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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,202	06/23/2009	7,207,949	03190.005200	2860

30328 7590 08/14/2009

NuVasive
c/o CPA Global
P.O. Box 52050
Minneapolis, MN 55402

EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED: 08/14/2009

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



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THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS
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30 ROCKEFELLER PLAZA
NEW YORK, NY 10112-3800

Date:

MAILED

AUG 14 2009

**Transmittal of Communication to Third Party Requester
Inter Partes Reexamination**

CENTRAL REEXAMINATION UNIT

REEXAMINATION CONTROL NO. : 95001202
PATENT NO. : 7207949
TECHNOLOGY CENTER : 3999
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified Reexamination proceeding. 37 CFR 1.903.

Prior to the filing of a Notice of Appeal, each time the patent owner responds to this communication, the third party requester of the inter partes reexamination may once file written comments within a period of 30 days from the date of service of the patent owner's response. This 30-day time period is statutory (35 U.S.C. 314(b)(2)), and, as such, it cannot be extended. See also 37 CFR 1.947.

If an ex parte reexamination has been merged with the inter partes reexamination, no responsive submission by any ex parte third party requester is permitted.

All correspondence relating to this inter partes reexamination proceeding should be directed to the Central Reexamination Unit at the mail, FAX, or hand-carry addresses given at the end of the communication enclosed with this transmittal.

**ORDER GRANTING/DENYING
REQUEST FOR INTER PARTES
REEXAMINATION**

Control No. 95/001,202	Patent Under Reexamination 7,207,949	
Examiner Cary E. O'Connor	Art Unit 3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

The request for *inter partes* reexamination has been considered. Identification of the claims, the references relied on, and the rationale supporting the determination are attached.

Attachment(s): PTO-892 PTO/SB/08 Other: _____

1. The request for *inter partes* reexamination is GRANTED.

An Office action is attached with this order.

An Office action will follow in due course.

2. The request for *inter partes* reexamination is DENIED.

This decision is not appealable. 35 U.S.C. 312(c). Requester may seek review of a denial by petition to the Director of the USPTO within ONE MONTH from the mailing date hereof. 37 CFR 1.927. EXTENSIONS OF TIME ONLY UNDER 37 CFR 1.183. In due course, a refund under 37 CFR 1.206(c) will be made to requester.

All correspondence relating to this *inter partes* reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of this Order.

DECISION ON REQUEST FOR INTER PARTES REEXAMINATION

A substantial new question of patentability affecting claims 1-38 of United States Patent Number 7,207,949 is raised by the request for *inter partes* reexamination.

Extensions of Time

Extensions of time under 37 CFR 1.136(a) will **not** be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 314(c) requires that *inter partes* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.937). Patent owner extensions of time in *inter partes* reexamination proceedings are provided for in 37 CFR 1.956. Extensions of time are not available for third party requester comments, because a comment period of 30 days from service of patent owner's response is set by statute. 35 USC 314(b)(3).

Notification of Concurrent Proceedings

The patent owner is reminded of the continuing responsibility under 37 CFR 1.985 to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 7,207,949 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP § 2686 and 2686.04.

Service of Papers

Any paper filed by either the patent owner or the third party requester ***must be served*** on the other party in the reexamination proceeding in the manner provided by 37 CFR 1.248. See 37 CFR 1.903 and MPEP 2666.06.

The prior art documents listed below are relied upon by requester in support of the request for inter partes in support of the request for inter partes reexamination.

- (1) WO 03/005887 to Blewett et al (hereinafter "Blewett"),
- (2) U.S. Patent No. 6,945,933 to Branch et al (hereinafter "Branch"),
- (3) U.S. Patent No. 5,772,661 to Michelson (hereinafter "Michelson"),
- (4) U.S. Patent Application Publication No. 2002/0072686 to Hoey et al (hereinafter "Hoey"),
- (5) WO 01/37728 to Kelleher et al (hereinafter "Kelleher"),
- (6) WO 00/38574 to Marino et al (hereinafter "Marino '574"),
- (7) U.S. Provisional Patent Application No. 60/325,424 to Gharib (hereinafter "Gharib"),
- (8) U.S. Patent No. 4,545,374 to Jacobson (hereinafter "Jacobson"),
- (9) U.S. Patent No. 6,847,849 to Mamo et al (hereinafter "Mamo"),
- (10) U.S. Patent Application Publication No. 2002/0007129 to Marino (hereinafter "Marino '129"), and
- (11) U.S. Patent No. 5,928,139 to Koros et al (hereinafter "Koros").

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The request indicates that the requester considers:

Blewett obviousness combinations:

(1) Claims 1-9, 11-27, 29-35 and 38 are unpatentable over Blewett in combination with Branch.

(2) Claims 10, 28, 36 and 37 are unpatentable over Blewett in combination with Branch and Michelson.

Branch obviousness combinations:

(3) Claims 1-9, 11, 12, 14-27, 29-32, 34, 35 and 38 are unpatentable over Branch in combination with Kelleher.

(4) Claims 13 and 33 are unpatentable over Branch in combination with Kelleher and Hoey.

(5) Claims 10, 28, 36 and 37 are unpatentable over Branch in combination with Kelleher and Michelson.

Marino '574 anticipation and obviousness combinations:

(6) Claims 1-4, 7, 9, 11, 15-17, 20-22, 25, 27, 29, 30 and 38 are unpatentable over Marino '574.

(7) Claims 10 and 28 are unpatentable over Marino '574 in combination with Michelson.

Gharib obviousness combinations:

(8) Claims 1-4, 7, 9, 11-22, 25, 27, 29-33 and 38 are unpatentable over Gharib in combination with Marino '574.

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(9) Claims 10, 28, 36 and 37 are unpatentable over Gharib in combination with Marino '574 and Michelson.

Jacobson anticipation and obviousness combinations:

(10) Claims 1, 3-6, 8-11, 16, 21-24, 27 and 28 are unpatentable over Jacobson.

(11) Claims 16, 17, 19, 21-24, 26-30, 34 and 35 are unpatentable over Jacobson in combination with Branch

Mamo obviousness combinations:

(12) Claims 1-6, 8, 9, 11, 14-24, 26, 27, 29, 30, 34, 35 and 38 are unpatentable over Mamo in combination with Branch.

(13) Claims 7, 12, 25, 31 and 32 are unpatentable over Mamo in combination with Branch and Marino '129.

(14) Claims 10 and 28 are unpatentable over Mamo in combination with Branch Michelson.

