UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/813,565	01/13/2015	8932055	7678.1035.1.1	7247

22913 7590 12/23/2014

Workman Nydegger
60 East South Temple
Suite 1000
Salt Lake City, UT 84111

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 48 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Roberto Armanino, Genova, ITALY;

Office of Petitions: Routing Sheet

Application No. 12/813,565

This application is being forwarded to your office for further processing. A decision has been rendered on a petition filed in this application.

- [X] **GRANTED**
- [ ] **DISMISSED**
- [ ] **DENIED**

Office of Petitions: Decision Count Sheet

Mailing Month 12

Application No. 12813565

For US serial numbers: enter number only, no slashes or commas. Ex: 10123456
For PCT: enter "51+single digit of year of filing+last 5 numbers", Ex. for PCT/US05/12345, enter 51512345

Deciding Official: WALSH, LIANA

Count (1) - Palm Credit 12/813,565

Decision: GRANT

FINANCE WORK NEEDED
☐ Select Check Box for YES

Decision Type: 510 - 37 CFR 1.137(b) FOR REVIVAL TO ACCEPT LATE

Notes:

Count (2)

Decision: n/a

FINANCE WORK NEEDED
☐ Select Check Box for YES

Decision Type: NONE

Notes:

Count (3)

Decision: n/a

FINANCE WORK NEEDED
☐ Select Check Box for YES

Decision Type: NONE

Notes:

Initials of Approving Official (if required)

If more than 3 decisions, attach 2nd count sheet & mark this box ☐

Printed on: *12/5/2014*

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/813,565	06/11/2010	Roberto Armanino	7678.1035.1.1	7247

22913 7590 12/10/2014

Workman Nydegger
60 East South Temple
Suite 1000
Salt Lake City, UT 84111

EXAMINER
SAUNDERS, MATTHEW P

ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
12/10/2014	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docketing@wnlaw.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Application of	:	
Armanino, Roberto	:	
Application No. 12/813,565	:	ON PETITION
Filed: June 11, 2010	:	
Attorney Docket No. 7678.1035.1.1	:	

This is a decision on the petition under 37 C.F.R. § 1.137(b), filed August 15, 2014, to revive the above-identified application, which is being properly treated under 37 CFR 1.137(a).

The petition is **GRANTED**.

The petition satisfies the requirements of 37 CFR 1.137(a) in that petitioner has supplied (1) the reply in the form of the Issue Fee Transmittal with payment of the $480.00 issue fee, (2) the petition fee of $850.00, and (3) a proper statement of unintentional delay.

With regards to item (3), petitioner has submitted an unintentionally delayed statement pursuant to 37 CFR 1.137(b). As of December 2013, 37 CFR 1.137(b) has been removed and all petitions to revive an unintentionally abandoned application must be under rule 37 CFR 1.137(a). Since the statement on the instant petition cites the old rule, the statement is being construed as the statement required by 37 CFR 1.137(a). Petitioner must notify the Office if this is **not** a correct interpretation of the statement contained in the instant petition.

Telephone inquiries concerning this decision should be directed to the undersigned at (571) 272-3206.

This matter is being referred to the Office of Data Management for processing into a patent.

/Liana Walsh/
Liana Walsh
Petitions Paralegal Specialist
Office of Petitions

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

22913 7590 03/12/2014
Workman Nydegger
60 East South Temple
Suite 1000
Salt Lake City, UT 84111

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/813,565	06/11/2010	Roberto Armanino	7678.1035.1.1	7247

TITLE OF INVENTION: METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	06/12/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
SAUNDERS, MATTHEW P	3732	433-032000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 WORKMAN NYDEGGER
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Roberto Armanino

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Genova, Italy

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☒ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
- ☒ Issue Fee
- ☒ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (**Please first reapply any previously paid issue fee shown above**)
- ☐ A check is enclosed.
- ☒ Payment by credit card. Form PTO-2038 is attached.
- ☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 23-3178 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ☒ Applicant asserting small entity status. See 37 CFR 1.27
  NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ☐ Applicant changing to regular undiscounted fee status.
  NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /John M. Guynn 36153/ Date August 15, 2014

Typed or printed name John M. Guynn Registration No. 36153

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/813,565	06/11/2010	Roberto Armanino	7678.1035.1.1	7247

22913 7590 03/12/2014

Workman Nydegger
60 East South Temple
Suite 1000
Salt Lake City, UT 84111

EXAMINER	
SAUNDERS, MATTHEW P	
ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 03/12/2014

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 199 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 199 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

FILED ELECTRONICALLY

PATENT APPLICATION
Docket No. 7678.1035.1.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:		)
	Roberto Armanino	)
Serial No.:	12/813,565	) Art Unit 3732
Filed:	June 11, 2010	)
Confirmation No.:	7247	)
For:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION	)
Examiner:	Matthew Saunders	)
Customer No.:	022913	)

PETITION UNDER C.F.R. § 1.137(b) TO REVIVE AN UNINTENTIONALLY ABANDONED APPLICATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner:

Pursuant to 37 C.F.R. § 1.137(b), Applicant hereby petitions to revive United States Patent Application Serial No. 12/813,565, which became unintentionally abandoned for failure to respond to the Notice of Allowance dated March 12, 2014.

In view of the requirements of 37 C.F.R. § 1.137(b):

1. Applicant asserts that the entire delay in filing a response to the Notice of Allowance dated March 12, 2014, from the due date for filing a required reply until the filing of a grantable petition pursuant to 37 C.F.R. § 1.137(b) was unintentional;

2. Applicant submits herewith an Issue Fee Transmittal, Comments on Reasons for Allowance and $480.00 Issue Fee in response to the Notice of Allowance dated March 14, 2014; and

3. Applicant submits herewith payment in the amount of $850.00 as set forth in 37 C.F.R. § 1.17(m) for filing this Petition under 37 C.F.R. § 1.137(b) to revive an unintentionally abandoned application.

Because this Application was assigned back to the inventor, it now qualifies for small entity status, as indicated on the Issue Fee Transmittal form submitted concurrently with the issue fee payment.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to Deposit Account No. 23-3178: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefor and charge any additional fees that may be required to Deposit Account No. 23-3178.

In view of the foregoing, applicant respectfully requests that this Petition to Revive an Unintentionally Abandoned Application be granted and the Issue Fee Transmittal and Comments on Reasons for Allowance processed accordingly.

Dated this 15th day of August 2014.

Respectfully submitted,

/John M. Guynn 36153/

JOHN M. GUYNN
Registration No. 36,153
WORKMAN NYDEGGER
Attorney for Applicant(s)
Customer No. 022913

JMG:kft
4713027_1.DOC

Electronic Patent Application Fee Transmittal

Application Number:	12813565
Filing Date:	11-Jun-2010
Title of Invention:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION
First Named Inventor/Applicant Name:	Roberto Armanino
Filer:	John Michael Guynn/Kelli Tyree
Attorney Docket Number:	7678.1035.1.1

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Pet. Revive Abandon App, Delay Pymt-Resp	2453	1	850	850
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Utility Appl Issue Fee	2501	1	480	480
Publ. Fee- Early, Voluntary, or Normal	1504	1	0	0
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1330**

Electronic Acknowledgement Receipt

EFS ID:	19881513
Application Number:	12813565
International Application Number:	
Confirmation Number:	7247
Title of Invention:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION
First Named Inventor/Applicant Name:	Roberto Armanino
Customer Number:	22913
Filer:	John Michael Guynn/Kelli Tyree
Filer Authorized By:	John Michael Guynn
Attorney Docket Number:	7678.1035.1.1
Receipt Date:	15-AUG-2014
Filing Date:	11-JUN-2010
Time Stamp:	16:54:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1330
RAM confirmation Number	2949
Deposit Account	233178
Authorized User	GUYNN, JOHN M.

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Post Allowance Communication - Incoming	7678_1035_1_1_Comments.pdf	22978 e1e5729cda21b6e07d7064a1958dd565e0f28174	no	2
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	7678_1035_1_1_Fee.pdf	201189 dadb032cbba465eed9625a7eb5df2f6c04408004	no	2
Warnings:					
Information:					
3	Petition for review by the Office of Petitions.	7678_1035_1_1_Petition.pdf	20831 f3f0722c21dbb34c4c988706a874e0cfd7303d0b	no	2
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	33497 db8de7d053e478cb9d90b6c3367f1b63a92e8636	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	278495		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
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.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
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.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

FILED ELECTRONICALLY

PATENT APPLICATION
Docket No. 7678.1035.1.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:		)
	Roberto Armanino	)
Serial No.:	12/813,565	) Art Unit 3732
Filed:	June 11, 2010	)
Confirmation No.:	7247	)
For:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION	)
Examiner:	Matthew Saunders	)
Customer No.:	022913	)

COMMENTS ON REASONS FOR ALLOWANCE

Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants respectfully submit that the claimed invention as set forth in each of the independent claims and the dependent claims must be read as a whole, and not as a single feature or subcombination of features which represent less than the entirety of the claimed invention as a whole. While a particular feature or subcombination of features referred to by the Examiner in the Statement of Reasons for Allowance may represent a basis for distinguishing the claimed invention over the prior art, Applicants further submit that this may not necessarily be the *sole* ground for distinguishing the claimed invention over the prior art of record. Accordingly, the Examiner's statement should, in Applicants' view, not be read as constituting or meaning that the invention can or should be reduced to a single "feature" of the invention or to a subcombination

of features that is less than the entire invention claimed as a whole, nor that the single feature referenced by the Examiner or subcombination of features referenced by the Examiner in the Statement of Reasons for Allowance is the only or sole grounds for distinguishing the invention over the prior art of record, or that applicants necessarily agree with any characterization of the prior set forth in the Statement of Reasons for Allowance.

With respect to the Examiner's Statement of Reasons for Allowance, such statements appear to focus on certain features recited in some of the claims, which are not found in all the claims, rather than considering the claim language as a whole as individually recited in each of the allowed claims. Nevertheless, the claims are believed to recite combinations of elements not disclosed or suggested by the prior art of record.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Dated this 15th day of August 2014.

Respectfully submitted,

/John M. Guynn 36153/

JOHN M. GUYNN
Registration No. 36,153
WORKMAN NYDEGGER
Attorney for Applicant(s)
Customer No. 022913

JMG:kft
4713046_1.DOC

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/813,565	06/11/2010	Roberto Armanino	7678.1035.1.1	7247

7590 06/30/2014

Workman Nydegger
60 East South Temple
Suite 1000
Salt Lake City, UT 84111

EXAMINER	
SAUNDERS, MATTHEW P	
ART UNIT	PAPER NUMBER
3732	
NOTIFICATION DATE	DELIVERY MODE
06/30/2014	ELECTRONIC

Notice of Abandonment

This application is abandoned in view of:

1. ☐ The applicant's failure to timely file a proper reply to the Office letter mailed on _____.
   (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission date _____), which is after the expiration of the period for reply (including a total extension of ____ month(s)) which expired on _____.
   (b) ☐ No reply has been received.
2. ☒ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
   (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission date _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
   (b) ☐ The submitted fee of $_____ is insufficient. A balance of $_____ is due.
   The issue fee required by 37 CFR 1.18 is $_____.
   The publication fee, if required by 37 CFR 1.18(d), is $_____.
   (c) ☒ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
   (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
   (b) ☐ No corrected drawing have been received.
4. ☐ Applicant's failure to timely file the inventor's oath or declaration no later than the date on which the issue fee was paid as required by the Notice Requiring Inventor's Oath or Declaration (PTO-2306).
   (a) ☐ An inventor's oath or declaration was received on _____ (with a Certificate of Mailing or Transmission date _____), which is after the date on which the issue fee was paid.
   (b) ☐ While an oath or declaration (or substitute statement) for one or more inventors was received, an oath or declaration (or substitute statement) for at least one other inventor has not been received.
   (c) ☐ No inventor's oath or declaration has been received.
5. ☐ Drawings received on _____ were disapproved by examiner. See examiner's response dated _____.
6. ☐ Corrected drawings were received on _____ , which is after the expiration of the one-month period for reply set in examiner's response dated _____.
7. ☐ No corrected drawings have been received in reply to one-month period set in examiner's response dated _____.
8. ☐ The reason(s) below:

Petitions to revive under 37 CFR 1.137(a) or (b), or request to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

/Brandi Tyler for/

(571)-272-4200 or 1(888)-786-0101
Patent Publication Branch
Office of Data Management

FORM PTO-ABN0 (Rev. 06/09)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

22913 7590 03/12/2014

Workman Nydegger
60 East South Temple
Suite 1000
Salt Lake City, UT 84111

EXAMINER
SAUNDERS, MATTHEW P

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 03/12/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/813,565	06/11/2010	Roberto Armanino	7678.1035.1.1	7247

TITLE OF INVENTION: METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	06/12/2014

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

22913 7590 03/12/2014
Workman Nydegger
60 East South Temple
Suite 1000
Salt Lake City, UT 84111

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/813,565	06/11/2010	Roberto Armanino	7678.1035.1.1	7247

TITLE OF INVENTION: METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	06/12/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
SAUNDERS, MATTHEW P	3732	433-032000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/813,565	06/11/2010	Roberto Armanino	7678.1035.1.1	7247

22913 7590 03/12/2014

Workman Nydegger
60 East South Temple
Suite 1000
Salt Lake City, UT 84111

EXAMINER	
SAUNDERS, MATTHEW P	
ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 03/12/2014

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 199 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 199 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 12/813,565	Applicant(s) ARMANINO, ROBERTO	
	Examiner MATTHEW SAUNDERS	Art Unit 3732	AIA (First Inventor to File) Status No

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed 12/26/2013*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-35*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 9/29/2010
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/HEIDI M EIDE/ Primary Examiner, Art Unit 3732	/MATTHEW SAUNDERS/ Examiner, Art Unit 3732

