

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte CAROL E. EBERHARDT

Appeal 2008-4550
Application 10/752,864
Technology Center 3700

Decided: November 18, 2008

Before DONALD E. ADAMS, ERIC GRIMES, and JEFFREY N.
FREDMAN, *Administrative Patent Judges*.

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DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a prosthetic heart valve. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Statement of the Case

Background

“There are four valves of the heart, the mitral valve, the aortic valve, the tricuspid valve, and the pulmonary valve. Anatomically and generally speaking, each valve forms or defines a valve annulus and valve leaflets” (Spec. 1:9-11). The Specification notes that “prosthetic heart valve design attempts to replicate the function of the valve being replaced and thus will include valve or leaflet-like structures” (Spec. 2:2-4). According to the Specification “the native human mitral valve is more oval or elongated than circular. Therefore, during implantation [into humans], the typical mitral valve prosthetic made from a porcine aortic valve must be forced to conform to the non-circular annulus of the native mitral valve” (Spec. 2:20-22).

Appellant invented “a prosthetic valve including a body, a first leaflet, and a second leaflet. The first leaflet extends across and is coupled to the body. The first leaflet is cut from a first porcine aortic valve and defines a first inner surface” (Spec. 4:22-25). Appellant further notes that the “second leaflet extends across and is coupled to the body opposite the first leaflet. The second leaflet is cut from a second porcine aortic valve and defines a second inner surface” (Spec. 4:25-27).

The Claims

Claims 1, 3-19, and 21-31 are on appeal. We will focus on claims 1, 6, 8, and 12, which are representative and read as follows:

1. A prosthetic valve comprising:
 - a body;
 - a first leaflet extending across and coupled to the body, the first leaflet being cut from a porcine aortic valve and defining a first inner surface; and
 - a second leaflet extending across and coupled to the body opposite the first leaflet, the second leaflet being cut from a porcine aortic valve and defining a second inner surface; wherein the prosthetic valve is configured such that upon closure of the first and second leaflets, the first inner surface and the second inner surface redundantly coapt.

6. The prosthetic valve of claim 1, wherein the first and second leaflets each define a cut edge fixed to the body, a free edge not fixed to the body, and the first and second inner surfaces coapt with each other along a catenary spaced from the free edges, and further wherein the catenary represents a line of interaction between the first and second leaflets nearest the cut edge.

8. The prosthetic valve of claim 6, wherein each of the free edges has a length that is longer than a length of the catenary.

12. The prosthetic valve of claim 10, wherein the first strut and the second strut are nonsymmetrically positioned with respect to the annular frame.

The prior art

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

Bochan	U.S. 3,118,468	Jan. 21, 1964
Brownlee	U.S. 4,340,977	Jul. 27, 1982

The issue

The Examiner rejected claims 7-16 under 35 U.S.C. § 103(a) as being obvious over Brownlee and Bochan (Ans. 3).

Appellant contends that “Brownlee teaches inlet and outlet opening sizes that are identical. Bochan teaches the same relationship. Thus, the Bochan valve does not ‘increase’ maximum fluid flow through the valve as compared to the Brownlee valve. As such, the alleged motivation to combine the references so as to ‘provide the patient with maximum fluid flow through the valve in the open position’ does not apply” (App. Br. 8). Appellant also contends that

the “essential” tapered contour of Bochan is not possible to achieve with the two harvested tissue leaflets set forth in independent claim 1. Thus, either a likelihood of success in modifying the tissue valve cusps of Brownlee pursuant to the teachings of Bochan does not exist, or if Brownlee was modified pursuant to the disclosure of Bochan, a molded, synthetic material would be required such that the porcine aortic valve leaflet limitations of claim 1 are not satisfied.

(App. Br. 9). Appellant also contends that “as with Brownlee, Bochan also fails [to] teach or reasonably suggest leaflets that redundantly coapt, as set forth in independent claim 1” (App. Br. 9).