(15) Claims 13 and 33 are unpatentable over Mamo in combination with Branch, Marino '129 and Hoey.

(16) Claim 36 is unpatentable over Mamo in combination with Branch and Koros.

Substantial New Question of Patentability

Under 35 U.S.C. 304, the Office must determine whether "a substantial new question of patentability" ("SNQP") affecting any claim of the patent has been raised. If an SNQP is found, an order for reexamination of the patent is granted. For an SNQP to be present, it is only necessary that:

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A. The prior art patents and/or printed publications raise a substantial question of patentability regarding at least one claim, i.e. the teaching of the (prior art) patents and printed publications is such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable; it is not necessary that the prior art establish a *prima facie* case of unpatentability; and

B. The same question of patentability as to the claim has not been decided by the Office in a previous examination or pending reexamination of the patent or in a final holding of invalidity by the Federal Courts in a decision on the merits involving the claim.

An SNQP as to a patent claim could be present even if the examiner would not necessarily reject the claim as either fully anticipated by, or obvious in view of, the prior art patents or printed publications. See MPEP 2242.

If an SNQP is found as to one claim, all claims will be reexamined during the ex parte reexamination process. See MPEP 2216.

WO 03/005887 to Blewett et al

The Blewett reference is a new teaching, not previously considered nor addressed in the prior examination of the patent or a final holding of invalidity by the Federal Courts. Blewett qualifies as prior art under 35 USC 102(a) based on its publication date of January 23, 2003. Branch qualifies as prior art under 35 USC 102(b) based on its effective filing date of June 26, 2002.

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The Blewett reference, taken with Branch raises an SNQ with respect to claims 1-9, 11-27, 29-35 and 38. The Blewett reference, taken with Branch and Michelson raises an SNQ with respect to claims 10, 28, 36 and 37.

Claims 1 (apparatus) and 16 (method) require, *inter alia*, a tubular distraction member, an elongated inner member having a stimulation electrode, a monitoring device and a retractor. Blewett teaches the use of a tubular distraction member 26, an elongated inner member 24 having a stimulation electrode and a monitoring device. Branch discloses the use of a retractor 20 for increasing the size of a working channel. Thus, there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not these claims are patentable.

Accordingly, Blewett, taken with Branch raises an SNQ as to claims 1-38, which has not been decided in a previous examination of the '949 patent.

U.S. Patent No. 6,945,933 to Branch

The Branch reference is a new teaching, not previously considered nor addressed in the prior examination of the patent or a final holding of invalidity by the Federal Courts. Branch qualifies as prior art under 35 USC 102(e) based on its effective filing date of June 26, 2002. Kelleher qualifies as prior art under 35 USC 102(b) based on its publication date of May 31, 2001.

The Branch reference, taken with Kelleher raises an SNQ with respect to claims 1-9, 11, 12, 14-27, 29-32, 34-35 and 38. The Branch reference, taken with Kelleher and

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Hoey, raises an SNQ with respect to claims 13 and 33. The Branch reference, taken with Kelleher and Michelson raises an SNQ with respect to claims 10, 28, 36 and 37.

Claims 1 (apparatus) and 16 (method) require, *inter alia*, a tubular distraction member, an elongated inner member having a stimulation electrode, a monitoring device and a retractor. Branch discloses the use of a tubular distraction set 66 and a retractor 20 for increasing the size of a working channel. Kelleher teaches the use of a surgical tool, including a cannula, having a stimulation electrode and a monitoring device. Thus, there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not these claims are patentable.

Accordingly, Branch, taken with Kelleher raises an SNQ as to claims 1-38, which has not been decided in a previous examination of the '949 patent.

WO 00/38574 to Marino et al

The Marino '574 reference is a new teaching, not previously considered nor addressed in the prior examination of the patent or a final holding of invalidity by the Federal Courts. Also, Marino '574 qualifies as prior art under 35 USC 102(b) based on its publication date of July 6, 2000.

The Marino '574 reference raises an SNQ with respect to claims 1-4, 7, 9, 11, 15-17, 20-22, 27, 29, 30 and 38. The Marino '574 reference, taken with Michelson raises an SNQ with respect to claims 10 and 28.

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Claims 1 (apparatus) and 16 (method) require, *inter alia*, a tubular distraction member, an elongated inner member having a stimulation electrode, a monitoring device and a retractor. Marino '574 teaches the use of a cannula 300, an elongated inner member 310 having a stimulation electrode, a monitoring device, and a retractor (expanding petals 314). Thus, there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not these claims are patentable.

Accordingly, Marino '574 raises an SNQ as to claims 1-4, 7, 9-11, 15-17, 20-22, 27-29, 30 and 38, which has not been decided in a previous examination of the '949 patent.

U.S. Provisional Patent Application No. 60/325,424 to Gharib

The U.S. Provisional Patent Application to Gharib does not qualify a prior art under the provisions of 35 USC 102 or 103(a) because it is not a patent or printed publication. Prior art considered during reexamination is limited to prior art patents or printed publications applied under the appropriate parts of 35 U.S.C. 102 and 103. MPEP 2209. A provisional patent application, itself (regardless of the publication of a related PCT application or US Patent application), is not patent or a printed publication and cannot be used as a basis for establishing a substantial new question of patentability in a reexamination proceeding.

U.S. Patent No. 4,545,374 to Jacobson

Jacobson was cited during the prosecution of the application that resulted in the '949 patent but was never used in a rejection against the claims in question. Jacobson qualifies as prior art under 35 USC 102(b) based on its patent date of October 8, 1985.

The Jacobson reference, taken alone, raises an SNQ with respect to claims 1, 3-6, 8-11, 16, 21-24, 27 and 28. The Jacobson reference, taken with Branch, raises an SNQ with respect to claims 16, 17, 19, 21-24, 26-30, 34 and 35.

Claims 1 (apparatus) and 16 (method) require, *inter alia*, a tubular distraction member, an elongated inner member having a stimulation electrode, a monitoring device and a retractor. Jacobson discloses the use of a tubular distraction member (speculum 10), an elongated inner member (anchor wires 14) having a stimulation electrode and a retractor assembly (rongeur forceps 60) for increasing the size of a working channel. Furthermore, Jacobson could be interpreted to include a tubular distraction member (cannula 10), an elongated inner member (trocar 12 and anchor wires 14) having a stimulation electrode and a retractor assembly (rongeur forceps 60 or speculum 10) for increasing the size of a working channel. Thus, there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not these claims are patentable.