1. The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Allowable Subject Matter

2. The following is an examiner's statement of reasons for allowance: The prior art of record fails to teach or render obvious a method and apparatus for disinfecting a root canal by applying an electric field within the root canal, the filed produced interacting with and killing microbes within the root canal preparation without damage to or substantially heating of tissue or material within the root canal preparation in combination with the other claimed limitations.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW SAUNDERS whose telephone number is (571)270-3250. The examiner can normally be reached on 9:30am - 6:30pm Monday to Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on 571-272-4364. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MATTHEW SAUNDERS/
Examiner, Art Unit 3732
2/6/2014

/HEIDI M EIDE/
Primary Examiner, Art Unit 3732

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L16	1	l15 and (root near canal)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/10 10:53
L15	11	l14 and field	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/10 10:53
L14	11	l13 and (dental or (root near canal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/10 10:52
L13	513	l12 and (electroporat$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/10 10:52
L12	1077	l7 and (electric with field)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/10 10:52
L11	0	l9 and (root with canal)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/10 10:52
L10	0	l9 and dental	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/10 10:52
L9	4	l8 and (eletroporat$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/10 10:51
L8	1052	l7 and (electric near field)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/10 10:51
L7	5325	604/20,41,44,46,48,49.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/10 10:51
S86	3	irriversible and electroporation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/27 10:15
S85	1	(eletric$2 near field) and (microbe or bateria$3 or pathogen)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/27 10:14

S84	1	(eletric near field) and (microbe or bateria$3 or pathogen)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/27 10:14
S83	40	S82 and (kill or steriliz$4 or apoptosis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/27 10:08
S82	82	S80 and microb$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/27 10:08
S81	4	S80 and teeth	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/27 10:07
S80	184	eletroporation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/27 10:07
S79	0	S78 and eletroporation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/27 10:07
S78	42512	"433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/27 10:07
S77	0	"433".clas. and eletroporation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/27 10:07
S76	4	"20020058232"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/27 10:01
S75	1	2002/0058232	USPAT	OR	OFF	2014/01/27 10:01
S71	39	"5421727"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/14 12:30
S70	7	"20040101809"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/14 11:10
S69	0	"20040101809"	USPAT	OR	OFF	2014/01/14 11:10
S68	1	("2008/0199830").URPN.	USPAT	OR	OFF	2014/01/14 11:09
S67	2	"20080199830"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/14 11:07
S66	0	("2010/0047735").URPN.	USPAT	OR	OFF	2014/01/14 11:07
S65	0	("2010/0047735").URPN.	USPAT	OR	OFF	2014/01/14 11:07

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L20	3	l19 and (root near canal)	US-PGPUB; USPAT; UPAD	OR	ON	2014/02/10 11:09
L19	31	l18 and dental	US-PGPUB; USPAT; UPAD	OR	ON	2014/02/10 11:09
L18	545	l17 and electrophor$4	US-PGPUB; USPAT; UPAD	OR	ON	2014/02/10 11:08
L17	4011	604/20,41,44,46,48,49.ccls.	US-PGPUB; USPAT; UPAD	OR	ON	2014/02/10 11:08
L6	0	l3 and eletric and field	US-PGPUB; USPAT; UPAD	OR	ON	2014/02/10 10:50
L5	0	l3 and electropor	US-PGPUB; USPAT; UPAD	OR	ON	2014/02/10 10:50
L4	12	l3 and electro	US-PGPUB; USPAT; UPAD	OR	ON	2014/02/10 10:50
L3	508	433/102.ccls.	US-PGPUB; USPAT; UPAD	OR	ON	2014/02/10 10:45
L2	331	433/102.ccls.	USPAT; UPAD	OR	ON	2014/02/10 10:45
L1	1610	433/29,32,102,224.ccls.	USPAT; UPAD	OR	ON	2014/02/10 10:45
S93	2	S87 and ((disinfect$3) and ((electric$3 or volt$3))).clm.	USPAT; UPAD	OR	ON	2014/01/27 10:25
S92	0	S87 and ((disinfect$3) and ((electric$3 or volt$3) and field)).clm.	USPAT; UPAD	OR	ON	2014/01/27 10:24
S91	0	S87 and ((disinfect$3 or (root and canal)) and ((electric$3 or volt$3) and field)).clm.	USPAT; UPAD	OR	ON	2014/01/27 10:23
S90	19	S87 and (disinfect$3 or (root and canal) and ((electric$3 or volt$3) and field)).clm.	USPAT; UPAD	OR	ON	2014/01/27 10:22
S89	262	S87 and (disinfect$3 or (root and canal) or ((electric$3 or volt$3) and field)).clm.	USPAT; UPAD	OR	ON	2014/01/27 10:21
S88	0	S87 and (eletric$3 with field)	USPAT; UPAD	OR	ON	2014/01/27 10:20
S87	1387	433/29,32,103,224.ccls.	USPAT; UPAD	OR	ON	2014/01/27 10:16
S74	1	"20070016278"	USPAT; UPAD	OR	ON	2014/01/22 09:27
S73	0	"2007016278"	USPAT; UPAD	OR	ON	2014/01/22 09:26
S72	305	433/32.ccls.2007016278	USPAT; UPAD	OR	ON	2014/01/22 09:26

2/ 10/ 2014 11:12:53 AM
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)				
			Application Number	12/813,565
			Filing Date	June 11, 2010
			First Named Inventor	Roberto Armanino
			Art Unit	3732
			Examiner Name	Not yet known
Sheet	1 of 2		Attorney Docket Number	7678.1035.1.1

U.S. PATENTS

Examiner Initials*	Cite No.	Patent Number	Issue Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	4,175,565	11-27-1979	Chiarenza et al.	
	2	4,291,125	09-22-1981	Greatbatch	
	3	4,854,865	08-08-1989	Beard et al.	
	4	5,383,935	01-24-1995	Shirkhanzadeh	
	5	5,462,644	10-31-1995	Woodson	
	6	5,725,377	03-10-1998	Lemler et al.	
	7	6,273,720	08-14-2001	Spalten	
	8	6,413,498	07-02-2002	Malmagro	
	9	6,482,309	11-19-2002	Green et al.	
	10	6,555,055	04-29-2003	Cisar et al.	
	11	6,778,861	08-17-2004	Liebrecht et al.	

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initials*	Cite No.	Publication Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	12	2004/0034395	02-19-2004	Dick	
	13	2006/0144718	07-06-2006	Lambie	
	14	2006/0265026	11-23-2006	Madjar et al.	
	15	2006/0293724	12-28-2006	Kronberg et al.	

EXAMINER SIGNATURE

Examiner Signature	/Matthew Saunders/	Date Considered	02/18/2014

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.S./

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12813565	ARMANINO, ROBERTO
	Examiner	**Art Unit**
	MATTHEW SAUNDERS	3732

CPC		
Symbol	**Type**	**Version**
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CPC Combination Sets				
Symbol	**Type**	**Set**	**Ranking**	**Version**
/				
/				

/MATTHEW SAUNDERS/ Examiner.Art Unit 3732 (Assistant Examiner)	01/18/2014 (Date)	**Total Claims Allowed:** 35	
/HEIDI M EIDE/ Primary Examiner.Art Unit 3732 (Primary Examiner)	02/10/2014 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 3

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12813565	ARMANINO, ROBERTO
	Examiner	**Art Unit**
	MATTHEW SAUNDERS	3732

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION											
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED						
433	32	A	6	1	C	3 / 00 (2006.0)							

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
433	224				

/MATTHEW SAUNDERS/ Examiner.Art Unit 3732 (Assistant Examiner)	01/18/2014 (Date)	**Total Claims Allowed:** 35
/HEIDI M EIDE/ Primary Examiner.Art Unit 3732 (Primary Examiner)	02/10/2014 (Date)	O.G. Print Claim(s) 1 O.G. Print Figure 3

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12813565	ARMANINO, ROBERTO
	Examiner	**Art Unit**
	MATTHEW SAUNDERS	3732

☒ **Claims renumbered in the same order as presented by applicant** ☐ **CPA** ☐ **T.D.** ☐ **R.1.47**

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	15	17	31	33										
2	2	16	18	32	34										
3	3	21	19	33	35										
4	4	22	20												
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19	13	27	29												
20	14	28	30												
13	15	29	31												
14	16	30	32												

/MATTHEW SAUNDERS/ Examiner.Art Unit 3732	01/18/2014	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	35	
/HEIDI M EIDE/ Primary Examiner.Art Unit 3732	02/10/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	3

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12813565	ARMANINO, ROBERTO
	Examiner	Art Unit
	Matthew Saunders	3732

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
433	32, 224	1/19/2012	JW
Updated	All	4/18/2012	JW
433	29, 32, 102, 224	2/11/2013	MPS
604	20, 41, 44, 46, 48, 49	2/11/2013	MPS
433	updated search	10/19/2013	MPS
604	updated search	10/19/2013	MPS
433	updated search	2/10/2014	MPS
604	updated search	2/10/2014	MPS

SEARCH NOTES		
Search Notes	Date	Examiner
Text Search	1/19/2012	JW
Text Search	4/18/2012	JW
IDS reference search	2/11/2013	MPS
EIC plus search	2/11/2013	MPS
Forward and Backwards search of relevent art	2/11/2013	MPS
Keyword in combination with classification (electric, field, microbe, poration, etc.)	2/11/2013	MPS
IDS reference search	2/11/2013	MPS
updated search	10/19/2013	MPS
Consulted with Kami Bosworth and William Carpenter for search in class 604	10/19/2013	MPS
STIC NPL search	1/18/2014	MPS

/MATTHEW SAUNDERS/ Examiner.Art Unit 3732	

SEARCH NOTES		
Search Notes	**Date**	**Examiner**
Updated classification and keyword search	1/18/2014	MPS

INTERFERENCE SEARCH			
US Class/ CPC Symbol	**US Subclass / CPC Group**	**Date**	**Examiner**
433	29,32,102,224	1/18/2014	MPS

/MATTHEW SAUNDERS/ Examiner.Art Unit 3732	

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12813565	ARMANINO, ROBERTO
	Examiner	Art Unit
	MATTHEW SAUNDERS	3732

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/19/2012	04/19/2012	02/11/2013	10/19/2013	01/18/2014				
1	1	✓	✓	✓	✓	=				
2	2	✓	✓	✓	✓	=				
3	3	✓	✓	✓	✓	=				
4	4	✓	✓	✓	✓	=				
5	5	✓	✓	✓	✓	=				
6	6	✓	✓	✓	✓	=				
7	7	✓	✓	✓	✓	=				
8	8	✓	✓	✓	✓	=				
9	9	✓	✓	✓	✓	=				
10	10	✓	✓	✓	✓	=				
11	11	✓	✓	✓	✓	=				
12	12	✓	✓	✓	✓	=				
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14	16	✓	✓	✓	✓	=				
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16	18	✓	✓	✓	✓	=				
21	19	✓	✓	✓	✓	=				
22	20	✓	✓	✓	✓	=				
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24	22	✓	✓	✓	✓	=				
25	23	✓	✓	✓	✓	=				
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18	27			✓	✓	=				
26	28			✓	✓	=				
27	29			✓	✓	=				
28	30			✓	✓	=				
29	31			✓	✓	=				
30	32			✓	✓	=				
31	33			✓	✓	=				
32	34			✓	✓	=				
33	35			✓	✓	=				

FILED ELECTRONICALLY

PATENT APPLICATION
Docket No. 7678.1035.1.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:		)
	Roberto Armanino	)
Serial No.:	12/813,565	) Art Unit) 3732
Filed:	June 11, 2010	)
Confirmation No.:	7247	)
For:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION	)
Examiner:	Matthew Saunders	)
Customer No.:	022913	)

AMENDMENT "D" AND RESPONSE

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Final Office Action of October 25, 2013, and concurrent with filing a request and certification under the After Final Consideration Pilot Program 2.0, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A method for disinfecting a root canal preparation of a patient, comprising:

electrically connecting a ground electrode to a body of the patient so as to provide an electrical ground;

inserting a monopolar probe into a root canal preparation of a tooth of the patient; and

applying an electrical voltage to the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal preparation, the electric field interacting with and killing microbes within the root canal preparation without damage to or substantial heating of ~~surrounding dental~~ tissue or material within the root canal preparation~~, including adjacent dentin~~.

2. (Original) A method as recited in claim 1, wherein the root canal preparation contains an aqueous conducting fluid when the electrical voltage is applied.

3. (Previously Presented) A method as recited in claim 2, wherein the aqueous conducting fluid does not include a chemical disinfectant such that the electric field kills the microbes without assistance of a chemical disinfectant.

4. (Previously Presented) A method as recited in claim 2, wherein the aqueous conducting fluid comprises a chemical disinfectant that assists the electric field in killing the microbes.

5. (Original) A method as recited in claim 4, wherein the chemical disinfectant comprises aqueous sodium hypochlorite.

6. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage in a range of about 1 volt to about 10,000 volts.

7. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage in a range of about 250 volts to about 2000 volts.

8. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage in a range of about 500 volts to about 1500 volts.

9. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage over a time duration in a range of about 10 nanoseconds to about 30 seconds.

10. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage over a time duration in a range of about 0.001 second to about 5 seconds.

11. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage over a time duration in a range of about 0.01 second to about 4 seconds.

12. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage that is pulsed, wherein individual pulses of the electric voltage have a time duration in a range of about 1 nanosecond to about 1000 milliseconds.

13. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage that is pulsed, wherein individual pulses of the electric voltage have a time duration in a range of about 5 nanoseconds to about 500 milliseconds.

14. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage that is pulsed, wherein individual pulses of the electric voltage have a time duration in a range of about 1 millisecond to about 200 milliseconds.

15. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises applying a number of individual pulses in a range of 2 to about 50 million.

16. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises applying a number of individual pulses in a range of about 10 to about 3 million.

17. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises applying a number of individual pulses in a range of about 15 to about 500,000.

18. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises providing a rest time between individual pulses in a range of about 1 second to about 5 seconds.

