IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Group Art Unit: 3731
PAI, Suresh, et al.	)	Confirmation No. 8932
Serial No.: 10/982,385	)	Examiner: SEVERSON, Ryan J.
Filed: November 5, 2004	)	
For: APPARATUS AND METHODS FOR SEALING A VASCULAR PUNCTURE	)	

REPLY BRIEF – 37 C.F.R. § 41.41

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
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Pursuant to 37 C.F.R. § 41.41 and M.P.E.P. § 1208, this Reply Brief is being filed to address the Examiner's Answer ("Answer") mailed March 12, 2010.

CERTIFICATE OF TRANSMISSION

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ARGUMENTS

A. Rejection of Claims 1, 3-14, 21-28, 31-40 and 60-70 Under 35 U.S.C. § 103(a) Over the Cates et al. Reference In View of the Sawhney Reference and the Zhu Reference

Appellant submits that the Answer, as it relates to claims 1, 3-14, 21-28, 31-40 and 60-70 standing rejected under 35 U.S.C. § 103(a) as being obvious over the Cates et al. reference in view of the Sawhney reference and the Zhu reference, does not support that the rejection is proper. As such, Appellant respectfully submits that this rejection should be withdrawn for the reasons stated herein.

1. The Cates et al. reference and the Zhu reference cannot be properly combined to teach a bioabsorbable proximal anchor used with a plug to maintain the plug inside a puncture lumen.

Appellant maintains that the Cates et al. reference and the Zhu reference cannot be combined to serve as a proper basis for the obviousness rejection. The Answer alleges that the Zhu reference "teaches a bioabsorbable proximal anchor (130, see paragraphs 76-78) may be used with a plug (see figures 17 and 18) to help maintain the plug inside the puncture lumen," and that it would be obvious to "include an anchor portion as taught by Zhu with the plug of Cates et al. in view of Sawhney to help maintain the plug inside the lumen" (Answer, p. 4, lines 3-8).

First, this is an improper interpretation of the Cates et al. reference and the Zhu reference and thus cannot serve as a basis for the rejection. Specifically, the Cates et al. reference and the Zhu reference, alone or in combination, do not teach maintaining a plug or sponge inside a puncture lumen. Appellant notes that it is unclear whether the Answer's reference to "puncture wound" refers to a puncture in a blood vessel, i.e., an "arteriotomy," which is what the Zhu reference is directed to treating, or to a puncture formed in tissue above a blood vessel, i.e., the passage that extends from the arteriotomy to the patient's skin, which is what the Cates et al.

reference is directed to treating. In either case regardless, the Cates et al. reference and the Zhu reference do not teach maintaining a plug inside a puncture lumen.

In the case of interpreting "puncture wound" as referring to a puncture in a vessel wall, i.e., an arteriotomy (referred to as the blood vessel puncture BVP in the Cates et al. reference), neither reference teaches maintaining a plug inside an arteriotomy. For example, the Cates et al. reference teaches placing a plug 12 adjacent a blood vessel puncture BVP, i.e., an arteriotomy, such that "[a]s soon as the body fluids contact the plug 12, it starts to soften and any seepage of blood through the blood vessel puncture BVP serves to start the formation of a coagulum at the exterior end of the puncture BVP" (the Cates et al. reference, col. 10, lines 3-7; Fig. 9) (emphasis added). In contrast, the Zhu reference teaches placing a sponge 80 over a puncture wound w, i.e., applied directly over an arteriotomy, such that the sponge 80 surrounds the puncture wound w (the Zhu reference, ¶ [0057]). These teachings demonstrate that the Cates et al. reference and the Zhu reference are not directed to "maintaining the plug inside the puncture lumen," as the Answer alleges.