Accordingly, Jacobson raises an SNQ as to claims 1, 3-6, 8-11, 16, 17, 19, 21-24, 26-30, 34 and 35 which has not been decided in a previous examination of the '949 patent.

U.S. Patent No. 6,847,849 to Mamo

The Mamo reference is a new teaching, not previously considered nor addressed in the prior examination of the patent or a final holding of invalidity by the Federal Courts. Mamo qualifies as prior art under 35 USC 102(e) based on its effective filing date of April 7, 2001.

The Mamo reference, taken with Branch raises an SNQ with respect to claims 1, 6, 8, 9, 11, 14-24, 26, 27, 29, 30, 34, 35 and 38. The Mamo reference, taken with Branch and Marino '129, raises an SNQ with respect to claims 7, 12, 25, 31 and 32. The Mamo reference, taken with Branch and Michelson, raises an SNQ with respect to claims 10 and 28. The Mamo reference, taken with Branch and Koros, raises an SNQ with respect to claim 36.

Claims 1 (apparatus) and 16 (method) require, *inter alia*, a tubular distraction member, an elongated inner member having a stimulation electrode, a monitoring device and a retractor. Mamo discloses the use of a tubular distraction member (needle 36), an elongated inner member 44 having a stimulation electrode thereon and a monitoring system. Branch discloses the use of a retractor 20 for increasing the size of a working channel. Thus, there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not these claims are patentable.

Accordingly, Mamo, taken with Branch raises an SNQ as to claims 1-36 and 38, which has not been decided in a previous examination of the '949 patent.

Conclusion

For the reasons given above, each of the references cited by the requester raises a substantial new question of patentability with respect to the subject patent. Accordingly, claims 1-38 of the subject patent will be reexamined.

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All correspondence relating to this *inters partes* reexamination proceeding should be directed as follows:

By EFS: Registered users may submit via the electronic filing system, EFS-Web, at:
<https://sportal.uspto.gov/authenticate/authenticateuserlocalepf.html>.

By Mail: Mail Stop *Inter Partes* Reexamine
ATTN: Central Reexamination Unit
Commissioner for Patents
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-9900 (for Central Reexamination Unit)

By hand: Customer Service Window
Randolph Building
401 Dulany St.
Alexandria, VA 22314

For EFS-Web transmissions, 37 CFR 1.8(a)(1) (i)(C) and (ii) states that correspondence (except for a request for reexamination and a corrected or replacement request for reexamination) will be considered timely filed if: (a) it is transmitted via the Office's electronic filing system in accordance with 37 CFR 1.6(a)(4); and, (b) includes a certificate of transmission for each piece of correspondence stating the date of transmission, which is prior to the expiration of the set period of time in the Office action.

Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number: (571) 272-7705. The examiner's supervisor is Andres Kashnikow whose phone number is: (571) 272-

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4361. Both the Patent Owner and the Third Party Requester are reminded that interviews that discuss the merits are prohibited in *inter partes* reexamination proceedings. Questions on strictly procedural matters may be discussed (see MPEP § 2685; 37 CFR § 1.955).

/Cary E. O'Connor/
Primary Examiner
Central Reexamination Unit
(571) 272-4715

Conferee

AK

Conferee

DT



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,202	06/23/2009	7,207,949	03190.005200	2860
30328	7590	08/14/2009	EXAMINER O'CONNOR, CARY E	
NuVasive c/o CPA Global P.O. Box 52050 Minneapolis, MN 55402			ART UNIT	PAPER NUMBER
			3993	
			MAIL DATE	DELIVERY MODE
			08/14/2009	PAPER

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

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

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30 ROCKEFELLER PLAZA
NEW YORK, NY 10112-3800

Date:

MAILED

AUG 14 2009

Transmittal of Communication to Third Party Requester
Inter Partes Reexamination

CENTRAL REEXAMINATION UNIT

REEXAMINATION CONTROL NO. : 95001202
PATENT NO. : 7207949
TECHNOLOGY CENTER : 3999
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified Reexamination proceeding. 37 CFR 1.903.

Prior to the filing of a Notice of Appeal, each time the patent owner responds to this communication, the third party requester of the inter partes reexamination may once file written comments within a period of 30 days from the date of service of the patent owner's response. This 30-day time period is statutory (35 U.S.C. 314(b)(2)), and, as such, it cannot be extended. See also 37 CFR 1.947.

If an ex parte reexamination has been merged with the inter partes reexamination, no responsive submission by any ex parte third party requester is permitted.

All correspondence relating to this inter partes reexamination proceeding should be directed to the Central Reexamination Unit at the mail, FAX, or hand-carry addresses given at the end of the communication enclosed with this transmittal.

OFFICE ACTION IN INTER PARTES REEXAMINATION	Control No.	Patent Under Reexamination	
	95/001,202	7,207,949	
	Examiner	Art Unit	
	Cary E. O'Connor	3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

Responsive to the communication(s) filed by:

Patent Owner on _____

Third Party(ies) on 23 June 2009

RESPONSE TIMES ARE SET TO EXPIRE AS FOLLOWS:

For Patent Owner's Response:

2 MONTH(S) from the mailing date of this action. 37 CFR 1.945. EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.956.

For Third Party Requester's Comments on the Patent Owner Response:

30 DAYS from the date of service of any patent owner's response. 37 CFR 1.947. NO EXTENSIONS OF TIME ARE PERMITTED. 35 U.S.C. 314(b)(2).

All correspondence relating to this inter partes reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of this Office action.

This action is not an Action Closing Prosecution under 37 CFR 1.949, nor is it a Right of Appeal Notice under 37 CFR 1.953.

PART I. THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892
2. Information Disclosure Citation, PTO/SB/08
3. _____

PART II. SUMMARY OF ACTION:

- 1a. Claims 1-38 are subject to reexamination.
- 1b. Claims _____ are not subject to reexamination.
2. Claims _____ have been canceled.
3. Claims _____ are confirmed. [Unamended patent claims]
4. Claims _____ are patentable. [Amended or new claims]
5. Claims 1-38 are rejected.
6. Claims _____ are objected to.
7. The drawings filed on _____ are acceptable are not acceptable.
8. The drawing correction request filed on _____ is: approved. disapproved.
9. Acknowledgment is made of the claim for priority under 35 U.S.C. 119 (a)-(d). The certified copy has:
 - been received. not been received. been filed in Application/Control No 95001202.
10. Other _____

INTER PARTES REEXAMINATION

This first Office action on the merits is being mailed together with the order granting reexamination. 37 CFR 1.935.

