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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RODERICK B. BROWN and MICHAEL AFREMOV

Appeal 2011-002656
Application 11/431,171
Technology Center 3700

Before FRANCISCO C. PRATS, MELANIE L. McCOLLUM, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a hernia patch for laparoscopic delivery. The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Statement of the Case

Background

“This invention relates to an apparatus to be used in hernia repair surgery, and more particularly to a prosthetic hernia repair patch that can be rolled into a tube for laparoscopic delivery through a trocar and which deploys to a generally planar form when ejected from the trocar into the abdominal cavity” (Spec. 1, ll. 4-7).

The Claims

Claims 1-14 are on appeal. Claim 1 is representative and reads as follows:

1. A hernia patch for laparoscopic delivery comprising:
 - (a) a frame member comprising a plurality of strands of a material exhibiting a shape memory property wound together as a cable and forming a closed loop of a predetermined shape configuration when unconstrained;
 - (b) a mesh fabric attached to the frame member and arranged to be rolled up or folded for insertion through a tubular cannula into an abdominal space and when ejected from the cannula will assume the predetermined shape configuration.

The issue

The Examiner rejected claims 1-14 under 35 U.S.C. § 103(a) as obvious over Brown¹ and Corcoran² (Ans. 3-8).

The Examiner finds that Brown teaches:

A hernia patch (10) for laparoscopic delivery comprising:
(a) a frame member (12) comprising a strand of a material

¹ Brown, R., US 5,824,082, issued Oct. 20, 1998.

² Corcoran et al., US 6,379,368 B1, issued Apr. 30, 2002.

exhibiting a shape memory property (Col. 1 Lines 62-63 and Col. 2 Lines 41-44) and forming a closed loop of a predetermined shape configuration when unconstrained (Col. 2 Lines 1-6); (b) a mesh fabric (14) attached to the frame member (Fig. 1) and arranged to be rolled up or folded for insertion through a tubular cannula into an abdominal space and when ejected from the cannula will assume the predetermined shape configuration.

(Ans. 4.) The Examiner finds that “Brown does not disclose that the frame member comprises a plurality of strands that are wound together as a cable” (*id.* at 5). The Examiner finds that “Corcoran discloses a patch (10) comprising a frame member (14, 28) comprising a plurality of strands (Fig. 3) of a material exhibiting a shape memory property (Col. 5 Lines 33-37) wound together as a cable” (*id.*). The Examiner finds that “Corcoran teaches that the strands are made from Nitinol (Col. 5 Lines 33-37) where each strand is at least 0.0005 inches in diameter (Col. 6 Lines 60-61), and that the cable comprises from at least two strands” (*id.*).

The Examiner finds it obvious to “provide Brown with a plurality of shape memory strands wound together as a cable in view of the teachings of Corcoran, in order to provide the frame with good flexibility, fatigue strength, and greater life cycle” (*id.*).

The issues with respect to this rejection are:

(i) Does the evidence of record support the Examiner’s conclusion that Brown and Corcoran render Claim 1 obvious?

(ii) If so, have Appellants presented evidence of secondary considerations, that when weighed with the evidence of obviousness, is sufficient to support a conclusion of non-obviousness?

Findings of Fact

1. Brown teaches a hernia patch which “comprises a wire frame that can be of various designs including, but not limited to, the form of a closed loop where the wire comprising the frame is a shape memory alloy.” (Brown, col. 1, ll. 60-63.)

2. Brown teaches that a “synthetic prosthetic material, such as woven polypropylene or expanded PTFE (Gortex), is attached to and supported by the wire frame” (Brown, col. 1, ll. 63-66).

3. Brown teaches that the wire frame supporting the mesh material may be formed from NiTiNOL or other suitable shape memory alloy and can be attached to the prosthetic material so that it has an hour-glass shape when the alloy is in its austenite form and a rolled, cylindrical shape when in a martensite form (Brown, col. 1, l. 66 to col. 2, l. 4).

4. Brown teaches that: when the patch is cooled, it can be readily formed into a cylindrical configuration for placement in a delivery trocar. When ejected out of the trocar into the patient’s abdominal cavity, it warms to the point where the alloy is in its austenite form so that it springs into its functional, predetermined configuration. The narrowed central portion of an hour-glass shape patch accommodates the inferior epigastric vessels and cord structures while the opposed end lobes will cover the direct and indirect hernia space. Because the frame is integral to the patch, it does not migrate and, accordingly, need not be sutured or stapled in place.

(Brown, col. 2, ll. 6-17.)

5. Corcoran teaches “an occlusion device for closure of a physical anomaly” (Corcoran, col. 2, ll. 2-3).

6. Corcoran teaches “the fixation devices and the attached foam sheets are collapsible so that the entire occlusion device can be moved through a catheter. The fixation devices hold the occlusion device in place once it is inserted into an aperture” (Corcoran, col. 2, ll. 24-28).

7. Corcoran teaches that the “fixation devices have a shape memory, which allows the fixation devices to return to their original shape, or ‘remember’ their shape even after being bent or deformed for passage through a catheter” (Corcoran, col. 2, ll. 30-33).