In the case of interpreting "puncture wound" as referring to a passage formed through tissue above the vessel (what is referred to as the access passage or AP in the Cates et al. reference), the Zhu reference does not disclose maintaining a plug within such a passage. In contrast, the Zhu reference teaches that a sponge 80 is placed over a wound w in a blood vessel in a flattened configuration, such that the surrounding tissue closes over the sponge 80 (the Zhu reference, ¶ [0059]; FIG. 11). The passage through tissue is retracted to allow access directly to the vessel wall with the arteriotomy therein. In addition, the lock apparatus 130 has a flattened configuration and "holds the sponge 80 tightly in place adjacent the wound w" in a flattened configuration to allow the surrounding tissue, i.e., the passage through the tissue, to close over

the sponge 80 and the lock apparatus 130 (the Zhu reference, ¶ [0076]; FIG. 18). In other words, as tissue collapses over the sponge 80, the sponge 80 is pressed to assume a flattened profile, and there is no lumen in which the sponge 80 is maintained. Instead, the Zhu sponge remains substantially larger than the passage through the tissue and is not located within the passage. As such, the Zhu reference cannot be combined with the Cates et al. reference to teach "maintaining the plug inside the puncture lumen."

Next, Appellant maintains that the devices described in the Cates et al. reference and the Zhu reference have substantially different functions such that these references cannot be properly combined and still perform their known functions. The Answer alleges, "the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference…the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." (Answer, p. 6, line 19 – p. 7, line 1.) This position in the Answer, however, undermines the importance of properly combining references.

Specifically, the Supreme Court emphasized the importance of the "functional approach" in combining references: "when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int'l. Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007) (emphasis added). However, the devices described in the Cates et al. reference and the Zhu reference cannot be combined and still perform the same functions they had been known to perform.

The Cates et al. reference teaches an applicator 14 carrying a relatively long, narrow collagen plug 12 that is directed through tissue surrounding a bodily puncture to be positioned in access passage AP adjacent blood vessel puncture BVP (the Cates et al. reference, col. 4, line 53

– col. 5, line 3). As the plug 12 softens from contacting bodily fluid, a compensator assembly 90 with a plate 91 and spring 94 extend to compensate for the lost volume; however, "[t]he strength of the spring is limited so that the plate 91 will not force the plug 12 through the puncture BVP, and "[t]he plate 91 is held in the retracted position until the barrel 50 releases the plug" (the Cates et al. reference, col. 9, lines 3-8) (emphasis added). As can be clearly seen in FIG. 9, the Cates plug 12 extends almost the entire length of the access passage AP after delivery.

The Zhu reference, however, discloses a wound closure assembly 30 in which a sponge 80 is advanced along a catheter 32 "into contact with the vessel wall 98 so as to surround the puncture wound w (the Zhu reference, ¶ [0057]), i.e., a large area flat sponge that is placed over the arteriotomy, analogous to a patch on a bicycle tire inner tube. In addition, a lock apparatus 130 "holds the sponge 80 tightly in place adjacent the wound w" (the Zhu reference, ¶ [0076]; FIG. 18).

While the Zhu reference teaches that the lock apparatus 130 holds the sponge 80 "tightly in place adjacent the wound w," i.e., around the vessel wall over the arteriotomy, the Cates et al. reference, on the other hand, explicitly teaches that the strength of the spring 94 is limited to prevent force from being imposed on the plug 12 and further to prevent the plug 12 from being pushed into the blood vessel puncture BVP. Thus, if the Zhu lock apparatus 130 were forced into the access passage AP to hold the Cates et al. plug against the BVP, this would clearly result in excessive force being exerted against the plug 12. In this case, the plug 12 could be pushed into the blood vessel puncture BVP, which teaches away from the description of the Cates et al. reference.

Also, the lock apparatus 130 in the Zhu reference would be incapable of holding the Cates et al. plug against the wound w (the BVP in the Cates et al. reference), because the Cates et al.

plug extends through the access passage AP almost to the patient's skin. As such, if the Zhu lock apparatus 130 were simply placed adjacent the back end of the Cates et al. plug 12 without applying force, the lock apparatus 130 would be located near the patient's skin and nowhere near the BVP. In this case, the lock apparatus 130 would be incapable of performing its known function of pressing the plug 12 of the Cates et al. reference against the vessel wall or preventing the distal end of the plug 12 from migrating away from the vessel wall. In other words, combining the Cates et al. plug 12 with lock apparatus 130 of the Zhu reference amounts to teaching away from each reference, wherein neither device can perform its known function. This stands in contrast to the functional approach outlined in *KSR* and thus is an improper combination.