Submissions

In order to ensure full consideration of any amendments, affidavits or declarations, or other documents as evidence of patentability, such documents must be submitted in response to this Office action. Submissions after the next Office action, which is intended to be a final action, will be governed by the requirements of 37 CFR 1.116, after final rejection and 37 CFR 41.33 after appeal, which will be strictly enforced.

Notification of Concurrent Proceedings

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 7,207,949 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Extensions of Time

Extensions of time under 37 CFR 1.136(a) will **not** be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 314(c) requires that *inter partes* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.937). Patent owner extensions of time in *inter partes* reexamination proceedings are provided for in 37 CFR 1.956. Extensions of time are not available for third party requester comments, because a comment period of 30 days from service of patent owner's response is set by statute. 35 USC 314(b)(3).

Amendments in Reexamination Procedures

Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 CFR 1.530(d)-(j), must be formally presented pursuant to 37 CFR 1.52(a) and (b), and must contain any fees required by 37 CFR 1.20(c). Amendments in an *inter partes* reexamination proceeding are made in the same manner that amendments in an *ex parte* reexamination are made. MPEP 2666.01. See MPEP 2250 for guidance as to the manner of making amendments in a reexamination proceeding.

Service of Papers

Any paper filed by either the patent owner or the third party requester ***must be served*** on the other party in the reexamination proceeding in the manner provided by 37 CFR 1.248. See 37 CFR 1.903 and MPEP 2666.06.

Prior art considered

The prior art documents listed below are relied upon by requester in support of the request for inter partes in support of the request for inter partes reexamination.

- (1) WO 03/005887 to Blewett et al (hereinafter "Blewett"),
- (2) U.S. Patent No. 6,945,933 to Branch et al (hereinafter "Branch"),
- (3) U.S. Patent No. 5,772,661 to Michelson (hereinafter "Michelson"),
- (4) U.S. Patent Application Publication No. 2002/0072686 to Hoey et al (hereinafter "Hoey"),
- (5) WO 01/37728 to Kelleher et al (hereinafter "Kelleher"),
- (6) WO 00/38574 to Marino et al (hereinafter "Marino '574"),
- (7) U.S. Provisional Patent Application No. 60/325,424 to Gharib (hereinafter "Gharib"),
- (8) U.S. Patent No. 4,545,374 to Jacobson (hereinafter "Jacobson"),
- (9) U.S. Patent No. 6,847,849 to Mamo et al (hereinafter "Mamo"),
- (10) U.S. Patent Application Publication No. 2002/0007129 to Marino (hereinafter "Marino '129"), and
- (11) U.S. Patent No. 5,928,139 to Koros et al (hereinafter "Koros").

Art Unit: 3993

Grounds of Rejections proposed by the third party requester

Blewett obviousness combinations:

Ground #1. Claims 1-9, 11-27, 29-35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blewett in view of Branch.

Ground #2. Claims 10, 28, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blewett in view of Branch as applied to claims 9 and 16 above, and further in view of Michelson.

Branch obviousness combinations:

Ground #3. Claims 1-9, 11, 12, 14-27, 29-32, 34, 35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Branch in view of Kelleher.

Ground #4. Claims 13 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Branch in view of Kelleher as applied to claims 12 and 32 above, and further in view of Hoey.

Ground #5. Claims 10, 28, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Branch in view of Kelleher as applied to claims 9 and 16 above, and further in view of Michelson.

Marino '574 anticipation and obviousness combinations:

Ground #6. Claims 1-4, 7, 9, 11, 15-17, 20-22, 25, 27, 29, 30 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Marino '574.

Ground #7. Claims 10 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marino '574 in view of Michelson.

Gharib obviousness combinations:

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Ground #8. Claims 1-4, 7, 9, 11-22, 25, 27, 29-33 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gharib in view of Marino '574.

Ground #9. Claims 10, 28, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gharib in combination with Marino '574, as applied to claim 1 and 16 above, and further in view of Michelson.

Jacobson anticipation and obviousness combinations:

Ground # 10 . Claims 1, 3-6, 8-11, 16, 21-24, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobson.

Ground # 11. Claims 16, 17, 19, 21-24, 26-30, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobson in view of Branch.

Mamo obviousness combinations:

Ground # 12. Claims 1-6, 8, 9, 11, 14-24, 26, 27, 29, 30, 34, 35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mamo in view of Branch.

Ground # 13. Claims 7, 12, 25, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mamo in view of Branch as applied to claims 1 and 16 above, and further in view of Marino '129.

Ground # 14. Claims 10 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mamo in view of Branch as applied to claims 9 and 16 above, and further in view of Michelson.

Ground # 15. Claims 13 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mamo in view of Branch and Marino '129 as applied to claims 12 and 32 above, and further in view of Hoey.

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Ground # 16. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mamo in view of Branch as applied to claim 16 above, and further in view of Koros.

DETAILED ACTION

Statutory Basis for Claim Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Proposed Claim Rejections

Ground #1

The request submits that claims 1-9, 11-27, 29-35 and 38 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Blewett in view of Branch.

Claims 1-5, 7-9, 11-23, 25-27, 29-35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blewett in view of Branch. Regarding claims 1 and 16, Blewett teaches a system 10 for accessing a surgical target site comprising a tubular distraction member (dilating catheter 26) for creating an initial distraction corridor to a spinal target site, an elongated inner member (K-wire 24) having a stimulating electrode on the distal end (page 8, last line to page 9, first line) disposed within the distraction member after the creation of the corridor and a monitoring system capable of stimulating the stimulation electrode, monitoring EMG activity in a muscle myotome associated with a nerve, and alerting a user of the presence of a nerve near the elongated inner element. The stimulation electrode is stimulated after creation of the corridor. The system includes a working cannula 28, rather than a retractor assembly, to establish an operative corridor. Branch teaches a surgical access system comprising a retractor assembly 20 having a plurality of blades 22, 42 capable of being advanced to a surgical target site in a closed position and opened to create an operative corridor to the site. The retractor assembly is advanced to the site after skin and tissue are dilated by a dilation (distraction) instrument set 66 and guidewires (column 6, lines 40-58). This allows the surgeon to provide greater access to the location beyond the locations provided through the working channel created by the blades in the closed position. It would have been obvious to one of ordinary skill in the art at the time the invention was