8. Corcoran teaches that:

Of particular benefit to the invention is the significant extension of cycle life the multi-wire strand **34** adds to the fixation devices. While an individual wire, when subjected to the repeated pulsings of a human heart, may likely suffer a fatigue failure and either fracture or break, a multi-wire strand greatly decreases the chances of such a failure. The reason being that when formed in a strand or a cable, the resulting cycle life of the strand or the cable approximates the cycle life of each individual wire. Small diameter wires have the greatest resistance to fatigue failure, and thus have the longest cycle life, because they are extremely elastic. However, this elasticity also means that the small diameter wires do not have enough stiffness to perform the function required of the fixation device, that is to occlude an anomaly and hold the device in place. When stranded, the small diameter wires retain the elasticity and resistance [sic] to fatigue failure, and yet also obtain the necessary stiffness required to allow the device to function. Thus, the resulting strand benefits from significantly increasing its cycle life while not greatly increasing in size. There are several

options for either strands or cables to be used in the present invention.
(Corcoran, col. 5, ll. 47-67.)

9. Corcoran teaches that a “cable refers to two or more strands laid together, and a strand refers to two or more wires laid together” (Corcoran, col. 6, ll. 1-2).

Principles of Law

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). “If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.” *Id.* at 417. As noted by the Court in *KSR*, “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” 550 U.S. at 421.

Analysis

Brown teaches a hernia patch which comprises a frame member composed of a shape memory nitinol wire which forms a closed loop of a predetermined shape when unconstrained (FF 1). Brown teaches a mesh fabric attached to the frame member (FF 2). Brown teaches that the hernia patch is arranged to be in a rolled, cylindrical form for insertion through a trocar and when ejected and warmed to body temperature, the patch will assume the predetermined shape configuration (FF 3-4).

The Examiner finds that “Brown does not disclose that the frame member comprises a plurality of strands that are wound together as a cable” (Ans. 5).

Corcoran teaches a patch for occlusion of a physical anomaly (FF 5) which can be rolled and moved through a catheter in one form (FF 6) and return when in place in the body into a second form (FF 7). Corcoran specifically teaches that multi strand wires, or cables (FF 9) improve the cycle life of the device since “the small diameter wires retain the elasticity and resistance [sic] to fatigue failure, and yet also obtain the necessary stiffness required to allow the device to function. Thus, the resulting strand benefits from significantly increasing its cycle life while not greatly increasing in size” (Corcoran, col. 5, ll. 61-66; FF 8).

Applying the *KSR* standard of obviousness to the findings of fact, we conclude that the person of ordinary creativity would have reasonably improved Brown’s hernia patch by forming the wire frame with multi-wire cables since Corcoran teaches that “the small diameter wires retain the elasticity and resistance [sic] to fatigue failure, and yet also obtain the necessary stiffness required to allow the device to function. Thus, the resulting strand benefits from significantly increasing its cycle life while not greatly increasing in size” (Corcoran, col. 5, ll. 61-66; FF 8). While the cited references demonstrate that the claimed combination is a “predictable use of prior art elements according to their established functions” *KSR*, 550 U.S. at 417, we also find that Corcoran provides teaching, suggestion, and motivation to substitute wire cables composed of small diameter wires for medical frames for the reasons given in Corcoran (FF 8).

Appellants contend that “neither of the references teach or suggest a frame for a fabric hernia patch in the form of a closed loop of plural strands of a material exhibiting shape memory properties wound as a cable where

the assembly can be rolled up in a compressed form for delivery through a tubular cannula into an abdominal space” (App. Br. 7-8).

We are not persuaded. Brown teaches each element of the hernia patch, including the closed form with a frame composed of shape memory material which can be rolled up for delivery into a cannula (FF 1-4). The only element missing from Brown is the use of a multi strand cable as the frame, an element expressly taught and suggested by Corcoran for similar devices which are also composed of shape memory material that may be rolled up for delivery into a cannula (FF 5-8).

Appellants “submit that there is no teaching, suggestion or motivation in the references for making the proposed modification to the Brown ‘082 reference” (App. Br. 8).

While *KSR* arguably eliminated that rigid requirement for an explicit teaching, suggestion, or motivation, in this particular case, the Examiner has provided a strong teaching, suggestion, and motivation to incorporate the multi-strand cables of Corcoran into the frame of Brown since Corcoran teaches that “the small diameter wires retain the elasticity and resistance [sic] to fatigue failure, and yet also obtain the necessary stiffness required to allow the device to function. Thus, the resulting strand benefits from significantly increasing its cycle life while not greatly increasing in size” (Corcoran, col. 5, ll. 61-66; FF 8). The issue of fatigue and elasticity would be equally relevant to a hernia patch as to a cardiac patch, since a hernia patch would also be subject to stresses as the patient moves while requiring some stiffness (*see* FF 4).

Appellants also contend that it “was not obvious to Dr. Brown at the time he conceived the invention of the ‘082 patent that a cable frame would have superior properties” (App. Br. 8).