19. (Original) A method as recited in claim 1, wherein applying an electrical voltage results in virtually no electrical current flow between the monopolar probe inserted within the root canal preparation and the ground electrode.

20. (Original) A method as recited in claim 1, wherein the monopolar probe inserted within the root canal preparation comprises silver.

21. (Original) A method as recited in claim 1, wherein the ground electrode further comprises an adhesive pad for holding the ground electrode to gingival tissue.

22. (Original) A method as recited in claim 1, wherein the monopolar probe has a length in a range of about 12 mm to about 20 mm.

23. (Original) A method as recited in claim 1, wherein the monopolar probe has a diameter in a range of about 0.06 mm to about 1 mm.

24. (Currently Amended) A method for disinfecting a root canal preparation of a patient, comprising:

providing a root canal preparation of the patient's tooth that contains an electrically conductive fluid;

electrically connecting a ground electrode to gingival tissue of the patient so as to provide an electrical ground;

inserting a monopolar probe into a root canal preparation of a tooth of the patient; and

applying an electrical voltage to the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal preparation, the electric field interacting with and killing microbes within the root canal preparation without damage to or substantial heating of ~~surrounding dental~~ tissue or material within the root canal preparation, ~~including adjacent dentin,~~ the electric field causing at least one of disruption of microbe cell walls or an inner biological mechanism of microbes that results in killing of the microbes.

25. (Currently Amended) An apparatus for use in disinfecting a root canal preparation of a patient, comprising:

a ground electrode configured for attachment to a body of a patient so as to provide an electrical ground;

a monopolar probe sized and configured for insertion into a root canal preparation of a tooth of a patient; and

means for applying an electrical voltage to the monopolar probe when inserted within a root canal preparation so as to produce an electric field within the root canal preparation that interacts with and kills microbes within the root canal preparation by at least one of disruption of microbe cell walls or an inner biological mechanism of microbes, the means for applying an electrical voltage being configured to apply an electrical voltage which produces an electric field that kills microbes when the monopolar probe is inserted within a root canal preparation without damage to or heating of ~~surrounding dental~~ tissue or material within the root canal preparation and without heating~~, including~~ adjacent dentin[[,]] by more than about 10°C.

26. (Previously Presented) A method as recited in claim 12, wherein there is a rest time between individual pulses in which the rest time is in a range of about 0.5 second to about 10 seconds.

27. (Previously Presented) A method as recited in claim 12, wherein there is a rest time between individual pulses in which the rest time is in a range of about 1 second to about 5 seconds.

28. (Previously Presented) A method as recited in claim 1, the electric field interacting with and killing microbes by electroporation and disruption of microbe cell walls.

29. (Previously Presented) A method as recited in claim 1, the electric field interacting with and killing microbes by microbe apoptosis causing an inner biological mechanism that results in killing of the microbes.

30. (Previously Presented) A method as recited in claim 1, the method resulting in at least a 2 log reduction of microbes within the root canal preparation.

31. (Previously Presented) A method as recited in claim 1, the method resulting in at least a 3 log reduction of microbes within the root canal preparation.

32. (Previously Presented) A method as recited in claim 1, the method resulting in at least a 4 log reduction of microbes within the root canal preparation.

33. (Previously Presented) A method as recited in claim 1, the electric field heating surrounding dental tissue by less than about 10°C.

34. (Previously Presented) A method as recited in claim 1, the electric field heating surrounding dental tissue by less than about 5°C.

35. (Previously Presented) A method as recited in claim 1, the electric field heating surrounding dental tissue by less than about 2°C.

REMARKS

Claims 1-35 are pending, wherein claims 1, 24 and 25 have been amended. No claims were added or cancelled. Reconsideration and allowance for the above-identified application are now respectfully requested.

This response is being filed under the After Final Consideration Pilot Program 2.0 together with the accompanying certification and request form. Claims 1, 24 and 25 were amended in a manner that is believed to place them in allowable condition.

As discussed in the Application, the claimed methods and apparatus are configured to kill microbes in a root canal preparation by application of an electric field without substantially damage to or heating of tissue or material within the root canal preparation. *See* Application, ¶¶ 0012 (method "results in substantially *no heating of ... materials within the root canal*") and 0027 (method designed "to *prevent* sparking or arcing, which can result in heat generation and/or *tissue damage*") (emphasis added). Therefore, the claimed methods and apparatus are configured to kill microbes in a root canal preparation as a result of the killing ability of the electric field itself rather than by intense heat.

The claimed methods and apparatus are in contrast to methods and apparatus configured to kill microbes through thermal ablation or disintegration of pulp tissue, as in the Endox system described in the cited prior art, which is specifically intended to, and in fact does, rely on rapidly heating dental pulp (including nerve tissue) and surrounding dental tissue to a very high temperature to vaporize and remove dental pulp by "thermoblation" (Valle) and/or "disintegration" of vascular nerve matter while "coagulat[ing] the part of the vascular bundle that is not destroyed" (Perdomini). As discussed more fully below, the cited prior art does not disclose or suggest "applying an electrical voltage to the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal preparation, the electric field interacting with and killing microbes within the root canal preparation *without damage to or substantial heating of tissue or material within the root canal preparation.*"

The Examiner rejects claims 1, 9-17, 20, 24, 25, and 28-35 under 35 U.S.C. § 103(a) as being unpatentable over Valle et al. "A new therapeutic protocol for pediatric endodontics: a case report", April 2006 ("Valle"). In making this rejection, the Examiner acknowledges that "Valle ... discloses *removing* dental pulp". Office Action, p. 3 (emphasis added). This is consistent with the teaching in Valle that "high frequency impulses go through the pulp tissue in the radicular canal, facilitating its *removal*.... High frequency current (9), in addition ...

[causes] a rapid and elevated increase in temperature that causes *vaporization (thermoblation) of the pulp tissue* and at least a conspicuous volume reduction, which facilitates its *removal*." Valle, p. 2 (emphasis added). Because removing dental pulp necessarily involves "substantially damage to or heating of tissue or material within the root canal preparation", but because claims 1, 24 and 25 as amended recite the step of "applying an electrical voltage to the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal preparation, the electric field interacting with and killing microbes within the root canal preparation *without damage to or substantial heating of tissue or material within the root canal preparation*" (emphasis added), Valle does not disclose or suggest the combination of elements recited in claims 1, 24 and 25 as amended. Moreover, it would be contrary to the teachings of Valle to provide a method or apparatus that did not involve "vaporization (thermoblation) of the pulp tissue ... which facilitates its removal". Accordingly, claims 1, 24 and 25, as well as the claims which depend therefrom, are patentable over Valle, alone or if combined with any other prior art of record. Moreover, dependent claims 2-23 and 26-35 recite additional elements that may further distinguish over the prior art of record.

The Examiner rejects claim 25 under 35 U.S.C. § 103(a) as being unpatentable over Perdomini et al. (US 6,482,008). Perdomini discloses a device that is configured to generate a "high frequency pulse" when used to disinfect a root canal of a tooth, and wherein "[t]he effect of this high frequency pulse ... is to *disintegrate the vascular nerve matter* and simultaneously *coagulate* the part of the vascular bundle that is not *destroyed*". Col. 1, lines 51-54 (emphasis added). Perdomini further teaches that "electronic devitalization can be done limiting the operation exclusively to *disintegration of the vascular nerve bundle*". Col. 2, lines 63-65 (emphasis added). Perdomini also teaches that "[t]he pulse of current emitted by the machine acts on the bundle comprising nerves, vein and artery in the [root] canal. The *bundle of nerves is disintegrated* and blood in the vein is coagulated at the same time. Practically speaking the *whole of the material* in the [root] canal *is removed* and the canal, as well as its branches (FIG. 4) is sterilized." Col. 5, lines 10-16 (emphasis added). Because "disintegration of the vascular nerve bundle" in the root canal so that "the whole of the material in the canal is removed" involves "substantially damage to or heating of tissue or material within the root canal preparation" but because claims 1, 24 and 25 as amended recite the step of "applying an electrical voltage to the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal preparation, the electric field interacting with and

killing microbes within the root canal preparation *without damage to or substantial heating of tissue or material within the root canal preparation*" (emphasis added), Perdomini does not disclose or suggest the combination of elements recited in claim 25 as amended. Moreover, it would be contrary to the teachings of Perdomini to modify the apparatus of Perdomini so as to no longer be configured to kill microbes in a root canal without "disintegration of the vascular nerve bundle". Accordingly, claim 25 is patentable over Perdomini, alone or if combined with any other prior art of record.

The Examiner rejects claims 2-8, 18, 19, 26 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Valle in view of Pond et al. (US 2010/0047735). Pond was only cited as allegedly disclosing "an aqueous fluid" and "a voltage in the range of 100-5000 V" but otherwise fails to cure the deficiencies of Valle noted above.

The Examiner rejects claims 20 and 21 under 35 U.S.C. § 103(a) as being unpatentable over Valle in view of Fontenot et al. (US 2008/0199830). Fontenot was only cited as allegedly disclosing "a silver probe" but otherwise fails to cure the deficiencies of Valle noted above.

The Examiner rejects claims 22 and 23 under 35 U.S.C. § 103(a) as being unpatentable over Valle in view of Perdomini. Perdomini was only cited as allegedly disclosing "a monopolar probe having a length of about 15 mm … and a diameter [in] a range of 0.25 to 0.1 mm" but otherwise fails to cure the deficiencies of Valle noted above.

Finally, the Examiner further acknowledges that Valle teaches a method in which "the pulp is heated to a substantial level and … to a temperature that would be damaged", Office Action, pp. 7-8, which further supports the patentability of the claims as now presented.

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Dated this 26th day of December 2013.

Respectfully submitted,

/John M. Guynn 36153/

JOHN M. GUYNN
Registration No. 36,153
WORKMAN NYDEGGER
Attorney for Applicant(s)
Customer No. 022913

JMG:kft
4333807_1.DOC

Doc Code: A.NE.AFCP
Document Description: After Final Consideration Pilot Program Request

PTO/SB/434 (05-13)

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0

Practitioner Docket No.:	Application No.:	Filing Date:
7678.1035.1.1	12/813,565	06/11/2010
First Named Inventor:	**Title:**	
Roberto Armanino	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION	

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.

1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) [a continuing application (*e.g.*, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)], or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c).
2. The above-identified application contains an outstanding final rejection.
3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect.
4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection.
5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response.
6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web).
7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.]
8. By filing this certification and request, applicant acknowledges the following:
    - Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0.
    - The examiner will verify that the AFCP 2.0 submission is compliant, *i.e.*, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions:
        - The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, by mailing an advisory action.
        - If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview.
            - The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate.
            - If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116.

Signature	Date
/John M Guynn 36153/	12/26/2013
Name (Print/Typed)	**Practitioner Registration No.**
John M Guynn	36,153

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.*

[✓] * Total of 1 forms are submitted.

Privacy Act Statement

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Electronic Acknowledgement Receipt

EFS ID:	17760771
Application Number:	12813565
International Application Number:	
Confirmation Number:	7247
Title of Invention:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION
First Named Inventor/Applicant Name:	Roberto Armanino
Customer Number:	22913
Filer:	John Michael Guynn
Filer Authorized By:	
Attorney Docket Number:	7678.1035.1.1
Receipt Date:	26-DEC-2013
Filing Date:	11-JUN-2010
Time Stamp:	15:53:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response After Final Action	7678_1035_1_1_Amd_D.pdf	61336 518a4140b25f4184ff8623d6d4757a23e57664cd	no	10

Warnings:	
Information:	

2	After Final Consideration Program Request	7678_1035_1_1_AF_2_0.pdf	226762 c9eb027e65fc2b39cc76fabbdd83af797dda35d9	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	288098

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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.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
12/813,565	06/11/2010	

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **12/26/2013**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 35	Minus	** 35	= 0	X $80 =	0
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $420 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/KIMBERLY WHITE/

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Workman Nydegger
60 East South Temple
Suite 1000
Salt Lake City, UT 84111

Courtesy Reminder for
Application Serial No: 12/813,565

Attorney Docket No: 7678.1035.1.1
Customer Number: 22913
Date of Electronic Notification: 10/25/2013

This is a courtesy reminder that new correspondence is available for this application. If you have not done so already, please review the correspondence. The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

An email notification regarding the correspondence was sent to the following email address(es) associated with your customer number:
Docketing@wnlaw.com

To view your correspondence online or update your email addresses, please visit us anytime at **https://sportal.uspto.gov/secure/myportal/privatepair.** If you have any questions, please email the Electronic Business Center (EBC) at EBC@uspto.gov or call 1-866-217-9197.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/813,565	06/11/2010	Roberto Armanino	7678.1035.1.1	7247

22913 7590 10/25/2013

Workman Nydegger
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EXAMINER	
SAUNDERS, MATTHEW P	
ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
10/25/2013	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docketing@wnlaw.com

Office Action Summary	Application No. 12/813,565	Applicant(s) ARMANINO, ROBERTO	
	Examiner MATTHEW SAUNDERS	Art Unit 3732	AIA (First Inventor to File) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/18/2013*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-35* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-35* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some * c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. 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 negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1, 9-17, 20, 24, 25, 28, 29, and 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valle et al. "A new therapeutic protocol for pediatric endodontics: a case report", April 2006.**

4. Regarding claims 1, 24, 25, Valle discloses a method for disinfection a root canal including the steps of electrically connecting a ground electrode to a patient (page 2 paragraph 5), inserting a monopolar probe into a root canal (Figs. 6 and 7), and applying an electric voltage to create an electric field that interacts with and kills microbes (page 2 paragraph 2 lines 15-21), while not damaging surrounding dental tissue (page 2 paragraph 3).

5. Valle fails to explicitly disclose that the limit to the damage of the surrounding dental tissues includes limited substantial heating to the dentin.

