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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/982,385	11/05/2004	Suresh S. Pai	ACI-013	8932
23410	7590	01/11/2012	EXAMINER	
Vista IP Law Group LLP 2040 MAIN STREET, Suite 710 IRVINE, CA 92614			SEVERSON, RYAN J	
			ART UNIT	PAPER NUMBER
			3731	
			MAIL DATE	DELIVERY MODE
			01/11/2012	PAPER

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SURESH S. PAI,
CELSO J. BAGAOISAN, and FARHAD KHOSRAVI

Appeal 2010-008125
Application 10/982,385
Technology Center 3700

Before DEMETRA J. MILLS, ERIC GRIMES, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims to an apparatus for sealing a puncture extending through living tissue. The Examiner entered rejections for obviousness.

We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Appellants' invention is directed to an apparatus for sealing puncture wounds which can result from procedures that access a patient's vasculature percutaneously; "[f]or example, a hollow needle may be inserted through a

patient's skin and overlying tissue into a blood vessel. A guide wire may be passed through the needle lumen into the blood vessel, whereupon the needle may be removed" (Spec. [0002]). After needle removal, an "introducer sheath may then be advanced over the guide wire into the vessel, e.g., in conjunction with or subsequent to one or more dilators" allowing access to the vessel for the purpose of performing medical procedures (*id.*).

Claims 1, 3-28, 31-40, and 60-70 stand rejected and appealed (App. Br. 2).¹ Claim 1 is representative and reads as follows:

1. An apparatus for sealing a puncture extending through tissue, comprising:
 - a tubular member comprising a proximal end, a distal end sized for insertion through the puncture, a lumen extending between the proximal and distal ends, and a distal opening in communication with the lumen;
 - a bioabsorbable plug disposed within the lumen and comprising a lumen extending between proximal and distal ends thereof, the plug comprising hydrogel;
 - a bioabsorbable anchor element disposed within the lumen proximal to the plug;
 - a pusher member slidable within the lumen of the tubular member for deploying the plug and anchor element through the lumen and out the distal opening of the tubular member; and
 - an elongate positioning member, the positioning member having an expandable element on a distal end thereof, the positioning member sized for slidably passing through the lumen of the tubular member and the lumen of the plug.

The following rejections are before us for review:

(1) Claims 1, 3-14, 21-28, 31-40, and 60-70, under 35 U.S.C. § 103(a) as obvious over Cates,² Sawhney,³ and Zhu⁴ (Ans. 3-5); and

¹ Appeal Brief entered November 3, 2009.

² U.S. Patent No. 6,162,240 (issued December 19, 2000).

(2) Claims 15-20, under 35 U.S.C. § 103(a) as being obvious over Cates, Sawhney, Zhu, and Vidal⁵ (Ans. 5-6).

DISCUSSION

The Examiner found that Cates described an apparatus substantially as claimed, except that Cates' device did not have a plug composed of hydrogel, and also did not have a bioabsorbable anchor proximal to its plug, as recited in independent claims 1, 28, and 60 (Ans. 3-4). The Examiner concluded, however, that modifying Cates' device to include those features would have been prima facie obvious, in view of the teachings of Sawhney and Zhu that such features were known to be useful on devices of the type described by Cates (*id.*).

“In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art.” *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992).

In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), while the Supreme Court emphasized “an expansive and flexible approach” to the obviousness question, it also reaffirmed the importance of determining “whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue.” *Id.* at 418 (emphasis added).

Thus, “[o]bviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim

³ U.S. Patent No. 6,605,294 B2 (issued August 12, 2003).

⁴ U.S. Patent App. Pub. No. 2002/0072767 A1 (published June 13, 2002).

⁵ U.S. Patent No. 5,334,216 (issued August 2, 1994).

under examination.” *Unigene Laboratories, Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011).

We agree with Appellants that the Examiner has not shown that the cited references would have rendered the claimed apparatus *prima facie* obvious to an ordinary artisan. In particular, we agree with Appellants that the Examiner has not adequately explained why the cited references would have suggested including Zhu’s bioabsorbable anchor in Cates’ device, proximal to Cates’ bioabsorbable plug, as the claims require.

Specifically, claim 1 recites a tissue puncture-sealing apparatus that has a bioabsorbable plug disposed in the lumen of a tubular member, and also has “a bioabsorbable anchor element disposed within the lumen proximal to the plug” (App. Br. 18 (claim 1)). The other independent claims recite similar devices that also have this feature (*id.* at 23 (claim 28) and 25 (claim 60)).

