the polymer, col. 28, lines 6-8, 15-22” (*id.*). We disagree with the Examiner’s finding. Choi teaches “[t]he polymers can be processed into articles, including delivery devices and coated onto an agent . . .” (Choi, col. 28, ll. 6-8). As to being processed into delivery devices, Choi teaches that the polymers “can be made into devices of various geometric shapes, for example flat, square, round, tubular, disc, ring, and the like” (Choi, col. 28, ll. 15-19). Thus, as Choi makes clear, the polymer itself is molded into the various shapes not coated onto other devices that have this shape (Br. 4). As to coating the polymer onto an agent, Choi teaches that “[t]he polymers prepared according to the invention, are useful for coating numerous agents such as for providing slow release fertilizers” (Choi, col. 31, ll. 15-17). At best, Choi teaches a device to aid in the healing of injuries (Choi, col. 33, ll. 59-64; Fig. 7). However, as Choi describes, this device is useful for administering drug to the skin, mucosa or an exposed wound (Choi, col. 33, ll. 67-68).

Nevertheless, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to use the coating of a bioerodible polymer with a therapeutic agent as taught by Choi . . . on the surface of the stent of Myers . . . such that a drug can be administered to the implantation site where trauma occurred such as an anti-inflammatory.

(*id.*)

What is missing from the combination of Myers and Choi, however, is any teaching to suggest that Choi's polymer can be used to coat a stent (Br. 6), let alone coat a stent with Choi's drug carrying polymer and then wrap the coated stent with PTFE tape. As set forth in *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007).

[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

While the Examiner asserts that a person of ordinary skill in the art would have found it obvious to coat Myers' stent with a polymer containing an anti-inflammatory (Answer 5), the Examiner fails to establish a factual basis to suggest that a person of ordinary skill in the art would recognize that a stent can be coated with Choi's drug carrying polymer and then wrapped with PTFE tape. Prima facie obviousness requires a teaching that all elements of the claimed invention are found in the prior art and a reason that would have prompted a person of ordinary skill in the relevant field to

modify the prior art to arrive at the claimed invention. *See KSR*, 127 S. Ct. at 1741, 82 USPQ2d at 1396.

On reflection, we find that the evidence of record is insufficient to support a prima facie case of obviousness. Accordingly, we reverse the rejection of claims 103-105, 107, and 113-117 under 35 U.S.C.

§ 103(a) as unpatentable over the combination of Myer and Choi.

Claim 106 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Myer, Choi and Michal. Claim 106 depends from and further limits therapeutic substance on the device of claim 103 to paclitaxel or an analog thereof. The Examiner relies on the combination of Myers and Choi as discussed above (Answer 6). The Examiner recognizes, however, that the combination of Myers and Choi fails to teach the use of paclitaxel on a stent (*id.*). To make up for this deficiency the Examiner relies on Michal to teach a stent coated with paclitaxel. Based on this evidence the Examiner finds that “[i]t would have been obvious to one of ordinary skill in the art to use the drug paclitaxel as taught by Michal . . . in the stent of Myers . . . as modified by Choi . . . in order to reduce restenosis” (*id.*).

For the reasons set forth above, we find that the combination of Myers and Choi is insufficient to establish a prima facie case of obviousness. Michal brings the Examiner a step closer to a prima facie case of obviousness by teaching drug coated stents. The combination of Myers, Choi and Michal, however, fails to teach one of ordinary skill in the art to coat a stent with a polymer and a therapeutic substance and then place a tubular outer layer comprising PTFE tape.

Michal teaches a stent with coating comprising a base coat and a top coat, wherein the top coat comprises a therapeutic agent (Michal, col. 2, ll. 13-14 and 28-29). In an alternative, Michal teaches the application of a therapeutic coating directly to the stent (Michal, col. 5, ll. 42-44). Nevertheless, in each instance Michal's therapeutic coating is the outermost layer. Neither the Examiner nor Michal provide a reason why a person of ordinary skill in the art would add an additional layer, e.g., a tubular outer layer comprising expanded, sintered PTFE tape, on top of the therapeutic coating. Prima facie obviousness requires a teaching that all elements of the claimed invention are found in the prior art and a reason that would have prompted a person of ordinary skill in the relevant field to modify the prior art to arrive at the claimed invention. *See KSR*, 127 S. Ct. at 1741, 82 USPQ2d at 1396. Accordingly, Michal fails to make up for the deficiency in the combination of Myers and Choi.