6. However, upon further consideration the heating recited in Valle only discloses removing dental pulp, heating of which would not necessarily damage the dentin. And the such substantial limiting of heating would be an obvious limitation to though having ordinary skill in the art as supported by Valle teaching that the periodontum would not be heated or damaged substantially and the heating only occurs within the root canal not the tooth dentin.

7. Regarding claim 14, Valle discloses the claimed invention as discussed above except for the time duration being of about 1 millisecond to about 200 milliseconds instead of 500 milliseconds. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a pulse duration of about 1 millisecond to about 200 milliseconds, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

8. Regarding claim 20, Valle discloses the claimed invention except for the probe being made of silver. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the conducting probe of silver, since 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.

9. Regarding claims 31-32, Valle discloses the claimed invention as discussed above including a reduction of microbes of greater than 99 percent or 2 log reduction but does not explicitly disclose 3 or 4 log reduction. However it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the reduction of greater than 99 percent be a 3 log reduction/99.9% or 4 log reduction/99.99%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

10. Regarding claims 33-35, Valle discloses the claimed invention as discussed above including the method of keeping the surrounding tissue from heating a few degrees celsius, but fails to explicitly disclose the few degrees being 10, 5, or 2 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to ensure the increase in temperature was less than any of 10, 5, or 2 degress, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

11. Regarding claims 9-13, Valle further discloses pulses of the electric field over pulsed applications for about $1/10^{th}$ of a second which is about 500 milliseconds, see paragraph 4.

12. Regarding claims 15-17, Valle further discloses applications of a pulse at a frequency of 312hz or 312 pulses a second, see paragraph 4.

13. Regarding claim 25, Valle teaches the structure as claimed in the method as described above.

14. Regarding claim 28 and 29, Valle further discloses where the electric field causes killing of microbes by an internal mechanism and electroporation, see paragraph 2 lines 18-21.

15. Regarding claim 30, Valle further discloses where the method results in at least a 2 log, or 99 percent reduction of microbes within the root, see paragraph 4 lines 1-2.

16. **Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Perdomini et al. (US 6,482,008 B2).**

17. Perdomini discloses an apparatus comprising means for electrically grounding a ground electrode to a body of a patient so as to provide an electrical ground (Fig. 1 elements 60 and 64), a mono-polar probe sized and configured for insertion into a root canal preparation of a tooth of a patient (Fig. 4 element 100), and means for applying an electrical voltage between the ground electrode and the mono-polar probe when inserted within a root canal preparation capable of producing an electrical field within the root canal preparation that inherently would interact with and kill microbes within the root canal preparation (Fig. 1 element 10, column 2 lines 51-55).

18. **Claims 2-8, 18, 19, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valle et al., "A new therapeutic protocol for pediatric endodontics: a case report" in view of Pond et al. (2010/0047735).**

19. Valle shows the method as described above, however, but does not show using an aqueous fluid.

Pond teaches an electroporation method with a fluid (paragraphs [0058]-[0059]) and that the fluid can be water (paragraph [0039]) and the use of sodium hypochlorite (paragraph [0016]).

It would have been obvious to one of ordinary skill in the art to modify Valle to include the use of an aqueous fluid as taught by Pond in order to better clean and disinfect the canal (paragraph [0016]).

20. Regarding claim 6, Valle teaches using a high frequency current, however, does not state the voltage used. However, Pond further discloses using a voltage in the range of 100-5000 V (paragraph [0061] lines 4-6).

It would have been obvious to one of ordinary skill in the art to modify Valle to include using a voltage as taught by Pond in order to better clean and disinfect the canal.

21. Regarding claims 18-19, 26 and 27 Pond further teaches that "However, it is understood that any operating parameters that would be used to improve the system would fall within the scope of the present invention." [0061], as such, the parameters in claims 18, 19, 26, and 27 would have been obvious to the skilled artisan in maximizing the system.

22. **Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valle et al., "A new therapeutic protocol for paediatric endodontics: a case report" in view of Fontenot et al (2008/0199830).**

Valle does not show the use of a silver probe.

Fontenot teaches using a silver probe [0029] [0060]. It would have been obvious to one of ordinary skill in the art to modify Valle to include the use of silver as shown by Fontenot in order to better create the electric field and disinfect the canal.

23. **Claim 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valle et al. "A new therapeutic protocol for pediatric endodontics: a case report", April 2006 in view of Perdonmini et al. (US 6,482,008).**

24. Valle discloses structure substantially identical to the instant application as discussed above but fails to explicitly disclose where the monopolar probe has a length of about 12 to 20 millimeters or a diameter in the range of 0.06mm to about 1mm.

25. However, Perdonmimi discloses a process for devitalizing teeth using a high-frequency electric current (title) with a monopolar probe having a length of about 15 mm (column 4 lines 3-4), and a diameter of a range of 0.25 to 0.1 mm (column 2 lines 14-15).

26. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the tip dimensions as taught by Perdomini into the monopolar probe as taught by Valle for the purpose of ensuring easy entrance of the probe into the root canal having matched sizes. The specific range is an obvious matter of choice in the degree of a known parameter.

Response to Arguments

27. Applicant's arguments filed 07/18/2013 have been fully considered but they are not persuasive. Upon further consideration of the cited prior art it is the Examiners position that the teaching of Valle is that method taught is that only the pulp is heated to

a substantial level and that only the pulp is heated to a temperature that would be damaged and not the dentin. Control of the heating resultant from the application of electric voltage has been demonstrated in the prior art of Valle as a parameter of concern and in the purview of those having ordinary skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW SAUNDERS whose telephone number is (571)270-3250. The examiner can normally be reached on 9:30am - 6:30pm Monday to Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on 571-272-4364. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MATTHEW P SAUNDERS/
Examiner, Art Unit 3732
2/11/2013

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12813565	ARMANINO, ROBERTO
	Examiner	Art Unit
	Matthew Saunders	3732

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
433	32, 224	1/19/2012	JW
Updated	All	4/18/2012	JW
433	29, 32, 102, 224	2/11/2013	MPS
604	20, 41, 44, 46, 48, 49	2/11/2013	MPS
433	updated search	10/19/2013	MPS
604	updated search	10/19/2013	MPS

SEARCH NOTES		
Search Notes	Date	Examiner
Text Search	1/19/2012	JW
Text Search	4/18/2012	JW
IDS reference search	2/11/2013	MPS
EIC plus search	2/11/2013	MPS
Forward and Backwards search of relevent art	2/11/2013	MPS
Keyword in combination with classification (electric, field, microbe, poration, etc.)	2/11/2013	MPS
IDS reference search	2/11/2013	MPS
updated search	10/19/2013	MPS
Consulted with Kami Bosworth and William Carpenter for search in class 604	10/19/2013	MPS

/MATTHEW SAUNDERS/ Examiner.Art Unit 3732	

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S46	76	"4027393"	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT; IBM_TDB	OR	ON	2013/10/08 15:19
S47	19	("2069112" | "4027393").PN. OR ("4126937").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/08 15:57
S48	30	"5421727"	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/08 16:59
S49	10	("4674499" | "4766896" | "4805616" | "4885004" | "5192280" | "5421727" | "5484435" | "6015406" | "6238394").PN. OR ("6382968").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/09 14:05
S50	3835	604/20.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/09 14:07
S51	694	S50 and electroporation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/09 14:20
S52	0	S51 and irriversible	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/09 14:20
S53	115	S51 and irreversible	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/09 14:20
S54	62	S53 and tumor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2013/10/09 14:22

			DERWENT; IBM_TDB			
S55	35	US-4811420-$.DID. OR US-2311201-$.DID. OR US-2233882-$.DID. OR US-3388270-$.DID. OR US-9004901-$.DID. OR US-1062067-$.DID. OR US-20080264807-$.DID. OR US-2010025-$.DID. OR US-20090269317-$.DID. OR US-20092444079-$.DID. OR US-2722296-$.DID. OR US-2010033-$.DID. OR WO-2009134876-$.DID. OR WO-2010151277-$.DID. OR US-2578847-$.DID. OR EP-1673149-$.DID. OR US-20040167458-$.DID. OR US-8209005-$.DID. OR US-20070043345-$.DID. OR US-2550846-$.DID. OR EP-1696812-$.DID. OR US-20050171574-$.DID. OR US-8048067-$.DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/09 14:28

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L25	0	606/409.ccls.	US-PGPUB; USPAT; UPAD	OR	ON	2013/10/19 21:30
L26	1249	604/60,41,44,46,48,49.ccls.	US-PGPUB; USPAT; UPAD	OR	ON	2013/10/19 21:30
L27	2683	433/29,32,102,224.ccls.	US-PGPUB; USPAT; UPAD	OR	ON	2013/10/19 21:35

10/19/2013 9:38:34 PM
C:\Users\msaunders\Documents\EAST\Workspaces\12813565.wsp

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12813565	ARMANINO, ROBERTO
	Examiner	Art Unit
	JOHN J WILSON	3732

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/19/2012	04/19/2012	02/11/2013	10/19/2013					
	1	✓	✓	✓	✓					
	2	✓	✓	✓	✓					
	3	✓	✓	✓	✓					
	4	✓	✓	✓	✓					
	5	✓	✓	✓	✓					
	6	✓	✓	✓	✓					
	7	✓	✓	✓	✓					
	8	✓	✓	✓	✓					
	9	✓	✓	✓	✓					
	10	✓	✓	✓	✓					
	11	✓	✓	✓	✓					
	12	✓	✓	✓	✓					
	13	✓	✓	✓	✓					
	14	✓	✓	✓	✓					
	15	✓	✓	✓	✓					
	16	✓	✓	✓	✓					
	17	✓	✓	✓	✓					
	18	✓	✓	✓	✓					
	19	✓	✓	✓	✓					
	20	✓	✓	✓	✓					
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	22	✓	✓	✓	✓					
	23	✓	✓	✓	✓					
	24	✓	✓	✓	✓					
	25	✓	✓	✓	✓					
	26			✓	✓					
	27			✓	✓					
	28			✓	✓					
	29			✓	✓					
	30			✓	✓					
	31			✓	✓					
	32			✓	✓					
	33			✓	✓					
	34			✓	✓					
	35			✓	✓					

FILED ELECTRONICALLY

PATENT APPLICATION
Docket No. 7678.1035.1.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:		)
	Roberto Armanino	)
Serial No.:	12/813,565	) Art Unit) 3732
Filed:	June 11, 2010	)
Confirmation No.:	7247	)
For:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION	)
Examiner:	Matthew Saunders	)
Customer No.:	022913	)

AMENDMENT "B" AND RESPONSE

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action of February 20, 2013, and concurrent with filing a two-month extension of time, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A method for disinfecting a root canal preparation of a patient, comprising:

electrically connecting a ground electrode to a body of the patient so as to provide an electrical ground;

inserting a monopolar probe into a root canal preparation of a tooth of the patient; and

applying an electrical voltage ~~between the ground electrode and~~ to the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal preparation, the electric field interacting with and killing microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue, including adjacent dentin.

2. (Original) A method as recited in claim 1, wherein the root canal preparation contains an aqueous conducting fluid when the electrical voltage is applied.

3. (Previously Presented) A method as recited in claim 2, wherein the aqueous conducting fluid does not include a chemical disinfectant such that the electric field kills the microbes without assistance of a chemical disinfectant.

4. (Previously Presented) A method as recited in claim 2, wherein the aqueous conducting fluid comprises a chemical disinfectant that assists the electric field in killing the microbes.

5. (Original) A method as recited in claim 4, wherein the chemical disinfectant comprises aqueous sodium hypochlorite.

6. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage in a range of about 1 volt to about 10,000 volts.

7. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage in a range of about 250 volts to about 2000 volts.

8. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage in a range of about 500 volts to about 1500 volts.

9. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage over a time duration in a range of about 10 nanoseconds to about 30 seconds.

10. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage over a time duration in a range of about 0.001 second to about 5 seconds.

11. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage over a time duration in a range of about 0.01 second to about 4 seconds.

12. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage that is pulsed, wherein individual pulses of the electric voltage have a time duration in a range of about 1 nanosecond to about 1000 milliseconds.

13. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage that is pulsed, wherein individual pulses of the electric voltage have a time duration in a range of about 5 nanoseconds to about 500 milliseconds.

14. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage that is pulsed, wherein individual pulses of the electric voltage have a time duration in a range of about 1 millisecond to about 200 milliseconds.

15. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises applying a number of individual pulses in a range of 2 to about 50 million.

16. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises applying a number of individual pulses in a range of about 10 to about 3 million.

17. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises applying a number of individual pulses in a range of about 15 to about 500,000.

18. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises providing a rest time between individual pulses in a range of about 1 second to about 5 seconds.

19. (Original) A method as recited in claim 1, wherein applying an electrical voltage results in virtually no electrical current flow between the monopolar probe inserted within the root canal preparation and the ground electrode.

20. (Original) A method as recited in claim 1, wherein the monopolar probe inserted within the root canal preparation comprises silver.

21. (Original) A method as recited in claim 1, wherein the ground electrode further comprises an adhesive pad for holding the ground electrode to gingival tissue.

22. (Original) A method as recited in claim 1, wherein the monopolar probe has a length in a range of about 12 mm to about 20 mm.

23. (Original) A method as recited in claim 1, wherein the monopolar probe has a diameter in a range of about 0.06 mm to about 1 mm.

24. (Currently Amended) A method for disinfecting a root canal preparation of a patient, comprising:

providing a root canal preparation of the patient's tooth that contains an electrically conductive fluid;

electrically connecting a ground electrode to gingival tissue of the patient so as to provide an electrical ground;

inserting a monopolar probe into a root canal preparation of a tooth of the patient; and

applying an electrical voltage ~~between the ground electrode and~~ to the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal preparation, the electric field interacting with and killing microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue, including adjacent dentin, the electric field causing at least one of disruption of microbe cell walls or an inner biological mechanism of microbes that results in killing of the microbes.