Zhu describes a tissue puncture-sealing apparatus that includes a relatively thin sponge 80 that contains a hemostatic agent and/or adhesive, the sponge being deployed directly on the outer surface of the punctured vessel while the tissue surrounding the vessel is retracted (Zhu [0055]-[0059]); *see also* Figure 6). Once the sponge is in place on the vessel surface, the retractors and sponge-applying device are removed, and the “surrounding body tissues 96 collapse around the sponge 80 and push member 84. The push member 84 [which is ultimately also removed] holds the sponge 80 in position while body tissue 96 surrounds the sponge 80 and while the adhesive cures” (*id.* at [0059]).

As the Examiner points out, in one embodiment Zhu’s device includes a “lock apparatus 130 [which] is employed to help hold the sponge 80 in

place against the artery wall **98**” (*id.* at [0076]; *see also* Figures 17 and 18). Thus, “the lock apparatus **130** holds the sponge **80** tightly in place adjacent the wound w as shown in **FIG. 18**” (*id.*).

In contrast to Zhu’s sponge and lock apparatus, which adhere closely to the punctured blood vessel and are surrounded by the overlying tissue, Cates’ device uses a relatively long collagen plug **12** that extends essentially from the surface of the skin to the wall of the punctured vessel, through the intervening punctured tissue, which Cates calls the “access passage AP” (*see, e.g.*, Cates, col. 10, l. 3; *see also* Figure 9).

As Cates explains, once the plug **12** is deployed in the access passage, “[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” (*id.* at col. 10, ll. 3-7). Ultimately, “[a]fter the physician checks to see if the seal has been affected, the projecting end of the control member **20** can be pulled out through the collagen plug **12** to complete the procedure and leave the collagen plug **12** in place forming the coagulum CAM as seen in **FIG. 9**” (*id.* at col. 10, ll. 17-22).

Thus, in contrast to Zhu’s vessel-adhering anchor feature, Cates’ plug is configured to extend through the tissue adjacent to the punctured vessel all the way through the access passage AP. Given that the express purpose of Zhu’s anchor is to ensure close adherence of the hemostatic sponge to the vessel wall, we are not persuaded that an ordinary artisan would have combined such an anchor with a device containing Cates’ plug, since Cates’ plug is specifically configured to extend far from the vessel wall. Moreover, given that Cates’ plug itself effectively acts to anchor the vessel puncture-

sealing coagulum CAM in place (*see id.* at Figure 9), we are further persuaded that the Examiner has not advanced an adequate rationale explaining why an ordinary artisan would have been prompted to deploy Zhu's anchor next to Cates' plug.

We agree with the Examiner that a claim "may be obvious in view of a combination of references, even if the features of one reference cannot be substituted physically into the structure of the other reference." *Orthopedic Equip. Co., Inc. v. United States*, 702 F.2d 1005, 1013 (Fed. Cir. 1983).

Ultimately, however, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

Here, for the reasons discussed, we are not persuaded that the cited references would have suggested an apparatus having the claimed combination of features to an ordinary artisan. We therefore reverse the Examiner's obviousness rejection of claims 1, 3-14, 21-28, 31-40, and 60-70 over Cates, Sawhney, and Zhu.

The Examiner also rejected claims 15-20 as obvious over Cates, Sawhney, Zhu, and Vidal (Ans. 5-6). The Examiner cited Vidal as evidence that an ordinary artisan would have considered it obvious to include bioabsorbable plugs, shaped as recited in these dependent claims, in a device such as that described by Cates (*id.*).

However, as the Examiner has pointed to no teaching in Vidal that remedies the deficiencies, discussed above, with respect to the anchor

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Application 10/982,385

feature required in each of the independent claims, we reverse this rejection as well.

SUMMARY

We reverse the Examiner's rejection of claims 1, 3-14, 21-28, 31-40, and 60-70 as obvious over Cates, Sawhney, and Zhu.

We also reverse the Examiner's obviousness rejection of claims 15-20 over Cates, Sawhney, Zhu, and Vidal.

REVERSED

alw



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23410	7590	06/03/2010	EXAMINER	
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			06/03/2010	PAPER

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Appeal No: 2010-008125

Application: 10/982,385

Appellant: Suresh S. Pai et al.

Board of Patent Appeals and Interferences Docketing Notice

Application 10/982,385 was received from the Technology Center at the Board on May 24, 2010 and has been assigned Appeal No: 2010-008125.

In all future communications regarding this appeal, please include both the application number and the appeal number.

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By order of the Board of Patent Appeals and Interferences.