The Examiner finds regarding the combination of Bochan and Brownlee that “the combination is a simple substitution [sic, substitution] of parts. The combination replaces the straight-line closure engagement of Brownlee with the elongated s-shaped closure engagement from Bochan” (Ans. 4-5). The Examiner find that the “motivation being it would be obvious to try this closure engagement in order to distribute shear forces,

created by back flow, along a greater length of material while maintaining the maximum open size” (Ans. 5).

The Examiner also states that

when looking at figure 4 of Bochan it is clear that the free edges 12 of both leaflets do not come together at a line. Both free edges remain open to the downstream flow. It is the interior surfaces of the leaflets that come together to form the s-shaped engagement 14. In view of the applicant's definition that redundantly coapt refers to closure of the valve at more than one line of interaction, and due to the limitations of manufacturing it is obvious that the leaflets will come together in an intersection that is wider than a single line.

(Ans. 5).

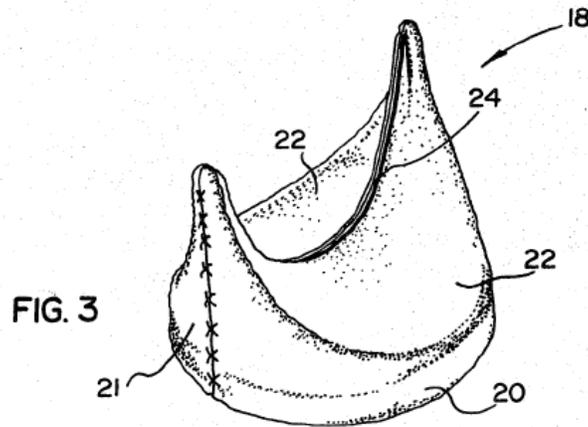
In view of these conflicting positions, we frame the obviousness issue before us as follows:

Would it have been obvious to an ordinary artisan to modify the prosthetic mitral valve of Brownlee to utilize the elongated s-shaped closure engagement from Bochan?

Findings of Fact (FF)

1. Brownlee teaches that the prosthetic valve comprises a body comprising “a mitral heart valve . . . comprising a stent including a circular base and a pair of upstanding diametrically opposed struts, separating a pair of diametrically opposed arcuately shaped depressed reliefs” (Brownlee, col. 4, ll. 24-28).

2. Brownlee teaches that the prosthesis valve comprises a first leaflet 22 which extends across and coupled to the body, as shown in figure 3 of Brownlee, reproduced below:



“FIG. 3 is a perspective view of the mitral valve of an embodiment of this invention in the closed position” (Brownlee, col. 5, ll. 42-43).

3. Brownlee teaches the use of porcine aortic valves, noting the prior art teaches a “valve [which] utilizes a whole porcine aortic valve which is pretreated before mounting on the stent” (Brownlee, col. 2, ll. 60-62). Brownlee further teaches that “[o]ther naturally-occurring materials, e.g., . . . porcine . . . of acceptable durability and biocompatibility may also be used” (Brownlee, col. 6, ll. 37-42).

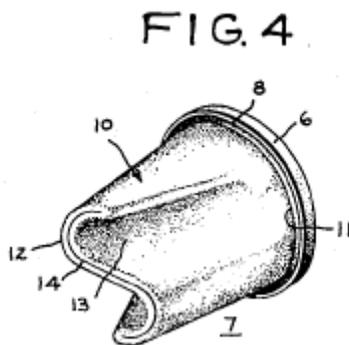
4. Brownlee teaches a second leaflet 22 which extends across and is coupled to the body opposite the first leaflet (*see* Brownlee, fig. 3).

5. Brownlee teaches that the “two equal cusps **22** . . . form a line of apposition in the plane defined by the tip of each stent strut **12** and the axis of symmetry of the valve **18**” (Brownlee, col. 6, ll. 14-16).

6. The Specification teaches that the “term ‘redundant coaptation’ is used to refer to closure of the valve at more than one line of interaction between the leaflets” (Spec. 1:20-21).