25. (Currently Amended) An apparatus for use in disinfecting a root canal preparation of a patient, comprising:

~~means for electrically connecting~~ a ground electrode configured for attachment to a body of a patient so as to provide an electrical ground;

a monopolar probe sized and configured for insertion into a root canal preparation of a tooth of a patient; and

means for applying an electrical voltage ~~between the ground electrode and~~ to the monopolar probe when inserted within a root canal preparation so as to produce an electric field within the root canal preparation that interacts with and kills microbes within the root canal preparation by at least one of disruption of microbe cell walls or an inner biological mechanism of microbes, the means for applying an electrical voltage being configured to apply an electrical voltage which produces an electric field that ~~results in killing of~~ kills microbes when the monopolar probe is inserted within a root canal preparation without damage to or heating of surrounding dental tissue, including adjacent dentin, by more than about 10°C.

26. (Previously Presented) A method as recited in claim 12, wherein there is a rest time between individual pulses in which the rest time is in a range of about 0.5 second to about 10 seconds.

27. (Previously Presented) A method as recited in claim 12, wherein there is a rest time between individual pulses in which the rest time is in a range of about 1 second to about 5 seconds.

28. (Previously Presented) A method as recited in claim 1, the electric field interacting with and killing microbes by electroporation and disruption of microbe cell walls.

29. (Previously Presented) A method as recited in claim 1, the electric field interacting with and killing microbes by microbe apoptosis causing an inner biological mechanism that results in killing of the microbes.

30. (Previously Presented) A method as recited in claim 1, the method resulting in at least a 2 log reduction of microbes within the root canal preparation.

31. (Previously Presented) A method as recited in claim 1, the method resulting in at least a 3 log reduction of microbes within the root canal preparation.

32. (Previously Presented) A method as recited in claim 1, the method resulting in at least a 4 log reduction of microbes within the root canal preparation.

33. (Previously Presented) A method as recited in claim 1, the electric field heating surrounding dental tissue by less than about 10°C.

34. (Previously Presented) A method as recited in claim 1, the electric field heating surrounding dental tissue by less than about 5°C.

35. (Previously Presented) A method as recited in claim 1, the electric field heating surrounding dental tissue by less than about 2°C.

REMARKS

Applicant and Applicant's attorneys express appreciation to the Examiner and the Examiner's supervisor for the courtesies extended during the recent interview held on July 11, 2013.

Claims 1-35 are pending, wherein claims 1, 24 and 25 have been amended. Reconsideration and allowance for the above-identified application are now respectfully requested.

As discussed during the Examiner Interview, the claimed methods and apparatus are configured to kill microbes in a root canal by application of an electric field without substantial heating of surrounding dental tissue, including adjacent dentin. As further discussed, this is contrast to killing microbes through thermal ablation of pulp tissue, as in the Endox system described in the cited prior art, which is specifically intended to, and in fact does, substantially and rapidly heat the dental pulp and surrounding dental tissue sufficient to completely vaporize all dental pulp by thermal ablation.

To further emphasize this distinction between the claimed invention and the prior art, the claims were amended to further specify that the surrounding dental tissue that is not substantially heat includes the adjacent dentin. As agreed to during the Examiner Interview, the claims as amended distinguish over the art of record. In contrast to the claimed invention, the Valle Article teaches that "high frequency impulses go through the pulp tissue in the radicular canal, facilitating its removal.... High frequency current (9), in addition ... [causes] a rapid and elevated increase in temperature that causes vaporization (thermoblation) of the pulp tissue and at least a conspicuous volume reduction, which facilitates its removal." Valle Article, page 2. Although Valle teaches that "the periodontium" is heated by "a few degrees Celsius," Valle does not teach or suggest that the thermal ablation procedure does not result in substantial heating of adjacent tooth dentin, which is immediately adjacent to and encloses the pulp chamber.

Perdomini et al. (US 6,482,008) similarly teaches that "[t]he effect of this high frequency pulse ... is to *disintegrate* the vascular nerve matter and simultaneously coagulate the part of the vascular bundle that is not destroyed". Col. 1, lines 51-54 (emphasis added). In addition, "electronic devitalization can be done limiting the operation exclusively to *disintegration* of the vascular nerve bundle". Col. 2, lines 63-65 (emphasis added); *see* claim 1.

The secondary references are insufficient to cure the deficiencies of the primary references noted above relative to their failure to teach or suggest methods and apparatus that kill

microbes using an electric field without substantial heating of surrounding dental tissue, including dentin. Accordingly, Applicant submits that the claims are unobvious over the prior art of record.

Finally, as was discussed and agreed to during the Examiner Interview, the claims as previously presented do not claim a natural phenomenon or natural law but rather a practical application of natural principles to disinfect a root canal. As such, and as further agreed, the claims are patent eligible under 35 U.S.C. § 101.

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Dated this 18th day of July 2013.

Respectfully submitted,

/John M. Guynn 36153/

JOHN M. GUYNN
Registration No. 36,153
WORKMAN NYDEGGER
Attorney for Applicant(s)
Customer No. 022913

JMG:kft
4136142_1.DOC

Electronic Patent Application Fee Transmittal

Application Number:	12813565
Filing Date:	11-Jun-2010
Title of Invention:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION
First Named Inventor/Applicant Name:	Roberto Armanino
Filer:	John Michael Guynn/Kelli Tyree
Attorney Docket Number:	7678.1035.1.1

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 2 months with $0 paid	1252	1	600	600

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**600**

Electronic Acknowledgement Receipt

EFS ID:	16358138
Application Number:	12813565
International Application Number:	
Confirmation Number:	7247
Title of Invention:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION
First Named Inventor/Applicant Name:	Roberto Armanino
Customer Number:	22913
Filer:	John Michael Guynn/Kelli Tyree
Filer Authorized By:	John Michael Guynn
Attorney Docket Number:	7678.1035.1.1
Receipt Date:	18-JUL-2013
Filing Date:	11-JUN-2010
Time Stamp:	18:32:09
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$600
RAM confirmation Number	5522
Deposit Account	233178
Authorized User	GUYNN, JOHN M.

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		7678_1035_1_1_Amendment.pdf	49347 0c84429080ad4f21478ecad795c89af6c633b250	yes	8

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	8

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30701 c79b2d8b4968563590fea38fd75ba3006b2f63e1	no	2

Warnings:

Information:

Total Files Size (in bytes):	80048

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
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.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
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.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
12/813,565	06/11/2010	

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **07/18/2013**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 35	Minus	** 35	= 0	X $80 =	0
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $420 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/DIANE FLOYD/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/813,565	06/11/2010	Roberto Armanino	7678.1035.1.1	7247

22913 7590 07/05/2013

Workman Nydegger
60 East South Temple
Suite 1000
Salt Lake City, UT 84111

EXAMINER	
SAUNDERS, MATTHEW P	
ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
07/05/2013	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docketing@wnlaw.com

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	12/813,565	ARMANINO, ROBERTO	
	Examiner	Art Unit	
	MATTHEW SAUNDERS	3732	

All participants (applicant, applicant's representative, PTO personnel):

(1) *MATTHEW SAUNDERS*.

(2) *Cris Rodriguez*.

(3) *John Guynn*.

(4) *Kelli Tyree*.

Date of Interview: *11 June 2013*.

Type: ☐ Telephonic ☐ Video Conference
☒ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☒101 ☐112 ☒102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *all*.

Identification of prior art discussed: *Valle et al.* .

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

A discussion of the 101 rejetion resulted in an agreement that the claims appear to overcome that statute. Discusses possible changes to the structural limitaions of the apparatus that would be necessary to create the eletric field which would not transfer any current. Discussed the proposed amendment to the method appears to overcome the current prior art through the limitation of not damaging the dentin during operation..

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/MATTHEW P SAUNDERS/ Examiner, Art Unit 3732	/Cris L. Rodriguez/ Supervisory Patent Examiner, Art Unit 3732

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/813,565	06/11/2010	Roberto Armanino	7678.1035.1.1	7247

22913 7590 02/20/2013

Workman Nydegger
1000 Eagle Gate Tower
60 East South Temple
Salt Lake City, UT 84111

EXAMINER	
SAUNDERS, MATTHEW P	

ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
02/20/2013	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docketing@wnlaw.com

Office Action Summary	Application No.	Applicant(s)	
	12/813,565	ARMANINO, ROBERTO	
	Examiner	Art Unit	
	MATTHEW SAUNDERS	3732	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2012*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-35* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-35* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *22 June 2010* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/29/2010*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: page ten line 19 element 125 referring to a patient.

2. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-24 and 26-35 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim limitation of “the electrical field interacting with and killing microbes" in claim 1, appears to be positively claiming a natural phenomenon.

5. Further claim 24 recites the limitation “the electric field causing at least one of disruption of microbe cell walls or an inner biological mechanism" in a positive manner, however these are natural phenomenon and the claim fails to recite language which is sufficient to transform the nature of the claims to merely

claiming a method which would result in the natural phenomenon instead of claiming the natural phenomenon itself.

6. Claims 28 and 29 both appear to be explicitly claiming the resulting phenomenon of the natural interaction of cells within an electrical field.

Claim Rejections - 35 USC § 102

7. 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 –
>
> (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.

8. **Claims 1, 9-13, 15-17, 24, 25, 28, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Valle et al. "A new therapeutic protocol for pediatric endodontics: a case report", April 2006.**

9. Regarding claims 1, 24, 25, Valle discloses a method for disinfection a root canal including the steps of electrically connecting a ground electrode to a patient (page 2 paragraph 5), inserting a monopolar probe into a root canal (Figs. 6 and 7), and applying an electric voltage to create an electric field that interacts with and kills microbes (page 2 paragraph 2 lines 15-21), while not damaging surrounding dental tissue (page 2 paragraph 3).

10. Regarding claims 9-13, Valle further discloses pulses of the electric field over pulsed applications for about $1/10^{th}$ of a second which is about 500 milliseconds, see paragraph 4.

11. Regarding claims 15-17, Valle further discloses applications of a pulse at a frequency of 312hz or 312 pulses a second, see paragraph 4.

12. Regarding claim 25, Valle teaches the structure as claimed in the method as described above.

13. Regarding claim 28 and 29, Valle further discloses where the electric field causes killing of microbes by an internal mechanism and electroporation, see paragraph 2 lines 18-21.

14. Regarding claim 30, Valle further discloses where the method results in at least a 2 log, or 99 percent reduction of microbes within the root, see paragraph 4 lines 1-2.

15. **Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Perdomini et al. (US 6,482,008 B2).**

16. Perdomini discloses an apparatus comprising means for electrically grounding a ground electrode to a body of a patient so as to provide an electrical ground (Fig. 1 elements 60 and 64), a mono-polar probe sized and configured for insertion into a root canal preparation of a tooth of a patient (Fig. 4 element 100), and means for applying an electrical voltage between the ground electrode and the mono-polar probe when inserted within a root canal preparation capable of producing an electrical field within the root canal preparation that inherently would interact with and kill microbes within the root canal preparation (Fig. 1 element 10, column 2 lines 51-55).

Claim Rejections - 35 USC § 103

17. 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 negatived by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. **Claims 14, 20, 31, 32, and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valle et al. "A new therapeutic protocol for pediatric endodontics: a case report", April 2006.**

20. Regarding claim 14, Valle discloses the claimed invention as discussed above except for the time duration being of about 1 millisecond to about 200 milliseconds instead of 500 milliseconds. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a pulse duration of about 1 millisecond to about 200 milliseconds, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

21. Regarding claim 20, Valle discloses the claimed invention except for the probe being made of silver. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the conducting probe of silver, since 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.

22. Regarding claims 31-32, Valle discloses the claimed invention as discussed above including a reduction of microbes of greater than 99 percent or 2 log reduction but does not explicitly disclose 3 or 4 log reduction. However it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the reduction of greater than 99 percent be a 3 log reduction/99.9% or 4 log reduction/99.99%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

23. Regarding claims 33-35, Valle discloses the claimed invention as discussed above including the method of keeping the surrounding tissue from heating a few degrees celsius, but fails to explicitly disclose the few degrees being 10, 5, or 2 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to ensure the increase in temperature was less than any of 10, 5, or 2 degress, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

24.

25. **Claims 2-8, 18, 19, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valle et al., "A new therapeutic protocol for pediatric endodontics: a case report" in view of Pond et al. (2010/0047735).**

26. Valle shows the method as described above, however, but does not show using an aqueous fluid.

Pond teaches an electroporation method with a fluid (paragraphs [0058]-[0059]) and that the fluid can be water (paragraph [0039]) and the use of sodium hypochlorite (paragraph [0016]).

It would have been obvious to one of ordinary skill in the art to modify Valle to include the use of an aqueous fluid as taught by Pond in order to better clean and disinfect the canal (paragraph [0016]).

27. Regarding claim 6, Valle teaches using a high frequency current, however, does not state the voltage used. However, Pond further discloses using a voltage in the range of 100-5000 V (paragraph [0061] lines 4-6).

It would have been obvious to one of ordinary skill in the art to modify Valle to include using a voltage as taught by Pond in order to better clean and disinfect the canal.

28. Regarding claims 18-19, 26 and 27 Pond further teaches that "However, it is understood that any operating parameters that would be used to improve the system would fall within the scope of the present invention." [0061], as such, the parameters in claims 18, 19, 26, and 27 would have been obvious to the skilled artisan in maximizing the system.

29. **Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valle et al., "A new therapeutic protocol for paediatric endodontics: a case report" in view of Fontenot et al (2008/0199830).**

Valle does not show the use of a silver probe.

Fontenot teaches using a silver probe [0029] [0060]. It would have been obvious to one of ordinary skill in the art to modify Valle to include the use of silver as shown by Fontenot in order to better create the electric field and disinfect the canal.

30. **Claim 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valle et al. "A new therapeutic protocol for pediatric endodontics: a case report", April 2006 in view of Perdonmini et al. (US 6,482,008).**

31. Valle discloses structure substantially identical to the instant application as discussed above but fails to explicitly disclose where the monopolar probe has a length of about 12 to 20 millimeters or a diameter in the range of 0.06mm to about 1mm.