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made to replace the working cannula of Blewett with the retractor system of Branch because the retractor system would allow for adjustability of the size of the working channel during surgery without having to remove the retractor system from the site as would be required when using the working cannula of Blewett which could cause trauma to the tissue. Furthermore, the method of accessing a spinal target site is inherently carried out with the use of the system of Blewett as modified by Branch. Regarding claims 2, 17 and 19, both Blewett and Branch teaches using a plurality of distraction members having increasing diameters (Blewett, page 10, lines 1-8; Branch, column 6, lines 47-53). Regarding claims 3-5 and 21-23, the inner element of Blewett is a K-wire having the stimulation electrode on the distal end (page 8, last line to page 9, first line) and has a substantially smaller diameter than a diameter of the distraction member (Fig. 1). Regarding claim 8, the retractor assembly of Branch is dimensioned to be advanced over a tubular distraction member after the distraction member has been advanced to the site (column 6, lines 53-55). Regarding claim 9, both Blewett and Branch disclose that the systems may be used to access a spinal target site. Regarding claims 11, 29 and 30, the monitoring system includes an electrical connection 22 to the inner member. Regarding claims 12 and 31, the monitoring system includes a display 36 operable to display an EMG response of the muscle myotome associated with the nerve. Regarding claims 13 and 33, the display is a touch-screen display (page 7, lines 7-12). Regarding claims 14, 34 and 35, the retractor assembly of Branch may include an illumination means (column 7, lines 38-47). As to claims 15 and 38, Blewett discloses that stimulation electrodes may be located at the distal end of the surgical access

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components 24-28, which includes the working cannula 28. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the blades of the retractor assembly of Branch with stimulation electrodes to prevent nerve damage during use of the retractor assembly. Regarding claim 20, the method includes the step of determining direction and approximate distance from the inner element to the nerve (Blewett, page 3, lines 4-8). As to claim 26, the retractor blades of Branch are advanced simultaneously. Regarding claim 27, Blewett discloses that the method may be used in lumbar levels L2-L5 in Table 2. Regarding claim 32, Figure 7 of Blewett shows that the display is capable of communicating alpha-numeric and graphical information.

Accordingly, this rejection of claims 1-5, 7-9, 11-23, 25-27, 29-35 and 38, based on Blewett in view of Branch, was proposed by the third party requester in the request for reexamination and is being adopted essentially as proposed in the request.

Regarding the proposed rejection of claims 6 and 24 based on the combination of Blewett and Branch, the third party requester states that "[t]he stimulation electrode at the distal end of the K-wire 24 must be un-insulated in order to act as an electrode." While this is true, Blewett does not disclose that the distal end of the K-wire acts as the electrode as required by the claims, "said stimulation electrode is an un-insulated region at said distal end of said K-wire." Accordingly, the rejection of these claims based on Blewett and Branch is not adopted as proposed in the request.

Ground #2

The request submits that claims 10, 28, 36 and 37 are unpatentable under 35 U.S.C. 103(a) as being obvious over Blewett in view of Branch, as applied to claims 9 and 16 above, and further in view of Michelson.

Claims 10, 28, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blewett in view of Branch as applied to claims 9 and 16 above, and further in view of Michelson. Regarding claims 10 and 28, neither Blewett nor Branch teach establishing the operative corridor to the spinal target site via a lateral, trans-psoas approach. Michelson teaches a system and method for accessing a spinal target site via a true lateral (trans-psoas) approach (column 1, lines 21-27). A guide pin 30, tubular distractor 100 and outer sleeve 140 are utilized to form a working corridor. Given the similarities of the systems taught by Blewett, Branch and Michelson, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform spinal surgery with a trans-psoas approach with the system of Blewett and Branch, in view of the teachings of Michelson. Regarding claims 36 and 37, the blades of Branch do not include a fixation element in the form of a shim having a pointed end. Michelson shows an outer tubular sleeve 140 which has the same function as the working cannula of Blewett and the retractor assembly of Branch. The tubular sleeve has pointed shims 149, 150 to maintain the distraction and alignment of the vertebrae. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the blades of Branch in the system of Blewett with pointed shims, as taught by Michelson, in order to maintain distraction and alignment of the vertebrae.

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Ground #3

The request submits that claims 1-9, 11, 12, 14-27, 29-32, 34, 35 and 38 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Branch in view of Kelleher.

Claims 1-9, 11, 12, 14-27, 29-32, 34, 35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Branch in view of Kelleher. Regarding claims 1 and 16, Branch teaches a surgical access system comprising a tubular distraction member (in set 66), an elongated inner member (column 6, lines 49-50) and a retractor assembly 20 having a plurality of blades 22, 42 capable of being advanced to a surgical target site in a closed position and opened to create an operative corridor to the site. The retractor assembly is advanced to the site after skin and tissue are dilated by a dilation (distraction) instrument set 66 and guidewires (column 6, lines 40-58). This allows the surgeon to provide greater access to the location beyond the locations provided through the working channel created by the blades in the closed position. Branch does not teach a stimulation electrode on the distal end of the inner member and a monitoring system capable of stimulating the stimulation electrode, monitoring EMG activity in a muscle myotome associated with a nerve, and alerting a user of the presence of a nerve near the elongated inner element. Kelleher teaches a system for detecting the presence of a nerve near a surgical tool during spinal surgery. The system comprises an electrode positioned on the distal end of a surgical tool (column 4, lines 1-3) and a capable of stimulating the stimulation electrode, monitoring EMG activity in a muscle myotome associated with a nerve, and alerting a user of the presence of a nerve near the elongated inner element. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system of Branch with a

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stimulation electrode on the distal end of any of the tools, including the inner member (guidewire) or retractor blades, and a monitoring system, as taught by Kelleher, in order to prevent damages to nerves during the procedure. Regarding claims 2, 17 and 19, Branch teaches using a plurality of distraction members having increasing diameters (Branch, column 6, lines 47-53). Regarding claims 3-5 and 21-23, the inner element of Branch, as modified by Kelleher, is a K-wire having the stimulation electrode on the distal end and inherently has a substantially smaller diameter than a diameter of the distraction member. Regarding claim 8, the retractor assembly of Branch is dimensioned to be advanced over a tubular distraction member after the distraction member has been advanced to the site (column 6, lines 53-55). Regarding claim 9, Branch discloses that the systems may be used to access a spinal target site. Regarding claims 11, 29 and 30, the monitoring system includes a controller 118 providing an electrical connection to the inner member. Regarding claims 12 and 31, the monitoring system includes displays 120-127 operable to display an EMG response of the muscle myotome associated with the nerve. Regarding claims 14, 34 and 35, the retractor assembly of Branch may include an illumination means (column 7, lines 38-47). As to claims 15 and 38, Kelleher discloses that stimulation electrodes may be located at the distal end of the surgical tools. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the blades of the retractor assembly of Branch with stimulation electrodes to prevent nerve damage during use of the retractor assembly. Regarding claim 20, the method includes the step of determining direction and approximate distance from the inner

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element to the nerve (Kelleher, page 17, lines 23-24). As to claim 26, the retractor blades of Branch are advanced simultaneously. Regarding claim 27, Kelleher shows that the method may be used in lumbar levels L1-L5 in Fig. 1. Regarding claim 32, Figure 8B of Kelleher shows that the display is capable of communicating graphical information.