Further, while the Answer dismisses the relative sizes of the Cates et al. and Zhu devices because size is not relied upon for the rejection, the relative sizes of the Cates et al. and Zhu devices actually do matter, because the relative sizes of the devices are necessary for them to perform their intended function. As explained above, FIG. 9 of the Cates et al. reference demonstrates that the Cates et al. plug 12 is a relatively narrow, long structure that extends through most of the access passage AP given the length of the collagen plug 12. It is this length that allows the plug 12 to fill and seal the access passage AP. If the lock apparatus 130 was positioned on the proximal end of the plug 12 away from the vessel, the lock apparatus 130 would consequently be located adjacent the patient's skin, which would not hold the plug 12 against the BVP, as intended by the Zhu reference.

Further, in direct contrast, the sponge 80 and the lock apparatus 130 in the Zhu reference require a flat, large cross-sectional area relative to the puncture wound w in order to surround the puncture wound w. Shrinking the lock apparatus 130 to size of the wound w would render it

incapable of performing its intended function. In particular, the collagen plug 12 of the Cates et al. reference is directed through an applicator 14 extending through a puncture in tissue and thus requires a narrow profile smaller than the BVP and AP, as shown in FIGS. 6 and 7. This renders the plug 14 incompatible with the large cross-section of the lock apparatus 130. Moreover, reducing the size of the lock apparatus 130 to match the profile of the plug 12 would render the lock apparatus 130 incapable of performing its known function, *i.e.*, to resist movement in the direction away from the wound w to hold the sponge 80 tightly in place against the wound w. This is because the lock apparatus 130 would necessarily be no larger than the collagen plug 12 itself (otherwise it could not fit within the applicator 14) and would place the lock apparatus 130 adjacent the patient's skin and not the BVP. As the M.P.E.P. states, "If proposed modification [*sic*] would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." M.P.E.P. § 2143.01(V) citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

In addition, the Answer alleges that the Zhu reference teaches "a bioabsorbable anchor" (Answer, p. 4, line 2). However, Appellant notes that the Answer does not address Appellant's position that the Zhu reference fails to provide an enabling disclosure of the lock apparatus 130 to qualify as prior art against the present application. As Appellant has previously asserted, the Zhu reference teaches no materials, methods for construction, or other information for making the lock apparatus 130, merely stating that the lock apparatus 130 is "formed of a material that can be absorbed by the body over time … other materials, such as stainless steel, can be advantageously used" (the Zhu reference, ¶ [0078]). Further, the Zhu reference is silent as to how the actuable or swept-back arms of the lock apparatus 130 can be made or actuated. In particular, the Zhu reference does not teach or suggest how such an apparatus could be made and actuated if it were

somehow shrunk and disposed within the Cates et al. applicator. Thus, the Zhu reference is not enabled sufficiently and may not be properly combined with the Cates et al. reference to render the present claims obvious.

For the reasons stated above, claims 1, 3-14, 21-28, 31-40 and 60-70 are not obvious over the Cates et al. reference, the Sawhney reference, and the Zhu reference, either alone or in combination with each other. Thus, Appellant respectfully requests that this rejection be withdrawn.

B. Rejection of Claims 15-20 Under 35 U.S.C. § 103(a) Over the Cates et al. Reference In View of the Sawhney Reference, the Zhu Reference, and the Vidal et al. Reference

Appellant respectfully submits that the Answer, as it relates to claims 15-20 standing rejected under 35 U.S.C. § 103(a) as being obvious over the Cates et al. reference in view of the Sawhney reference, the Zhu reference, and the Vidal et al. reference, does not support that the rejection is proper. As such, Appellant respectfully submits this rejection should be withdrawn for the reasons stated herein.

Specifically, claims 15-20 depend from claim 1 and are thus patentable over the Cates et al. reference, the Sawhney reference, and the Zhu reference for at least the reasons discussed above regarding claim 1. The Vidal et al. reference fails to supplement these references to support the obviousness rejections, as the Vidal et al. reference does not teach the limitations that are missing from the other references to render claim 1 obvious. Therefore, claims 15-20 are not obvious over the Cates et al. reference, the Sawhney reference, the Zhu reference, and the Vidal et al. reference, alone or in combination with one another. Thus, Appellant respectfully requests that this rejection be withdrawn.

CONCLUSION

Based on the above arguments, Appellant respectfully submits that the rejected claims are patentable over the cited prior art and, therefore, should be allowed to issue.

Respectfully submitted,
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