32. However, Perdonmimi discloses a process for devitalizing teeth using a high-frequency electric current (title) with a monopolar probe having a length of about 15 mm (column 4 lines 3-4), and a diameter of a range of 0.25 to 0.1 mm (column 2 lines 14-15).

33. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the tip dimensions as taught by Perdomini into the monopolar probe as taught by Valle for the purpose of

ensuring easy entrance of the probe into the root canal having matched sizes. The specific range is an obvious matter of choice in the degree of a known parameter.

Response to Arguments

34. Applicant's arguments filed 07/20/2012 have been fully considered but they are not persuasive. The applicant has argued that the prior art of record fails to teach the use of electric field for the disinfection of microbes from a root canal, however the cited art of Valle does disclose the use of such an electric field and the resulting effect of electroporation.

35. Of further note it is still not clear from the present disclosure, nor applicants response, at exactly what point the parameters used for the field only opens pores long enough for materials to pass in without damaging the cells, and at what point, the parameters kill the cells, and as such, it is not clear what claims are commensurate with applicant's arguments.

Conclusion

36. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See form PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW SAUNDERS whose telephone number is (571)270-3250. The examiner can normally be reached on 9:30am - 6:30pm Monday to Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on 571-272-4364. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MATTHEW P SAUNDERS/
Examiner, Art Unit 3732
2/11/2013

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

Notice of References Cited	Application/Control No. 12/813,565	Applicant(s)/Patent Under Reexamination ARMANINO, ROBERTO	
	Examiner MATTHEW SAUNDERS	Art Unit 3732	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-1,713,971 A	05-1929	LOWRY NELSON H et al.	606/49
*	B	US-4,243,388 A	01-1981	Arai, Toshio	433/27
*	C	US-4,291,125 A	09-1981	Greatbatch, Wilson	424/618
*	D	US-5,421,727 A	06-1995	Stevens et al.	433/224
*	E	US-5,462,644 A	10-1995	Woodson, Lewis P.	205/701
*	F	US-6,482,008 B2	11-2002	Perdomini et al.	433/224
*	G	US-6,641,396 B2	11-2003	Pasquantonio et al.	433/217.1
*	H	US-2004/0059285 A1	03-2004	Mathiesen et al.	604/065
*	I	US-2004/0101809 A1	05-2004	Weiss et al.	433/224
*	J	US-2006/0286511 A1	12-2006	Aleksandrovskiy et al.	433/215
*	K	US-2008/0199830 A1	08-2008	Fontenot et al.	433/215
*	L	US-2009/0326436 A1	12-2009	Rubinsky et al.	604/20
*	M	US-2010/0047735 A1	02-2010	Pond, Gary J.	433/29

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Valle et al, " a new theraputic protocol for paediatric endodontics:a case report", 9-2005, ctsocumoo G lt Endo-vol. 19-n.3,pp. 210-213, see http://www.d-p-s.uk.com/comfort-zone/downloads/Endox%20ROME%20 papaer.pdf.
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12/813,565
Filing Date	June 11, 2010
First Named Inventor	Roberto Armanino
Art Unit	3732
Examiner Name	Not yet known
Sheet 1 of 2	Attorney Docket Number 7678.1035.1.1

U.S. PATENTS

Examiner Initials*	Cite No.	Patent Number	Issue Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	4,175,565	11-27-1979	Chiarenza et al.	
	2	4,291,125	09-22-1981	Greatbatch	
	3	4,854,865	08-08-1989	Beard et al.	
	4	5,383,935	01-24-1995	Shirkhanzadeh	
	5	5,462,644	10-31-1995	Woodson	
	6	5,725,377	03-10-1998	Lemler et al.	
	7	6,273,720	08-14-2001	Spalten	
	8	6,413,498	07-02-2002	Malmagro	
	9	6,482,309	11-19-2002	Green et al.	
	10	6,555,055	04-29-2003	Cisar et al.	
	11	6,778,861	08-17-2004	Liebrecht et al.	

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initials*	Cite No.	Publication Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	12	2004/0034395	02-19-2004	Dick	
	13	2006/0144718	07-06-2006	Lambie	
	14	2006/0265026	11-23-2006	Madjar et al.	
	15	2006/0293724	12-28-2006	Kronberg et al.	

EXAMINER SIGNATURE

Examiner Signature	/Matthew Saunders/	Date Considered	02/11/2013

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.S./

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12813565	ARMANINO, ROBERTO
	Examiner	Art Unit
	JOHN J WILSON	3732

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/19/2012	04/19/2012	02/11/2013						
	1	✓	✓	✓						
	2	✓	✓	✓						
	3	✓	✓	✓						
	4	✓	✓	✓						
	5	✓	✓	✓						
	6	✓	✓	✓						
	7	✓	✓	✓						
	8	✓	✓	✓						
	9	✓	✓	✓						
	10	✓	✓	✓						
	11	✓	✓	✓						
	12	✓	✓	✓						
	13	✓	✓	✓						
	14	✓	✓	✓						
	15	✓	✓	✓						
	16	✓	✓	✓						
	17	✓	✓	✓						
	18	✓	✓	✓						
	19	✓	✓	✓						
	20	✓	✓	✓						
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	22	✓	✓	✓						
	23	✓	✓	✓						
	24	✓	✓	✓						
	25	✓	✓	✓						
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	32			✓						
	33			✓						
	34			✓						
	35			✓						

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L6	3047	433/29,32,102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/02/11 13:11
L7	1453	604/60,41,44,46,48,49.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/02/11 13:11
L8	88	(l6 or l7) and (electric near field)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/02/11 13:12
L9	32	l8 and probe	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/02/11 13:12
S1	2	"20100047735"	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT; IBM_TDB	OR	ON	2012/07/18 08:52
S2	9	US-20080199830-$.DID. OR US-20040101809-$.DID. OR US-20070105799-$.DID. OR US-20030060856-$.DID. OR US-6593130-$.DID. OR US-4352852-$.DID. OR US-6419642-$.DID. OR US-20020090594-$.DID. OR US-20060286511-$.DID.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/18 08:52
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S10	43	S9 and (steraliz$5 or disinfect$3 or sanatize$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/01/24 20:01
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S28	4	S27 and (microbe or bateria$3 or pathogen)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/02/11 11:04

S29	2	S28 and selective	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/02/11 11:05
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Un nuovo protocollo terapeutico in endopedodonzia: caso clinico

A new therapeutic protocol for paediatric endodontics: a case report

RIASSUNTO

Scopo: presentare la procedura clinica di utilizzo dell'apparecchio ENDOX®, Endodontic System in endopedodonzia.

Sommario
Il trattamento dell'elemento deciduo con compromissione pulpare si rende necessario per molteplici ragioni: la terapia non è, infatti, solo di tipo sintomatico, volta cioè all'eliminazione del dolore, ma rientra in un programma più ampio di tipo preventivo.
In questo lavoro viene presentato un caso clinico nel quale è stato usato un dispositivo elettronico che, sotto controllo endometrico, invia impulsi calibrati di corrente ad alta frequenza per la sterilizzazione del sistema scanalare. La procedura clinica è risultata di facile attuazione ed è stato raggiunto sia un buon grado di disinfezione dei canali trattati che un'ottima compliance da parte del paziente grazie ai tempi clinici ridotti. Il caso illustrato mostra come l'utilizzo di tale apparecchio renda il trattamento endodontico degli elementi dentali della serie decidua sicuro e rapido, incrementando il successo terapeutico.

Punti chiave di apprendimento:
- La necessità di recupero dei decidui con compromissione pulpare.
- La terapia endodontica dei decidui.
- L'utilizzo dell'ENDOX®, Endodontic System in endopedodonzia.

ABSTRACT

Aim: to illustrate the clinical use ENDOX®, Endodontic System in paediatric endodontics.

Summary
The treatment of the deciduous teeth with irreversible pulpitis is often mandatory, due to many reasons: the endodontic treatment, in fact, is not only required to eliminate pain and/or discomfort, but it is part of a comprehensive therapeutic plan of dental prevention, as well. To achieve more predictable and consistent results a new technique has been developed, with the aid of an electronic device which transmits specific impulses to increase disinfection of the ndodontic space. The clinical procedure is described in the present case report and was found to be easy to perform and comfortable for the young patients . It is felt that the clinical use of the tested device is an aid to make endodontic treatment of the deciduous teeth more easy and rapid, thus increasing success rate

Key learning points:
- Why and when deciduous teeth must be endodontically treated.
- Operative techniques to endodontically treat deciduous teeth.
- The clinical use ENDOX®, Endodontic System in paediatric endodontics.

Lila Beach, April 2006
Translation of article: "Un nuovo protocol terapeutico in endopedondonzia: caso clinico
"A new therapeutic protocol for paediatric endodontics: a case report"
From publication indicated on front page.

Introduction

The anatomic peculiarity and physiological process of root reabsorption make paediatric endodontics a science subject to continuous adaptations in order to reach the final objective, that is to eliminate pain that afflicts young patients, resolve inflammation, restore the function and maintain the tooth in the dental arch. Currently deciduous elements are considered of extraordinary importance, as they have been recognized as a fundamental for the harmonious growth of maxillary function as well as the masticatory, phonetic and aesthetic functions. In the light of this fundamental supposition the motivation of the paediatric endodontist to maintain the deciduous elements in the oral cavity of a child is the consideration that it is the best way to maintain the space because without interfering with the eruption of the permanent tooth, it maintains in a uniform and constant way the space in the three dimensions, impeding the extrusion of the antagonist tooth and consents an adequate bone and periodontal support of the underlying permanent tooth, facilitating the eruption (1). It should be made clear that the mixed dentition is a dynamic entity that poorly adapts to space maintainers, which are static elements.

All researchers now underline the role of bacteria and their secondary products in the etiology of the disease of the pulp and periapical tissues. It is well known that infectious or non infectious pulp necrosis provokes almost constantly a delay in root absorption of the deciduous element, while an abscess on the deciduous necrotic element can impede the normal mineralization of the underlying permanent tooth. As a consequence of this affirmation, the most important and fundamental objective of the endodontic treatment of a deciduous element is the elimination of microrganisms situated in the radicular canal system. Considering the variety of bacteria present in the oral cavity and also in the infected root canal space, results most important the use of all mechanical and chemical means of ample spectrum of bactericide action. Today, traditional endodontics use substances able to unite the mechanical action to removal of bacteria in the root canal space with a cleansing disinfecting action that are more and more efficient and this allows for a higher increase in success in modern endodontics. The operator must know the objectives, know how to choose the type of solution and the method of irrigation and must know as well what influence the morphology of the canal can have with the action of the irrigating substances while all of this is even more important in paediatric endodontics, especially because of the peculiar anatomy of the canals. In order to optimize the phases of cleansing and disinfection of the odonto, the scope of this study has been that of evaluating the efficacy of an operative protocol in paediatric endodontics that uses an alternative system to conventional methods, that is, to use an electronic device to facilitate the execution of an operative therapy bettering the microbiological control and reducing drastically operating time. The principle of functioning of the device, Endox® (fig 1) is based on an electronic function that upon measuring the apex, sends a calibrated impulse of high frequency current vehicled by a fine electrode (needle) inserted into the radicular canal. These high frequency impulses go through the pulp tissue and its ramifications and vaporizes the finer parts (lateral canals and apical delta), while reducing the volume of the pulp in the radicular canal, facilitating its removal. The elimination of the bacteria and the consequent passage of electrical current and the electromagnetic field that is developed, such effect derives from multiple mechanisms, in particular electroporation, a method used in genetic engineering to alter transitorily the permeability of the cell membrane. Such an increase in impermeability is demonstrated as sufficient to inactivate microrganisms found in the radicular canal system including dentinal tubules.

High frequency current (9), in addition determines in particular conditions (low resistance present in the apex and in correspondence to lateral canals) a rapid and elevated increase in temperature that causes the vaporization (thermoblation) of the pulp tissue and at least a conspicuous volume reduction, which facilitates its removal. The increase in temperature inside the canal does not transmit to nearby tissue, for example the periodontium in which the increase is registered in a few degrees Celsius.

From studies reported in literature, the use of this device in infected canals seems to determine a reduction of the bacteria population of more than 99%. Through the introduction into the canal of a fine surgical steel needle, a brief and calibrated impulse of high frequency current (312Hz) for about one tenth of a second.

Two electrodes are attached to the equipment, a neutral electrode to be held in the patient's hand and another positive electrode, needle probe in which a needle of varying size based on the canal lumen of the tooth to be treated.

The equipment has an apical measurement function, which is based on the method of electronic impedance, low resistance between the needle and the oral mucosa can cause a false reading (example: saliva, acute caries, dental fractures etc). The tooth on which it is to be used should result on the external part, dry and clean avoiding all contact between the needle and any metal parts. On the control panel of the equipment there are tooth selection buttons, providing a proper frequency for different teeth to be treated; four selections are available: incisor, canine, premolar and molar. Upon reaching the proper length it is possible to commute the equipment from apical measurement function to the function for electrical impulses by pressing a foot pedal. In this phase the equipment commutes in 3-4 seconds and is ready for a high frequency impulse in the area where we have established to work. In open apex canals the ray of action from the tip of needle is about 1.2mm, therefore considering the length of the canal will require multiple impulses.

The scope of this study is to evaluate the bactericide effect of Endox in treatments of deciduous teeth that present irreversible pulpathy, evaluating the effective capacity of disinfection, the reliability of its use, the tolerability of paediatric patients during treatment.