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10/982,385	11/05/2004	Suresh S. Pai	ACI-013	8932
23410	7590	05/18/2010	EXAMINER	
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			ART UNIT	PAPER NUMBER
			3731	
			MAIL DATE	DELIVERY MODE
			05/18/2010	PAPER

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10982385	11/5/2004	PAI ET AL.	ACI-013

Vista IP Law Group LLP
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EXAMINER

Ryan J. Severson

ART UNIT	PAPER
3731	20100514

3731 20100514

DATE MAILED:

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Commissioner for Patents

The reply brief filed 5/11/2010 has been entered. The application has been forwarded to the Board of Patent Appeals and Interferences for decision on the appeal.

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773

/Ryan J Severson/
Examiner, Art Unit 3731

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)	
<u>SEALING A VASCULAR PUNCTURE</u>)	

REPLY BRIEF – 37 C.F.R. § 41.41

Mail Stop Appeal Brief - Patents
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Alexandria, VA 22313-1450

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

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being transmitted to Mail Stop Appeal Brief - Patents, Commissioner for Patents, P.O. BOX 1450, Alexandria, VA 22313-1450 on the date shown below via the USPTO EFS-Web filing system.

May 11, 2010
Date of transmission

/patricia j. english/
Patricia J. English

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 actuatable 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,
VISTA IP LAW GROUP LLP

Dated: May 11, 2010

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Electronic Acknowledgement Receipt

EFS ID:	7592417
Application Number:	10982385
International Application Number:	
Confirmation Number:	8932
Title of Invention:	Apparatus and methods for sealing a vascular puncture
First Named Inventor/Applicant Name:	Suresh S. Pai
Customer Number:	23410
Filer:	William A. English/Patricia English
Filer Authorized By:	William A. English
Attorney Docket Number:	ACI-013
Receipt Date:	11-MAY-2010
Filing Date:	05-NOV-2004
Time Stamp:	18:06:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Reply Brief Filed	ACI013_ReplyBrief.pdf	131626 04a8231d4bb9144e894697726e3ce5d19fc514c6	no	9

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/982,385	11/05/2004	Suresh S. Pai	ACI-013	8932
23410	7590	03/12/2010	EXAMINER	
Vista IP Law Group LLP 2040 MAIN STREET, Suite 710 IRVINE, CA 92614			SEVERSON, RYAN J	
			ART UNIT	PAPER NUMBER
			3731	
			MAIL DATE	DELIVERY MODE
			03/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

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

Application Number: 10/982,385
Filing Date: November 05, 2004
Appellant(s): PAI ET AL.

William A. English
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/15/2009 appealing from the Office action mailed 3/3/2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,162,240	Cates et al.	12-2000
6,605,294	Sawhney	08-2003

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2002/0072767	Zhu	06-2002
5,334,216	Vidal et al.	08-1994

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 3-14, 21-28, 31-40, and 60-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cates et al. (6,162,240) in view of Sawhney (6,605,294) and Zhu (2002/0072767).

Cates et al. disclose the apparatus substantially as claimed, including a tubular member (50, see figures 1 and 2), a bioabsorbable plug (12, see figures 8 and 9), a pusher member (90, see figure 2), and an elongate positioning member (11) with an expandable distal end (21, see figures 6-8). The positioning member is withdrawn through a lumen in the plug and pusher member after insertion of the plug (see figures 8 and 9).

Regarding claims 1, 28, and 60, Cates et al. do not disclose the plug comprises hydrogel. Attention is drawn to Sawhney, who teaches puncture plugs may be made from hydrogel (see column 4, lines 59-64) to create a device that is capable of expanding and sealing to the exact size and shape of the puncture it is sealing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the plug of Cates et al. with a hydrogel, as taught by Sawhney, to create a device that is capable of expanding and sealing to the exact size and shape of the puncture it is sealing.

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Further regarding claims 1, 28, and 60, the combination of Cates et al. and Sawhney does not disclose a bioabsorbable anchor located proximal of the plug. Attention is drawn to Zhu, who 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. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made 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 puncture lumen.

Regarding claims 5-8, the plug material of Sawhney can have first and second precursors (see column 7, line 30). The plug further has a pH-activating agent (see column 7, lines 33-37) that incites a reaction and causes the expansion of the plug to seal and adhere to the puncture walls.

Regarding claims 9, 11, 31, and 61, the plug material of Sawhney can be made from a lyophilized hydrogel (see column 20, example 14).

Regarding claims 10, 32, and 62, the plug of Cates et al. in view of Sawhney is pro-thrombotic because it stops the flow of blood.

Regarding claims 12, 33, and 63, the plug is cylindrical (figure 9 of Cates et al.).

Regarding claims 13 and 14, the plug composition of Sawhney may vary to provide faster rates of deployment in certain portions (see column 17, example 3 and column 20, example 15) and larger sizes of expansion in certain portions (see column 7, lines 46-51).