On reflection, we find that the evidence of record is insufficient to support a prima facie case of obviousness. Accordingly, we reverse the rejection of claim 106 under 35 U.S.C § 103(a) as unpatentable over the combination of Myers, Choi, and Michal.

3. Claims 108-111 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Myers, Choi, and Wijay. Claims 108-111 depend directly or indirectly from claim 103.

The Examiner relies on the combination of Myers and Choi as set forth above (Answer 6). The Examiner finds that the combination of Myers and Choi fail to teach a non-foreshortening stent (*id.*). The Examiner relies on Wijay to teach stents "having a plurality of undulating elements with at

least one linear connector” and a stent design that “allows the length to remain substantially constant in the deployed state” (*id.*). Based on this evidence the Examiner concludes that

[i]t would have been obvious to one of ordinary skill in the art to use the stent design as taught by Wijay in the stent of Myers et al. as modified by Choi et al. in order to provide the maximum support to the vessel and reduce twisting and unwanted turbulence of blood flow  
(*id.*)

For the reasons set forth above, we find that the combination of Myers and Choi is insufficient to establish a prima facie case of obviousness. As discussed above with Michal, Wijay brings the Examiner a step closer to a prima facie case of obviousness by teaching stents layered with polymeric sheaths that are impregnated with biocompatible substances (Wijay, col. 2, ll. 57-59). In addition, Wijay explains that “[m]ost sheath-type coatings reduce endothelial cell growth through the stent, which is a major requirement in successful stenting of body cavities such as arteries and veins” (Wijay, col. 2, ll. 59-62). The combination of Myers, Choi and Wijay, however, fails to teach one of ordinary skill in the art to place a coating comprising a polymer and a therapeutic substance beneath a tubular outer layer comprising PTFE tape.

To the contrary, Wijay teaches that it is the polymeric sheath that is impregnated with biocompatible substance and layered onto the stent. Neither the Examiner nor Wijay provide a reason why a person of ordinary skill in the art would add an additional layer, e.g., a tubular outer layer comprising expanded, sintered PTFE tape, on top of the therapeutic coating. Prima facie obviousness requires a teaching that all elements of the claimed invention are found in the prior art and a reason that would have prompted a

person of ordinary skill in the relevant field to modify the prior art to arrive at the claimed invention. *See KSR*, 127 S. Ct. at 1741, 82 USPQ2d at 1396. Accordingly, Wijay fails to make up for the deficiency in the combination of Myers and Choi.

On reflection, we find that the evidence of record is insufficient to support a prima facie case of obviousness. Accordingly, we reverse the rejection of claim 108-111 under 35 U.S.C. § 103(a) as unpatentable over the combination of Myers, Choi, and Wijay.

4. Claims 108-110 and 112 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Myer, Choi and Becker. Claims 108-110 and 112 depend directly or indirectly on claim 103.

The Examiner relies on the combination of Myers and Choi as set forth above (Answer 6). The Examiner finds that the combination of Myers and Choi fail to teach a non-foreshortening stent (Answer 7). The Examiner relies on Becker to teach a stent design that “allows the length to remain substantially constant in the deployed state” (*id.*). Based on this evidence the Examiner concludes that

[i]t would have been obvious to one of ordinary skill in the art to use the stent design as taught by Becker in the stent of Myers et al. as modified by Choi et al. in order to provide the maximum support to the vessel and increasing the effective range of the stent

(*id.*)

For the reasons set forth above, we find that the combination of Myers and Choi is insufficient to establish a prima facie case of obviousness. Becker fails to teach or provide a reason to incorporate a coating comprising

therapeutic agent and a polymer onto the stent and then add an additional layer, e.g., a tubular outer layer comprising expanded, sintered PTFE tape, on top of the therapeutic coating. Prima facie obviousness requires a teaching that all elements of the claimed invention are found in the prior art and a reason that would have prompted a person of ordinary skill in the relevant field to modify the prior art to arrive at the claimed invention. *See KSR*, 127 S. Ct. at 1741, 82 USPQ2d at 1396. Accordingly, Becker fails to make up for the deficiency in the combination of Myers and Choi.