Clinical Case

The patient is 8 years old and comes for visit of control. Upon the clinical examination a fistula is located in correspondence with element 8.4 (fig 2). A digital intraoral periapical ex-ray was done, it was possible to observe a vast area of osteolysis both to the root fork and to the distal canal of the element observed. (fig 3)

An endodontic treatment was done for the resolution of the lesion and the conservation in arch of the element until its physiological exchange. Element 8.4 was isolated with a rubber dam; disinfected the operator field with chlorhexidine 2%, the pulp chamber was opened with a round bur 0,14 mounted on an high speed handpiece using irrigation of sterile physiological solution from the internal circuit of the dental chair. (fig 4) Once the openings of the root canals were visible, file n15 was used to verify the patency and evaluate the anatomy. The cleansing with physiological solution was done, because the use of hypochlorite is not recommended to be used with the equipment, the explanation resides in the fact that an eventual residual of this substance in the apical zone would crystallize with an effect that would immediately be pushed outside the apex with an instantaneous increase in temperature that is had following the electrical impulse.

After drying with sterile paper cones from 20 to 30, the first microbiological collection was made (fig 5) with sterile paper cones held inside the canal for about one minute and then placed in a sterile phial containing 2ml of physiological solution for suitable transport. After the first collection, the canals were treated with Endox® with an appropriate needle (fig 6) (red needle length 24mm 0.15 diam) and from the pre-operatory ex-ray it was possible to see that the lesion originated in the distal canal: for this reason more electromagnetic impulses near the opening and in the third apical (fig7) were performed. It was necessary in order to allow the needle to enter the canal to enlarge the entrance of the canal opening with a ProFile 0.4 followed by cleansing with physiological solution.

At the end of the treatment, a second endodontic collection was made following the same procedure as the first.

The canals were then filled with pure zinco oxide eugenol. The patient as called back after one week for the final reconstruction of the crown in composite and to verify the retraction of the fistula process (fig8). Later, it was monitored by controls at a distance of one month to evaluate the healing of the periapical lesion (fig9).

The samples collected were sent to the laboratory and an aerobic culture was performed to evaluate the CFU (Unit Forming Colonies). Three different culture mediums were used to develop bacterial colonies and mycete communities: the first culture (Agar blood salt mannitol Mac Conkey) to develop cocci and bacill, a second culture (Saburò) for eventual mycetes and a third culture (plain Agar Muller-Hinton) specifically for enterococcus faelcalis. The cultures were set up for 48 hours at 37° C in Mac-sud ovens and then sent to be read with electronic readers Mini-Api to count the colonies developed.

Results

From the results obtained in this research it is concluded that good capacity of disinfection is reached in the canals treated. This is confirmation both by laboratory tests through the identification of the CFU. (CFU pre-treatment ±145.000, CFU post treatment ±11.000) that provides clinical evaluation in reference to the phlogistic process of the element examined; in addition a certain degree of osteoinduction promoted by the piezoelectric effect determined by the application of the electromagnetic field.

Conclusions

Our objective was to analyze the *in vitro* antibacterial activity and the tolerability of the new method on paediatric patients. Examining the results it is possible to affirm that the operative protocol offers excellent guarantees for its use, however the most important function is certainly the possibility to have control of disinfection in the endodont in a simple way, and above all no pain results and time in the chair is reduced, these characteristics well adapt to the use of this therapeutic procedure in the field of paediatric endodontics.

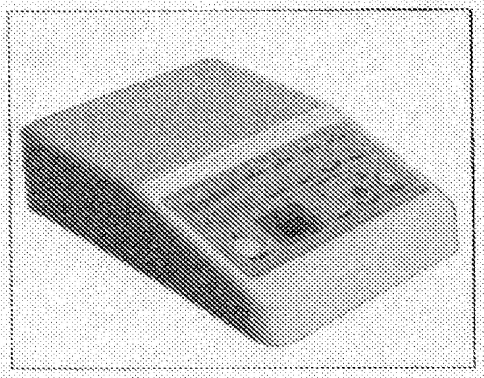

Fig. 1 - *L'ENDOX®.*

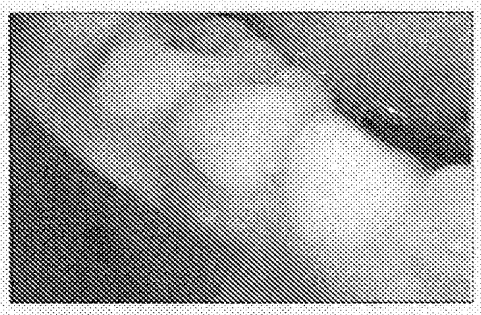

Fig. 2 - *5.4 necrotico con fistola.*

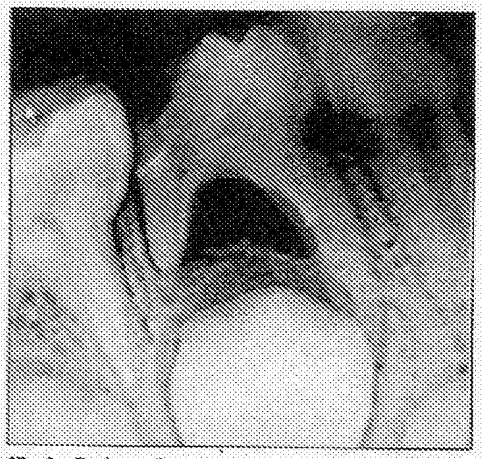

Fig. 3 - *Radiografia preoperatoria.*

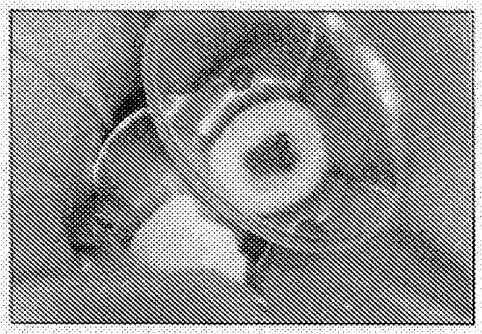

Fig. 4 - *Apertura camera.*

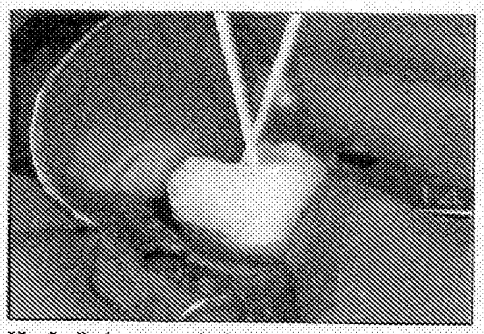

Fig. 5 - *Prelievo microbiologico.*

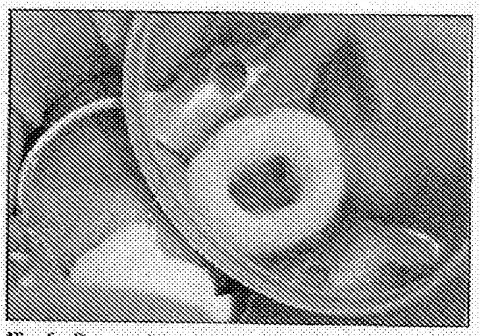

Fig. 6 - *Penetrazione sonda.*

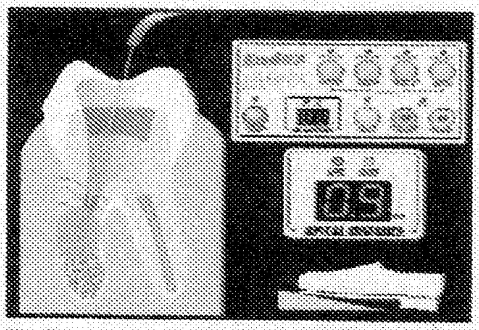

Fig. 7 - *Impulsi elettromagnetici.*

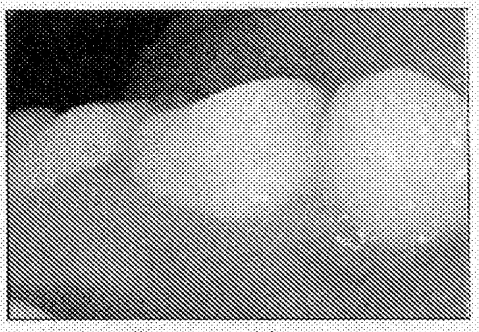

Fig. 8 - *Controllo a 5 giorni dal trattamento.*

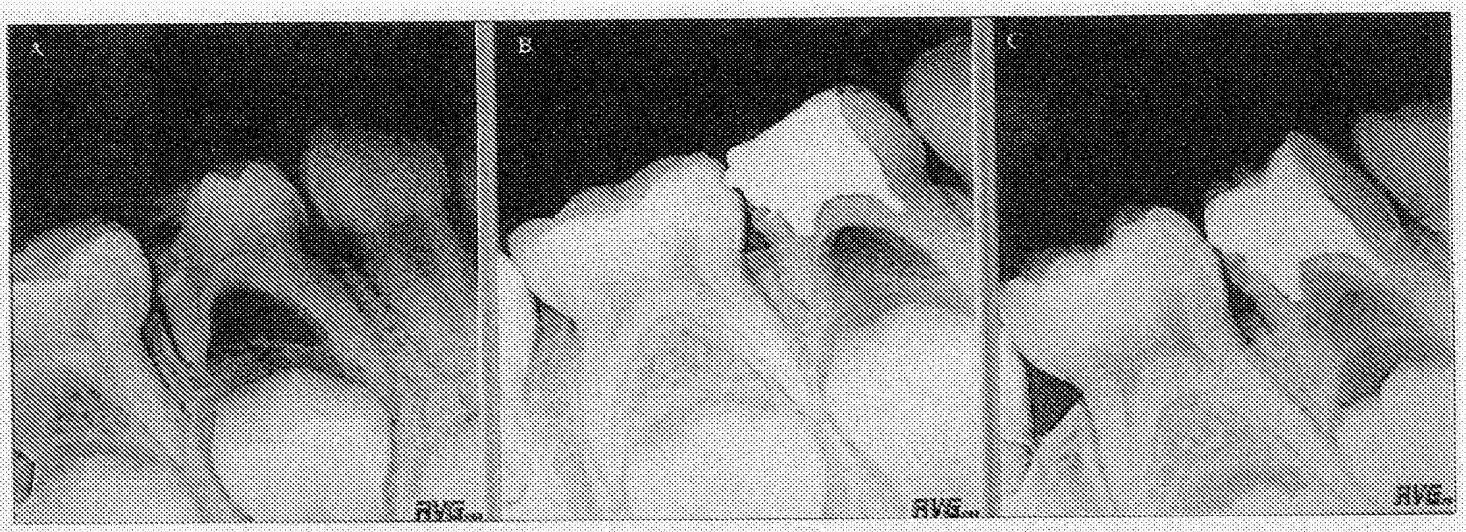

Fig. 9 - Radiografie: A) preoperatoria, B) controllo a 1 mese, C) controllo a 3 mesi.

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
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	Examiner	Art Unit
	JOHN J WILSON	3732

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Class	Subclass	Date	Examiner
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SEARCH NOTES		
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IDS reference search	2/11/2013	MPS
EIC plus search	2/11/2013	MPS
Forward and Backwards search of relevent art	2/11/2013	MPS
Keyword in combination with classification (electric, field, microbe, poration, etc.)	2/11/2013	MPS
IDS reference search	2/11/2013	MPS

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/MATTHEW SAUNDERS/ Examiner.Art Unit 3732	

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/813,565	06/11/2010	Roberto Armanino	7678.1035.1.1	7247

22913 7590 07/24/2012

Workman Nydegger
1000 Eagle Gate Tower
60 East South Temple
Salt Lake City, UT 84111

EXAMINER	
SAUNDERS, MATTHEW P	
ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
07/24/2012	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docketing@wnlaw.com

Applicant-Initiated Interview Summary	**Application No.** 12/813,565	**Applicant(s)** ARMANINO, ROBERTO	
	Examiner MATTHEW SAUNDERS	**Art Unit** 3732	

All participants (applicant, applicant's representative, PTO personnel):

(1) *MATTHEW SAUNDERS*.

(2) *Cris Rodriguez*.

(3) *John M. Guynn*.

(4) *Kelli Tyree*.

Date of Interview: *18 July 2012*.

Type: ☐ Telephonic ☐ Video Conference
☒ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☒102 ☐103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1*.

Identification of prior art discussed: *Valle, Fontenot, Weiss*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

No decision was made regarding the prior art of record. The proposed amemendment seems to raise issues of 101. Further consideration of issues pertaining to Valle et al. and the mechanisms of action would be focused on.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/MATTHEW P SAUNDERS/ Examiner, Art Unit 3732	/Cris L. Rodriguez/ Supervisory Patent Examiner, Art Unit 3732

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	12/813,565	Filing Date	2010-06-11	Docket Number (if applicable)	7678.1035.1.1	Art Unit	3732
First Named Inventor	Roberto Armanino			Examiner Name	Matthew Saunders		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☐ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 233178

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/John M. Guynn, 36,153/	Date (YYYY-MM-DD)	2012-07-20
Name	John M. Guynn	Registration Number	36153

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	12813565
Filing Date:	11-Jun-2010
Title of Invention:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION
First Named Inventor/Applicant Name:	Roberto Armanino
Filer:	John Michael Guynn
Attorney Docket Number:	7678.1035.1.1

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	1202	10	60	600
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	1801	1	930	930
		Total in USD ($)		**1530**

Electronic Acknowledgement Receipt

EFS ID:	13306192
Application Number:	12813565
International Application Number:	
Confirmation Number:	7247
Title of Invention:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION
First Named Inventor/Applicant Name:	Roberto Armanino
Customer Number:	22913
Filer:	John Michael Guynn
Filer Authorized By:	
Attorney Docket Number:	7678.1035.1.1
Receipt Date:	20-JUL-2012
Filing Date:	11-JUN-2010
Time Stamp:	20:49:50
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1530
RAM confirmation Number	6247
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1		7678-1035-1-1AmendB.pdf	158613 99b6d966d487cd575c187528180e58c583c6dd99	yes	14

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment Submitted/Entered with Filing of CPA/RCE	1	1
Claims	2	6
Applicant Arguments/Remarks Made in an Amendment	7	14

Warnings:					
Information:					
2	Request for Continued Examination (RCE)	7678_1035_1_1_RCE.pdf	706021 12cb9abebb56adaaf4eb590bbf034eaa380747ff	no	3
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	32111 37f756ae579b8f16a61c4b87c38c71c88d1bf5ed	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	896745		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
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.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
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.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

FILED ELECTRONICALLY

PATENT APPLICATION
Docket No. 7678.1035.1.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:		)
	Roberto Armanino	)
Serial No.:	12/813,565	) Art Unit 3732
Filed:	June 11, 2010	)
Confirmation No.:	7247	)
For:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION	)
Examiner:	Matthew Saunders	)
Customer No.:	022913	)

AMENDMENT "B" AND RESPONSE

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Final Office Action of April 20, 2012, and concurrent with filing a Request for Continued Examination, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Previously Presented) A method for disinfecting a root canal preparation of a patient, comprising:

electrically connecting a ground electrode to a body of the patient so as to provide an electrical ground;

inserting a monopolar probe into a root canal preparation of a tooth of the patient; and

applying an electrical voltage between the ground electrode and the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal preparation, the electric field interacting with and killing microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue.