Accordingly, this rejection of claims 1-5, 7-9, 11, 12, 14-23, 25-27, 29-32, 34, 35 and 38, based on Branch in view of Kelleher, was proposed by the third party requester in the request for reexamination and is being adopted essentially as proposed in the request.

Regarding the proposed rejection of claims 6 and 24 based on the combination of Branch and Kelleher, the third party requester states that "[t]he stimulation electrode at the distal end of the K-wire 24 must be un-insulated in order to act as an electrode." While this is true, Kelleher does not disclose that the distal end of the tool acts as the electrode as required by the claims, "said stimulation electrode is an un-insulated region at said distal end of said K-wire." Accordingly, the rejection of these claims based on Branch and Kelleher is not adopted as proposed in the request.

Ground #4.

The request submits that claims 13 and 33 are unpatentable under 35 U.S.C. 103(a) as being obvious over Branch in view of Kelleher, as applied to claims 12 and 32 above, and further in view of Hoey.

Claims 13 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Branch in view of Kelleher as applied to claims 12 and 32 above, and further in

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view of Hoey. The display of Kelleher is not a touch screen display. Hoey teaches a tissue discriminating system including a touch screen display for receiving commands from a user to control an electrical probe. It would have been obvious to one of ordinary skill in the art to use a touch screen display in the system of Branch and Kelleher, as taught by Hoey, in order to aid the user in controlling the system.

Accordingly, this rejection of claims 13 and 33, based on Branch in view of Kelleher and Hoey, was proposed by the third party requester in the request for reexamination and is being adopted essentially as proposed in the request.

Ground #5.

The request submits that claims 10, 28, 36 and 37 are unpatentable under 35 U.S.C. 103(a) as being obvious over Branch in view of Kelleher, as applied to claims 9 and 16 above, and further in view of Michelson.

Claims 10, 28, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Branch in view of Kelleher as applied to claims 9 and 16 above, and further in view of Michelson. Regarding claims 10 and 28, Branch does not teach establishing the operative corridor to the spinal target site via a lateral, trans-psoas approach. Michelson teaches a system and method for accessing a spinal target site via a true lateral (trans-psoas) approach (column 1, lines 21-27). A guide pin 30, tubular distractor 100 and outer sleeve 140 are utilized to form a working corridor. Given the similarities of the systems taught by Branch and Michelson, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform spinal surgery with a trans-psoas approach with the system of Branch and

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Kelleher, in view of the teachings of Michelson. Regarding claims 36 and 37, the blades of Branch do not include a fixation element in the form of a shim having a pointed end. Michelson shows an outer tubular sleeve 140 which has the same function as the retractor assembly of Branch. The tubular sleeve has pointed shims 149, 150 to maintain the distraction and alignment of the vertebrae. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the blades of Branch with pointed shims, as taught by Michelson, in order to maintain distraction and alignment of the vertebrae.

Accordingly, this rejection of claims 10, 28, 36 and 37, based on Branch in view of Kelleher and Michelson, was proposed by the third party requester in the request for reexamination and is being adopted essentially as proposed in the request.

Ground #6.

The request submits that claims 1-4, 7, 9, 11, 15-17, 20-22, 25, 27, 29, 30 and 38 are unpatentable under 35 U.S.C. §102 as being anticipated by Marino '574.

Claims 1, 3, 4, 7, 9, 11, 15-17, 20-22, 25, 27, 29, 30 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Marino '574. Marino '574 teaches a method and system for accessing a surgical target site comprising a tubular distraction member 315, an elongated inner member 310 to be received within the distraction member, a stimulation electrode 320 on the distal end 302 of the inner member, and a retractor assembly comprising a plurality of blades 314 capable of being advanced to the target site in a closed position and opened to create an operative corridor. The system inherently includes a monitoring system because the electrodes are electrically

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stimulated to sense the position of a nerve through EMG monitoring and the user is alerted if the inner member 310 approaches a nerve. Regarding claims 3, 4, 21 and 22, the inner element of Marino '574 has the stimulation electrode on the distal end and has a substantially smaller diameter than a diameter of the distraction member (Fig. 28). Regarding claim 9, Marino '574 discloses that the systems may be used to access a spinal target site (page 2, lines 5-11). Regarding claims 11, 29 and 30, the monitoring system inherently includes an electrical connection to the inner member. As to claims 15 and 38, the blades (petals 314) include electrodes 316. Regarding claim 20, the method includes the step of determining the position of a nerve from the inner element. Regarding claim 27, Marino '574 discloses that the system may be used in spinal surgery.

Accordingly, this rejection of claims 1, 3, 4, 7, 9, 11, 15-17, 20-22, 25, 27, 29, 30 and 38, based on Marino '574, was proposed by the third party requester in the request for reexamination and is being adopted essentially as proposed in the request.

Regarding the proposed rejection of claim 2 based on Marino '574, third party requester asserts that if the inner cannula 315 was considered the initial tubular distractor the cannula 300 would be a secondary tubular distraction member and because the cannulae are put together prior to insertion, their advancement occurs prior to the advancement of the blades to the surgical target site. However, the claim states "dimensioned to be advanced over said tubular distraction member to create a distraction corridor prior to advancing said retractor blades". This requires their relative advancement take place during the formation of the distraction corridor. In Marino '574,

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because the blades are part of the cannula 300, any advancement of the cannula 300 to create a distraction corridor would result in simultaneous advancement of the blades. Accordingly, the secondary cannula 300 cannot be advanced over cannula 315 during creation of the distraction corridor prior to advancement of the blades. Accordingly, the rejection of these claims based on Marino '574 is not adopted as proposed in the request.

Ground #7.

The request submits that claims 10 and 28 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Marino '574 in view of Michelson.

Claims 10 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marino '574 in view of Michelson. Regarding claims 10 and 28, Marino '579 does not teach establishing the operative corridor to the spinal target site via a lateral, trans-psoas approach. Michelson teaches a system and method for accessing a spinal target site via a true lateral (trans-psoas) approach (column 1, lines 21-27). A guide pin 30, tubular distractor 100 and outer sleeve 140 are utilized to form a working corridor. It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform spinal surgery with a trans-psoas approach with the system of Marino '574, in view of the teachings of Michelson, in order to avoid bony elements of the spinal column.