We are not persuaded. Corcoran clearly provides evidence that the ordinary artisan, aware of Corcoran’s teaching regarding multi-strand cables, would have found such cables superior for forming medical devices which require both stiffness and elasticity (FF 8).

Appellants contend that the “Examiner gave short shrift to appellants’ commercial success evidence” (App. Br. 9).

We are not persuaded by the commercial success evidence. In the Nuss Declaration,³ Mr. Nuss states that “[h]ernia patches made in accordance with the teachings of the above-captioned patent application are currently being marketed by MMDI under the trademarks, REBOUND HRD and REBOUND HRD V” (Nuss Dec. 1 ¶ 4). However, none of the exhibits referenced by the Nuss Declaration demonstrate that the reason the “Rebound HRD” hernia patches were recognized with awards was due to the device being composed of a frame with multiple strands, rather than a single cable strand as in Brown’s prior art teaching. Consequently, Appellants have not shown a nexus between the commercial success and the use of multiple strands. In the case of evidence of commercial success, the Federal Circuit has acknowledged that the Appellant bears the burden of establishing that nexus, stating:

In the *ex parte* process of examining a patent application...
the PTO lacks the means or resources to gather evidence

³ Declaration of Stephen Nuss, filed May 28, 2010.

which supports or refutes the applicant's assertion that the sales constitute commercial success. *Cf. Ex parte Remark*, 15 USPQ2d 1498, 1503 (Bd.Pat.App. & Int.1990) (evidentiary routine of shifting burdens in civil proceedings inappropriate in *ex parte* prosecution proceedings because examiner has no available means for adducing evidence). Consequently, the PTO must rely upon the applicant to provide hard evidence of commercial success.

In re Huang, 100 F.3d 135, 139-40 (Fed. Cir. 1996). Thus, “the applicant must submit some factual evidence that demonstrates the nexus between the sales and the claimed invention—for example, an affidavit from the purchaser explaining that the product was purchased due to the claimed features.” *Id.* at 140.

No such evidence of a nexus between the multistrands and the success is present in the instant application. Mr. Nuss does present sales data, showing increased sales between January 2008 and April 2009, but there is no evidence that the increased sales were due to the use of multi-strand cables as in the instant invention rather than increased advertising, marketing or other expenses using the \$150,000 budget (*see, e.g.*, App. Br. 10). *See In re DBC*, 545 F.3d 1373, 1384 (Fed. Cir. 2008) (“[E]vidence of commercial success alone is not sufficient to demonstrate nonobviousness of a claimed invention. Rather, the proponent must offer proof ‘that the sales were a direct result of the unique characteristics of the claimed invention--as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter.’”)

We have also considered the Brown Declaration,⁴ where Dr. Brown states that based on “feedback I have received from my colleagues” the commercial success is due to advantages including “delivery of the hernia patch laparoscopically through a smaller sized incision,” “an improved ability to secure the mesh to the NiTiNol frame,” and “prevent the shrinkage or distortion of polypropylene mesh” (Brown Dec. 3-4 ¶ 13). These statements do not, however, provide specific evidence from actual buyers regarding their reasons for purchasing the device. They therefore do not provide adequate evidence of a nexus between the claimed device and the asserted commercial success. *See In re Huang*, 100 F.3d at 139-40 (holding an inventor’s affidavit stating an opinion as to purchaser’s reasons for buying claimed product insufficient to outweigh prima facie obviousness).

We also conclude that even if the commercial success evidence provides a secondary consideration, the showing is insufficient to overcome the strong showing of obviousness in this case. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007) (“[W]e hold that even if Pfizer showed that amlodipine besylate exhibits unexpectedly superior results, this secondary consideration does not overcome the strong showing of obviousness in this case. Although secondary considerations must be taken into account, they do not necessarily control the obviousness conclusion. *Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed.Cir.1988)”). Here, the case of obviousness is very strong, wherein the only alteration in the prior art hernia patch of Brown is the use of multi-wire strands as taught by Corcoran, who provides a number of specific strong motivations to use

⁴ Declaration of Dr. Roderick B. Brown, filed May 28, 2010.

such multi-wire strands in fixation devices such as the hernia patch of Brown (FF 1-9). We do not find the evidence of commercial success sufficient to overcome this strong showing of obviousness.

Although Appellants nominally argue the rejection of dependent claims 2, 3, 7-9 and 14 separately (App. Br. 4), the arguments presented do not point out with particularity or explain why the limitations of the dependent claims are separately patentable. A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim. *See* 37 C.F.R. § 41.37(c)(1)(vii) (2010).

Conclusion of Law

(i) The evidence of record supports the Examiner's conclusion that Brown and Corcoran render Claim 1 obvious.

(ii) Appellants have not presented evidence of secondary considerations, that when weighed with the evidence of obviousness, is sufficient to support a conclusion of non-obviousness.

SUMMARY

In summary, we affirm the rejection of claim 1 under 35 U.S.C. § 103(a) as obvious over Brown and Corcoran. Pursuant to 37 C.F.R. § 41.37(c)(1), we also affirm the rejection of claims 2-14 as these claims were not argued separately.

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

AFFIRMED

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