7. Bochan teaches that a valve “with a continuous substantially matching S-shaped slit formed therein. In response to pressure within the hollow portion, it is deformable to cause the sides of the slit to spread apart, and conversely, in response to back pressure outside the hollow portion, the sides of the slit are pressed against each other to cause the slit to be tightly closed” (Bochan, col. 1, ll. 55-62). Because the sides of the S-shaped slit are pressed together when the valve is closed, the inner surfaces of the slit close at more than one line of interaction or “redundantly coapt.”

8. Bochan discloses an S-shaped slit in figure 4 as reproduced below:



“FIGURE 4 is a view in perspective of the unitary valve member” (Bochan, col. 2, ll. 15-16).

9. The Examiner found that “it would be obvious to try this closure engagement in order to distribute shear forces, created by back flow, along a greater length of material while maintaining the maximum open size” (Ans. 5).

10. Bochan teaches that the “elimination of any substantial stress on the valve is a highly desirable feature in that it is stress which weakens the material of the valve and shortens its life” (Bochan, col. 3, ll. 10-13)

11. Bochan teaches that “the maximum dimensions of the valve outlet member remain substantially unchanged whether the valve is open or closed, and wherein . . . excessive stressing of the material of the valve is avoided” (Bochan, col. 1, ll. 40-44).

Principles of Law

In *KSR*, the Supreme Court rejected the rigid application of the teaching, suggestion, and motivation test by the Federal Circuit, stating that

The principles underlying [earlier] cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.

KSR Int’l v. Teleflex Inc., 127 S. Ct. 1727, 1740 (2007). Instead, the Supreme Court found that “a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.*

Analysis

Claim 1

Brownlee teaches a prosthetic valve which comprises a body (FF 1) with a first leaflet that extends across and is coupled to the body and defines an inner surface and a second leaflet that extends across and is coupled to

the body and defines a second inner surface (FF 2). Brownlee teaches that the leaflets can be formed from porcine material, including porcine aortic valves (FF 3). Brownlee further teaches that the leaflets coapt (FF 4-5).

The Specification defines “redundant coaption” as “closure of the valve at more than one line of interaction between the leaflets” (Spec. 1:20-21). Bochan teaches a valve which forms an “s-shaped” slit which closes the valve at more than one line of interaction between the leaflets (FF 7-8).

Applying the *KSR* standard of obviousness to the Examiner’s findings and the findings of fact, using the Bochan “S-shaped” valve in the prosthetic valve of Brownlee represents a combination of known elements which yield the predictable effects taught by Bochan such as avoiding excessive stress on the valve material (FF 11). Bochan further comments that the “elimination of any substantial stress on the valve is a highly desirable feature in that it is stress which weakens the material of the valve and shortens its life” (Bochan, col. 3, ll. 10-13; FF 10). The combination of the valve of Bochan with that of Brownlee is merely a “predictable use of prior art elements according to their established functions.” *KSR*, 127 S. Ct. at 1740.

Appellant contends that “the alleged motivation to combine the references so as to ‘provide the patient with maximum fluid flow through the valve in the open position’ does not apply” (App. Br. 8). We need not completely disagree with Appellant’s argument to disagree with Appellant’s conclusion regarding prima facie obviousness. The Examiner found two different motivations, the motivation argued by Appellant and the motivation that “an s-shaped engagement allows for full expansion and encounters less force/stress, which leads to an extended life of the device”

(Ans. 5). This second motivation, to extend the life of the device, provides a specific reason to modify Brownlee to use the s-shaped engagement of Bochan (FF 7-10).

The “extended life” advantage disclosed by Bochan is also a design advantage which provides a specific reason to modify the valve of Brownlee to an s-shape as taught by Bochan (FF 7-10). *See KSR*, 127 S.Ct. at 1740.