On reflection, we find that the evidence of record is insufficient to support a prima facie case of obviousness. Accordingly, we reverse the rejection of claim 108-110 and 112 under 35 U.S.C. § 103(a) as unpatentable over the combination of Myers, Choi, and Becker.

5. Claims 118 and 119 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Myer, Choi, and Banas. Claims 118 and 119 depend ultimately from claim 103.

The Examiner relies on the combination of Myers and Choi as set forth above (Answer 6). The Examiner finds that the combination of Myers and Choi fail to teach PTFE particles used to bond the tubular inner and outer layers (Answer 7). The Examiner relies on Banas to teach “an aqueous polymer solution of PTFE between the inner graft and outer graft layer to bond the layers (*id.*). In addition, the Examiner relies on Banas to teach an outer tubular layer that is heated to bond to the base (*id.*). Based on this evidence the Examiner concludes that

[i]t would have been obvious to one of ordinary skill in the art to substitute the adhesive material and use PTFE particles (in solution) as taught by Banas in the stent of Myers et al. as

modified by Choi et al. in order to provide a good bond so the layers do not separate in the vessel. Using like materials *enhances* the bond as opposed to the adhesive material used by Myers using dissimilar material to bond the layers.

(*id.*)

While this may be true, Banas fails to teach or provide a reason to incorporate a coating comprising therapeutic agent and a polymer onto the stent and then add an additional layer, e.g., a tubular outer layer comprising expanded, sintered PTFE tape, on top of the therapeutic coating. Prima facie obviousness requires a teaching that all elements of the claimed invention are found in the prior art and a reason that would have prompted a person of ordinary skill in the relevant field to modify the prior art to arrive at the claimed invention. *See KSR*, 127 S. Ct. at 1741, 82 USPQ2d at 1396. Therefore, Banas fails to make up for the deficiencies in the combination of Myers and Choi.

Accordingly, we find that the evidence of record is insufficient to support a prima facie case of obviousness. Accordingly, we reverse the rejection of claim 118 and 119 under 35 U.S.C. § 103(a) as unpatentable over the combination of Myers, Choi, and Banas.

#### OTHER ISSUES

We recognize the Examiner's assertion that Appellant's information disclosure statements "include references showing that coatings with therapeutic material on intraluminal devices are well known in the art" (Office Communication, dated April 21, 2006). The Examiner appears to assert that there may be other evidence on this record that may support a prima facie case of obviousness. However, since this evidence was not

relied upon by the Examiner in support of the rejection of record, we have not included it as part of our deliberations.

In the event of further prosecution, we encourage the Examiner to take a step back and consider all of the available prior art to determine if the prior art provides some rationale for combining the elements of Appellant's claimed stent in the specific arrangement provided by Appellants in their claimed invention. In this regard, we direct the Examiner's attention to Buirge.<sup>1</sup> Buirge teaches a stent comprising an inner polymeric layer, an outer polymeric layer and a therapeutic layer. While we take no position on the merits of Buirge as it relates to Appellant's claimed invention, we note that Buirge teaches a stent configuration wherein a therapeutic layer is positioned between two other layers. We also note that the Specification, on page 7, provides a reason for using PTFE in vascular devices. Lee<sup>2</sup> describes a PTFE graft having pharmacological agents on either side of the PTFE film (see Lee, col. 4, l. 49 to col. 10).

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<sup>1</sup> United States Patent No. 5,735,897, which issued April 7, 1998 and claims priority, *inter alia*, to Application No. 08/300,742, filed September 2, 1994, now abandoned.

<sup>2</sup> United States Patent No. 5,123,917, which issued Jun. 23, 1992.

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CONCLUSION

In summary, we reverse the rejections of record.

REVERSED

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