Regarding claims 21, 22, 34, and 36, the anchor of Zhu has barbs (132).

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Regarding claims 23-25, 35, 36, 65, and 66, Zhu does not disclose the anchor be made from hydrogel. Attention is again drawn to Sawhney, which teaches hydrogel may be used in various medical settings including sealing biopsy puncture tracts and wounds (see columns 9 and 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the absorbable anchor of Zhu of absorbable hydrogel, as taught by Sawhney, to create an anchor that is capable of conforming to the exact size and shape of the puncture.

Regarding claims 26, 27, 37, 38, 67, and 68, Sawhney discloses the materials may have varying expansion rates (see column 7, lines 11-18).

Regarding claims 39, 40, 69, and 70, the positioning member and pusher member can have movement limited by the contact between the expandable portion of the positioning member and the end of the tubular member, which is coupled to the pusher member (see figure 2 of Cates).

Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cates et al. (6,162,240) in view of Sawhney (6,605,294), Zhu (2002/0072767), and Vidal et al. (5,334,216).

Regarding claim 15, the combination of Cates et al. with Sawhney and Zhu does not disclose the plug has a frustoconical shape. Attention is drawn to Vidal et al., who teach a plug may have a frustoconical shape (see figures 1 and 2) to allow it to be implanted more easily in a puncture. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to shape the plug in a frustoconical manner to allow it to be implanted more easily in a puncture.

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Regarding claims 16-20, the combination of Cates et al. with Sawhney and Zhu does not disclose the plug is a sheet of material rolled into an elongate shape. Attention is drawn again to Vidal et al., who teach a rolled sheet may be used as a plug (see figures 1 and 2) to allow the plug to be compressed to a smaller diameter before implantation to allow for easier delivery. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the plug with a rolled sheet, as taught by Vidal et al., to allow the plug to be compressed to a smaller diameter before implantation to allow for easier delivery.

Regarding claims 17 and 18, Sawhney discloses the plug material may have varying shapes and sizes (see column 11, lines 31-36) and therefore is capable of having varying thickness at desired ends.

Regarding claim 19, the material may also be made porous (see column 17, example 4 of Sawhney) and therefore the density may be greater in portions of the plug as compared to other portions. The more porous areas are less dense.

Regarding claim 20, the material may be compressed, as explained by Vidal et al. in claim 16 above.

(10) Response to Argument

Appellant argues the lock apparatus (anchor) of Zhu can not be combined with the Cates et al. device. However, Examiner notes that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined

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teachings of the references would have suggested to those of ordinary skill in the art.

See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Further still, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Therefore, arguments based on the size of the anchor of Zhu relative to the device of Cates et al. are not persuasive because the size of the structure was not relied upon at any point, and the manner of introducing the anchor in Zhu (i.e. by the use of Zhu's retractor) has also not been relied upon to reject the claims. As a whole, Zhu teaches an anchor structure may be deployed proximal to a plug structure to maintain the plug structure within the puncture wound. Since the anchor of Zhu clearly has a hole disposed there through that receives a positioning member, one of ordinary skill in the art would have recognized that an anchor having a similar shape could be used with the device of Cates et al. Applicant has only provided opinions and speculative arguments and no factual evidence as to why the combination could not be made.

In response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

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reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Appellant argues that the teaching of using the hydrogel of Sawhney to replace the collagen of Cates et al. would not be obvious because the formation of coagulum is important in Cates et al. to maintain the plug in the lumen. However, the hydrogel of Sawhney expands rapidly and anchors itself into tissue (see column 4, lines 64-67) and therefore the plug if made of hydrogel can still “coagulate” the opening, or otherwise stated it will form a mass, clump, or clot because the material anchors itself into the tissue. Substituting one material for the other would not prevent the plug from performing its intended function (sealing a puncture). The objective of both Cates et al. and Sawhney is to stop bleeding, and they show two suitable alternative materials for meeting this objective. Further still, Examiner notes it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Appellant argues with respect to claim 11 that the prior art fails to show a laminate structure. However, claim 11 only requires a laminate structure having “one or more layers”. Therefore, a material having a single layer can be considered a laminate structure according to the limitation set forth in the claim. Examiner takes the position that the lyophilized material (which is claimed) as set forth in column 20, example 14 of Sawhney meets the claim limitation because it is the same material and comprises at least one layer.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Ryan J. Severson/

Examiner, Art Unit 3731

Conferees:

/Anhtuan T. Nguyen/

Supervisory Patent Examiner, Art Unit 3731

/Michael J Milano/

Primary Examiner