Accordingly, this rejection of claims 10 and 28, based on Marino '574 and Michelson, was proposed by the third party requester in the request for reexamination and is being adopted essentially as proposed in the request.

Ground #8.

The request submits that claims 1-4, 7, 9, 11-22, 25, 27, 29-33 and 38 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Gharib in view of Marino '574.

It was established that Gharib in combination with Marino '574 did not present an SNQ as to claims 1-4, 7, 9, 11-22, 25, 27, 29-33 and 38. (Order, pg. 9). As a result, the Examiner will not address the above proposed rejection.

Ground #9.

The request submits that claims 10, 28, 36 and 37 are unpatentable under 35 U.S.C. 103(a) as being obvious over Gharib in view of Marino '574, as applied to claims 9 and 16 above, and further in view of Michelson.

It was established that Gharib in combination with Marino '574 did not present an SNQ as to claims 10, 28, 36 and 37. (Order, pg. 9). As a result, the Examiner will not address the above proposed rejection.

Ground # 10.

The request submits that claims 1, 3-6, 8-11, 16, 21-24, 27 and 28 are unpatentable under 35 U.S.C. §102 as being anticipated by Jacobson.

Claims 1, 3-6, 8-11, 16, 21-24, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobson. Regarding claim 1, Jacobson teaches a method and system for accessing a surgical target site comprising a tubular distraction member (cannula 11), an elongated inner member (anchor wires 14) to be received within the distraction member, a stimulation electrode (anchor wires act as electrodes (column 49-52)) on the distal end of the inner member, and a retractor assembly 10 comprising a

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plurality of blades capable of being advanced to the target site in a closed position and opened to create an operative corridor (column 5, lines 45-53). The system inherently includes a monitoring system because the electrodes are electrically stimulated to sense the position of a nerve through EMG monitoring and the user is alerted if the inner member approaches a nerve through movement in one of the patient's legs.

Regarding claims 8 and 16, alternatively, the system may be interpreted as comprising a tubular distraction member (speculum) which is used to create an initial distraction corridor (column 5, lines 45-53), an elongated inner member (anchor wires 14) to be received within the distraction member, a stimulation electrode (anchor wires act as electrodes (column 49-52)) on the distal end of the inner member, and a retractor assembly (ranger forceps 18) comprising a plurality of blades capable of being advanced to the target site in a closed position and opened to create an operative corridor after the creation of the initial dissection corridor by removing tissue (column 7, lines 40-43). Regarding claims 3-6, 21-24, the inner element is considered a K-wire which may have the electrode on the distal end or may be a non-insulated portion of the wire. of has the stimulation electrode on the distal end and has a substantially smaller diameter than a diameter of the distraction member (Fig. 28). Regarding claim 9, Jacobson discloses that the systems may be used to access a spinal target site. Regarding claims 10 and 28, Jacobson discloses that a lateral approach is used to establish the operative corridor. Regarding claim 11, the monitoring system includes an electrical connection 86 to the inner member. Regarding claim 27, Jacobson discloses that the system may be used for surgery in the lumbar region of the spine.

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Accordingly, this rejection of claims 1, 3-6, 8-11, 16, 21-24, 27 and 28, based on Jacobson, was proposed by the third party requester in the request for reexamination and is being adopted essentially as proposed in the request.

Ground # 11.

The request submits that claims 16, 17, 19, 21-24, 26-30, 34 and 35 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Jacobson in view of Branch.

Claims 16, 17, 19, 21-24, 26-30, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobson in view of Branch. In the scenario where the speculum 10 is considered to be the retractor assembly, the speculum is removed after the cannula is inserted. Branch teaches a surgical access system comprising a retractor assembly 20 having a plurality of blades 22, 42 capable of being advanced to a surgical target site in a closed position and opened to create an operative corridor to the site. The retractor assembly is advanced to the site after skin and tissue are dilated by a dilation (distractor) instrument set 66 and guidewires (column 6, lines 40-58). This allows the surgeon to provide greater access to the location beyond the locations provided through the working channel created by the blades in the closed position. It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the speculum of Jacobsen with the retractor system of Branch because the retractor system would allow for adjustability of the size of the working channel during surgery without having to remove the retractor system from the site. As to claim 26, the retractor blades of Branch are advanced simultaneously. Regarding claims 17

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and 19, Branch teaches using tissue dilators of increasing size (column 5, lines 47-53). Regarding claims 21-24, the inner element is considered a K-wire which may have the electrode on the distal end or may be a non-insulated portion of the wire. of has the stimulation electrode on the distal end and has a substantially smaller diameter than a diameter of the distraction member (Fig. 28). Regarding claim 9, Jacobson discloses that the systems may be used to access a spinal target site. As to claim 26, the retractor blades of Branch are advanced simultaneously. Regarding claim 27, Jacobson discloses that the system may be used for surgery in the lumbar region of the spine. Regarding claim 28, Jacobson discloses that a lateral approach is used to establish the operative corridor. Regarding claims 29 and 30, the monitoring system includes an electrical connection 86 to the inner member. Regarding claims 34 and 35, the retractor assembly of Branch may include an illumination means (column 7, lines 38-47).

Accordingly, this rejection of claims 16, 17, 19, 21-24, 26-30, 34 and 35 based on Jacobson and Branch, was proposed by the third party requester in the request for reexamination and is being adopted essentially as proposed in the request.

Ground # 12.

The request submits that claims 1-6, 8, 9, 11, 14-24, 26, 27, 29, 30, 34, 35 and 38 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Mamo in view of Branch.