We are not persuaded by Appellant’s contention that “the ‘essential’ tapered contour of Bochan is not possible to achieve with the two harvested tissue leaflets set forth in independent claim 1” (App. Br. 9). Appellant has not provided any evidence that the leaflets cannot be formed into the contours of Bochan. *See In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) (“Attorney’s argument in a brief cannot take the place of evidence.”). Also, a patent is presumed to be enabled. *See 35 U.S.C. § 282*. The burden rests with the Appellant to establish that the prior art is not enabling. *See Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003)(“In patent prosecution, the examiner is entitled to reject application claims as anticipated by a prior art patent without conducting an inquiry into whether or not that patent is enabled or whether or not it is the claimed material (as opposed to the unclaimed disclosures) in that patent that are at issue. . . . The applicant, however, can then overcome that rejection by proving that the relevant disclosures of the prior art patent are not enabled.”).

We also do not find persuasive Appellant’s contention that Bochan does not teach “leaflets that redundantly coapt.” Appellant’s own Specification states that the “term ‘redundant coaptation’ is used to refer to

closure of the valve at more than one line of interaction between the leaflets” (Spec. 1:20-21). Appellant’s figures differentiate prior art valves in figures 1A and 1B from inventive valves in figures 6 and 7 by the presence of a curved line of interaction in figures 6 and 7, rather than the straight line found in the prior art (*see* Spec., figures 1A, 1B, 6 and 7). Bochan clearly demonstrates the closure of a valve with an s-shape that is virtually identical to the shape shown in figure 2 of the Specification. Bochan’s valve is reasonably interpreted as closing at more than one line of interaction (FF 8).

Claims 6, 8, 12

Appellant contends that Bochan does not teach that “the first and second inner surfaces coapt with each other along a catenary spaced from the free edges” as required by claim 6, that “each of the free edges has a length longer than a length of the catenary” as required by claim 8 or that “the first strut and second strut are nonsymmetrically positioned with respect to the annular frame” as required by claim 12.

We agree with the Examiner’s finding that “the free edges 12 of Bochan are aligned side by side and the interior surfaces mate below them. Therefore the interior surfaces of Bochan coapt at a line spaced below the free edges” (Ans. 6). As shown in figure 4 of Bochan, interior surfaces of the valve coapt (FF 8).

We also agree with the Examiner that “the catenary . . . is simply a curved imaginary line connecting the two posts along the engagement surface. It is inherent that a curved surface is going to be longer than a straight imaginary surface having the same starting and ending points” (Ans. 6). In fact, since the Bochan leaflets form virtually identical shapes as those

disclosed in Appellant's Specification in figures 2, 6, and 7, it is necessarily the case that the Bochan satisfies this claim limitation. *See In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) (“Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.”)

We also agree with the Examiner that Appellant “failed to define with what respect he is referring to. If one looks at the frame from the side, as shown in figure 1, both struts are disposed on the same side making the implant asymmetrical. One could also rotate the frame and view it so that the struts are aligned offset making the[m] asymmetrical” (Ans. 6). Appellant argues that the relationship should be “with respect to the annular frame” (Rep. Br. 8), but does not identify any support for that position in the Specification. “[A]rguments of counsel cannot take the place of evidence lacking in the record.” *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F3d 588, 595 (Fed. Cir. 1997) *quoting Knorr v. Pearson*, 671 F.2d 1368, 1373 (CCPA 1982). *See also, In re Lindner*, 457 F.2d 506, 508 (CCPA 1972) (“mere lawyers' arguments unsupported by factual evidence are insufficient”).

Conclusions of Law

It would have been obvious to an ordinary artisan to modify the prosthetic mitral valve of Brownlee to utilize the elongated s-shaped closure engagement from Bochan.

SUMMARY

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In summary, we affirm the rejection of claims 1, 6, 8, and 12 under 35 U.S.C. § 103(a) over Brownlee and Bochan. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 3-5, 7, 9-11, 13-19, and 21-31 as these claims were not argued separately.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

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