Claims 1-6, 8, 9, 11, 14-24, 26, 27, 29, 30, 34, 35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mamo in view of Branch. Regarding claim 1,

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Mamo teaches a method and system for accessing a surgical target site comprising a tubular distraction member (needle 36), an elongated inner member (guidewire 44) to be received within the distraction member, a stimulation electrode 61 on the distal end of the inner member. The position of the inner member can be sensed by applying an electrical signal to the inner member to evoke a patient response. The system inherently includes a monitoring system because the electrodes are electrically stimulated to sense the position of a nerve through EMG monitoring and the user is alerted if the inner member approaches a nerve through patient response such as a motor or sensory response. Branch teaches a surgical access system comprising a retractor assembly 20 having a plurality of blades 22, 42 capable of being advanced to a surgical target site in a closed position and opened to create an operative corridor to the site. The retractor assembly is advanced to the site after skin and tissue are dilated by a dilation (distraction) instrument set 66 and guidewires (column 6, lines 40-58). This allows the surgeon to provide greater access to the location beyond the locations provided through the working channel created by the blades in the closed position. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system of Mamo with the retractor system of Branch because the retractor system would allow for adjustability of the size of the working channel during surgery without having to remove the retractor system from the site. Furthermore, the method of accessing a spinal target site is inherently carried out with the use of the system of Mamo as modified by Branch. Regarding claims 2, 17 and 19, Branch teaches using a plurality of distraction members having increasing diameters (Branch,

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column 6, lines 47-53). Regarding claims 3-6 and 21-24, the inner element of Mamo is a K-wire having the stimulation electrode formed by an exposed portion of the wire on the distal end and has a substantially smaller diameter than a diameter of the distraction member. Regarding claim 8, the retractor assembly of Branch is dimensioned to be advanced over a tubular distraction member and guide wire after the distraction member has been advanced to the site (column 6, lines 53-55). Regarding claim 9, both Mamo and Branch disclose that the systems may be used to access a spinal target site. Regarding claims 11, 29 and 30, the monitoring system inherently includes an electrical connection to the inner member. Regarding claims 14, 34 and 35, the retractor assembly of Branch may include an illumination means (column 7, lines 38-47). As to claims 15 and 38, Mamo discloses that stimulation electrodes may be located at the distal end of all of the instruments in the system. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the blades of the retractor assembly of Branch with stimulation electrodes to prevent nerve damage during use of the retractor assembly. Regarding claim 20, Mamo uses electrical stimulation and depth markers on the needle to determine distances to target nerves. As to claim 26, the retractor blades of Branch are advanced simultaneously. Regarding claim 27, Branch discloses that the retractor can be used in any surgical approach to the spine.

Accordingly, this rejection of claims 1-6, 8, 9, 11, 14-24, 26, 27, 29, 30, 34, 35 and 38, based on Mamo and Branch, was proposed by the third party requester in the request for reexamination and is being adopted essentially as proposed in the request.

Ground # 13.

The request submits that claims 7, 12, 25, 31 and 32 are unpatentable under 35 U.S.C. 103(a) as being obvious over Mamo in view of Branch, as applied to claims 9 and 16 above, and further in view of Marino '129.

Claims 7, 12, 25, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mamo in view of Branch as applied to claims 1 and 16 above, and further in view of Marino '129. Marino '129 teaches a detection system that includes an EMG electrode 24 that detects an EMG response of a muscle associated with a nerve that receives an electrical stimulation from a proximity electrode. The system includes a display to view the EMG responses and includes a plot of the EMG signal. It would have been obvious to one of ordinary skill in the art to provide the system of Mamo with the monitoring system of Marino '129 because Marino '129 discloses that the monitoring system is an improvement over visual monitoring (used in Mamo).

Accordingly, this rejection of claims 7, 12, 25, 31 and 32, based on Mamo, Branch and Marino '129, was proposed by the third party requester in the request for reexamination and is being adopted essentially as proposed in the request.

Ground # 14.

The request submits that claims 10 and 28 are unpatentable under 35 U.S.C. 103(a) as being obvious over Mamo in view of Branch, as applied to claims 9 and 16 above, and further in view of Michelson.

Claims 10 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mamo in view of Branch as applied to claims 9 and 16 above, and further in view of

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Michelson. Neither Mamo nor Branch teaches establishing the operative corridor to the spinal target site via a lateral, trans-psoas approach. Michelson teaches a system and method for accessing a spinal target site via a true lateral (trans-psoas) approach (column 1, lines 21-27). A guide pin 30, tubular distractor 100 and outer sleeve 140 are utilized to form a working corridor. It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform spinal surgery with a trans-psoas approach with the system of Mamo and Branch, in view of the teachings of Michelson.

Accordingly, this rejection of claims 10 and 28, based on Mamo, Branch and Michelson, was proposed by the third party requester in the request for reexamination and is being adopted essentially as proposed in the request.

Ground # 15.

The request submits that claims 13 and 33 are unpatentable under 35 U.S.C. 103(a) as being obvious over Mamo in view of Branch, as applied to claims 12 and 32 above, and further in view of Hoey.

Claims 13 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mamo in view of Branch and Marino '129 as applied to claims 12 and 32 above, and further in view of Hoey. The display of Marino '129 is not a touch screen display. Hoey teaches a tissue discriminating system including a touch screen display for receiving commands from a user to control an electrical probe. It would have been obvious to one of ordinary skill in the art to use a touch screen display in the system of

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Mamo, Branch and Marino '129, as taught by Hoey, in order to aid the user in controlling the system.

Accordingly, this rejection of claims 13 and 33, based on Mamo, Branch and Marino '129 and Hoey, was proposed by the third party requester in the request for reexamination and is being adopted essentially as proposed in the request.

Ground # 16.

The request submits that claim 36 is unpatentable under 35 U.S.C. 103(a) as being obvious over Mamo in view of Branch, as applied to claim 16 above, and further in view of Koros.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mamo in view of Branch as applied to claim 16 above, and further in view of Koros. The blades of Branch do not include a fixation element in the form of a shim having a pointed end. Koros shows a retractor assembly including a plurality of blades 30, 32. Koros includes a fixation element (blade extension 54) to hold the blades to the operating site. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the blades of Branch with a fixation element, as taught by Koros, in order to hold the blades relative to the surgical site.

Accordingly, this rejection of claim 36, based on Mamo, Branch and Koros, was proposed by the third party requester in the request for reexamination and is being adopted essentially as proposed in the request.

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All correspondence relating to this *inters partes* reexamination proceeding should be directed as follows:

By EFS: Registered users may submit via the electronic filing system, EFS-Web, at:
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ATTN: Central Reexamination Unit
Commissioner for Patents
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-9900 (for Central Reexamination Unit)

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401 Dulany St.
Alexandria, VA 22314

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Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number: (571) 272-7705.

The examiner's supervisor is Andres Kashnikov whose phone number is: (571) 272-

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4361. Both the Patent Owner and the Third Party Requester are reminded that interviews that discuss the merits are prohibited in *inter partes* reexamination proceedings. Questions on strictly procedural matters may be discussed (see MPEP § 2685; 37 CFR § 1.955).

/Cary E. O'Connor/
Primary Examiner
Central Reexamination Unit
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Conferee AK

Conferee J7