2. (Original) A method as recited in claim 1, wherein the root canal preparation contains an aqueous conducting fluid when the electrical voltage is applied.

3. (Previously Presented) A method as recited in claim 2, wherein the aqueous conducting fluid does not include a chemical disinfectant such that the electric field kills the microbes without assistance of a chemical disinfectant.

4. (Previously Presented) A method as recited in claim 2, wherein the aqueous conducting fluid comprises a chemical disinfectant that assists the electric field in killing the microbes.

5. (Original) A method as recited in claim 4, wherein the chemical disinfectant comprises aqueous sodium hypochlorite.

6. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage in a range of about 1 volt to about 10,000 volts.

7. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage in a range of about 250 volts to about 2000 volts.

8. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage in a range of about 500 volts to about 1500 volts.

9. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage over a time duration in a range of about 10 nanoseconds to about 30 seconds.

10. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage over a time duration in a range of about 0.001 second to about 5 seconds.

11. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage over a time duration in a range of about 0.01 second to about 4 seconds.

12. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage that is pulsed, wherein individual pulses of the electric voltage have a time duration in a range of about 1 nanosecond to about 1000 milliseconds.

13. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage that is pulsed, wherein individual pulses of the electric voltage have a time duration in a range of about 5 nanoseconds to about 500 milliseconds.

14. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage that is pulsed, wherein individual pulses of the electric voltage have a time duration in a range of about 1 millisecond to about 200 milliseconds.

15. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises applying a number of individual pulses in a range of 2 to about 50 million.

16. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises applying a number of individual pulses in a range of about 10 to about 3 million.

17. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises applying a number of individual pulses in a range of about 15 to about 500,000.

18. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises providing a rest time between individual pulses in a range of about 1 second to about 5 seconds.

19. (Original) A method as recited in claim 1, wherein applying an electrical voltage results in virtually no electrical current flow between the monopolar probe inserted within the root canal preparation and the ground electrode.

20. (Original) A method as recited in claim 1, wherein the monopolar probe inserted within the root canal preparation comprises silver.

21. (Original) A method as recited in claim 1, wherein the ground electrode further comprises an adhesive pad for holding the ground electrode to gingival tissue.

22. (Original) A method as recited in claim 1, wherein the monopolar probe has a length in a range of about 12 mm to about 20 mm.

23. (Original) A method as recited in claim 1, wherein the monopolar probe has a diameter in a range of about 0.06 mm to about 1 mm.

24. (Currently Amended) A method for disinfecting a root canal preparation of a patient, comprising:

providing a root canal preparation of the patient's tooth that contains an electrically conductive fluid;

electrically connecting a ground electrode to gingival tissue of the patient so as to provide an electrical ground;

inserting a monopolar probe into a root canal preparation of a tooth of the patient; and

applying an electrical voltage between the ground electrode and the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal preparation, the electric field interacting with and killing microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue, the electric field causing at least one of disruption of microbe cell walls or an inner biological mechanism of microbes that results in killing of the microbes.

25. (Currently Amended) An apparatus for use in disinfecting a root canal preparation of a patient, comprising:

means for electrically connecting a ground electrode to a body of a patient so as to provide an electrical ground;

a monopolar probe sized and configured for insertion into a root canal preparation of a tooth of a patient; and

means for applying an electrical voltage between the ground electrode and the monopolar probe when inserted within a root canal preparation so as to produce an electric field within the root canal preparation that interacts with and kills microbes within the root canal preparation by at least one of disruption of microbe cell walls or an inner biological mechanism of microbes that results in killing of microbes without damage to or ~~substantial~~ heating of surrounding dental tissue by more than about 10°C.

26. (New) A method as recited in claim 12, wherein there is a rest time between individual pulses in which the rest time is in a range of about 0.5 second to about 10 seconds.

27. (New) A method as recited in claim 12, wherein there is a rest time between individual pulses in which the rest time is in a range of about 1 second to about 5 seconds.

28. (New) A method as recited in claim 1, the electric field interacting with and killing microbes by electroporation and disruption of microbe cell walls.

29. (New) A method as recited in claim 1, the electric field interacting with and killing microbes by microbe apoptosis causing an inner biological mechanism that results in killing of the microbes.

30. (New) A method as recited in claim 1, the method resulting in at least a 2 log reduction of microbes within the root canal preparation.

31. (New) A method as recited in claim 1, the method resulting in at least a 3 log reduction of microbes within the root canal preparation.

32. (New) A method as recited in claim 1, the method resulting in at least a 4 log reduction of microbes within the root canal preparation.

33. (New) A method as recited in claim 1, the electric field heating surrounding dental tissue by less than about 10°C.

34. (New) A method as recited in claim 1, the electric field heating surrounding dental tissue by less than about 5°C.

35. (New) A method as recited in claim 1, the electric field heating surrounding dental tissue by less than about 2°C.

REMARKS

Applicant and Applicant's attorneys express appreciation to the Examiner and the Examiner's supervisor for the courtesies extended during the recent interview held on July 18, 2012. Reconsideration and allowance for the above-identified application are now respectfully requested. Claims 1-35 are pending, wherein claims 24 and 25 have been amended and new claims 26-35 were added in order for Applicant to more particularly claim what he regards as his invention.

As discussed during the Examiner Interview, the claimed methods differ from the cited art in that the claimed methods utilize an electric field to kill microbes (*e.g.*, through electroporation of the microbe cell walls) without damage to or substantial heating of surrounding dental tissue. In contrast, one of the cited art references specifically causes vaporization and thermoblation of pulp tissue and the other cited art involves applying a current to human cells to facilitate permeation of antimicrobial agents into human tissues and cells.

The Office Action rejects claims 1, 9-14, 24 and 25 under 35 U.S.C. § 102(b) as being anticipated by the Valle et al. article ("Valle"). As discussed and agreed to during the Examiner interview, Valle does not anticipate the claimed invention because Valle specifically describes "vaporization" and "thermoblation" of pulp tissue to facilitate its removal. In contrast, claim 1 as previously presented claims, in combination with the other recited elements, "applying an electrical voltage … to produce an electric field within the root canal preparation … without damage to or substantial heating of surrounding dental tissue." Vaporization and thermoblation both require "substantial heating" and therefore Valle does not anticipate the claimed invention. Nor would it be obvious to modify Valle in such a manner as to prevent the disclosed method from "vaporization" and "thermoblation" of pulp tissue as these are important and critical steps to the method in Valle. Accordingly, the claims are patentable and unobvious over Valle, alone or if combined with any other art of record.

The Office Action rejects claims 2-19 under 35 U.S.C. § 103(a) as being unpatentable over Valle. For the reasons given above, claims 2-19, which depend from claim 1, are patentable over Valle, alone or if combined with any other art of record. Moreover, claims 2-19 recite additional elements that may further distinguish over Valle. For example, claims 2-19 recite specific parameters for achieving the type of electric field recited in claim 1, which kills microbes "without damage to or substantial heating of surrounding dental tissue". Because Valle discloses a method that causes "vaporization" and "thermoblation" of pulp tissue, it would not

have been obvious how or why to select parameters and modify Valle in such a way as to cause formation of the electric field as recited in claim 1

The Office Action rejects claims 20 and 21 under 35 U.S.C. § 103(a) as being unpatentable over Valle in view of Fontenot (US 2008/0199830). Fontenot was cited as allegedly disclosing the use of a silver probe but otherwise fails to cure the deficiencies of Valle noted above. For example, using a silver probe would not be expected to, by itself and without further modification of Valle, create the type of electric field defined in claim 1.

The Office Action rejects claim 22 under 35 U.S.C. § 103(a) as being unpatentable over Valle in view of Riitano et al. (US 2002/0090594). Riitano was cited as allegedly disclosing the length of the instrument but otherwise fails to cure the deficiencies of Valle noted above. For example, using a specific length of probe would not be expected to, by itself and without further modification of Valle, create the type of electric field defined in claim 1.

The Office Action rejects claim 23 under 35 U.S.C. § 103(a) as being unpatentable over Valle in view of Aleksandrovskiy et al. (US 2006/0286511). Aleksandrovskiy was cited as allegedly disclosing the diameter of the instrument but otherwise fails to cure the deficiencies of Valle noted above. For example, using a specific diameter of probe would not be expected to, by itself and without further modification of Valle, create the type of electric field defined in claim 1.

The Office Action rejects claims 1-6, 20, 21, 24 and 25 under 35 U.S.C. § 103(a) as being unpatentable over Fontenot in view of Weiss et al. (US 2004/0101809). As discussed during the Examiner Interview, Fontenot discloses devices "for the active *delivery of medicaments* into hard and soft tissues, particularly those of the oral cavity. The devices apply an AC voltage with a DC offset to *drive medicaments into the tissues*." Abstract (emphasis added). Similarly, and as further discussed, Weiss discloses "*mobilizing a medicament into the dentinal wall of a tooth* comprising a charged substance within a cavity of a tooth and subjecting the substance to an electric charge." Abstract (emphasis added). Accordingly, the combination of Fontenot and Weiss involves forcing a medicament into human tissue and cells through the use of electric power or an electric charge. In both references, as well as the combination thereof, the purpose of the disclosed methods is to improve movement of a *medicament* into human tissue so that the *medicament* is more effective in performing its intended function, such as providing antimicrobial activity. Thus, even if one were to combine Fontenot and Weiss, the combination would neither teach nor suggest the method of claim 1 as amended, which includes:

electrically connecting a ground electrode to a body of the patient so as to provide an electrical ground;

inserting a monopolar probe into a root canal preparation of a tooth of the patient; and

applying an electrical voltage between the ground electrode and the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal preparation, *the electric field interacting with and killing microbes* within the root canal preparation without damage to or substantial heating of surrounding dental tissue.

As further discussed during the Examiner Interview, the discussions in Fontenot and Weiss relative to "electroporation" are both in connection with increasing permeability of *human* cells through electroporation to more quickly diffuse medicaments into the cells and tissue. As further discussed, human cells are eukaryotic cells, which are quite different from microbe cells, which are prokaryotic cells. They have very different cell walls and would be expected to react very differently to different types of chemical or electrical stimuli.

Moreover, the act of "the electric field interacting with and killing microbes" is an affirmative act performed according to the method of claim 1. It is not simply a desired result. Nor is the claimed act inherently performed by Fontenot and Weiss. If the methods of Fontenot and Weiss could directly kill microbes with an electric field, there would be little point in Fontenot and Weiss both disclosing the necessity and importance of opening up and forcing medicaments into human cells or tissue in order to kill microbes. And for something to be obvious by inherency, the claim element in question must have been known to be present in the prior art at the time of the invention. There is no evidence from which it can be reasonably concluded that the methods in Fontenot and Weiss inherently involve "*the electric field interacting with and killing microbes*" and, moreover, that this was known at the time of the invention. To assert that they do and this was known at the time of the invention without supporting evidence would be using Applicant's own disclosure against Applicant. Instead, there must be objective evidence that the missing step was both inherently present and known to be present at the time of the invention. Reliance on Applicant's own disclosure does not meet this evidentiary burden.

In any event, Fontenot and Weiss fail to teach or suggest applying an electric field across a root canal preparation in a manner so that *the electric field itself* interacts with and kills microbes without damaging or substantially heating surrounding dental tissue. In view of the foregoing, Applicant submits that claim 1 is patentable an unobvious over the combination of Fontenot and Weiss.

During the Examiner Interview it was suggested that the step of "the electric field interacting with and killing microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue" might be a "law of nature" and therefore raises an issue under 35 U.S.C. § 101. In response, Applicant submits that the combination of killing microbes without damage to or substantial heating of surrounding dental tissue is not a law of nature. That is clear from the teachings of Valle in which microbes are killed while causing extreme damage to pulp tissue by vaporization or thermoblation. Moreover, even if killing microbes with an electric field were somehow a law of nature, it is most certainly a practical application of the law of nature and is defined in such a way that it does not preempt all possible applications of this "law of nature". Accordingly, the claims fully satisfy the requirements of 35 U.S.C. § 101 and do not attempt to claim a law of nature in such a way as to preempt all applications of the law of nature.

Independent claims 24 and 25 are similarly patentable over the combination of Fontenot and Weiss for substantially the same reasons given above relative to claim 1. In addition, they were amended to further specify that "the electric field caus[es] at least one of disruption of microbe cell walls or an inner biological mechanism of microbes that results in killing of the microbes. *See* Application, paragraphs 0032-0033. Fontenot and Weiss do not disclose or suggest any such act (claim 24) or means for performing this act (claim 25). Accordingly, claims 24 and 25 are further patentable over the art of record for this additional reason.

Claim 25 was further amended to claim "means for applying an electrical voltage … so as to produce an electric field … without damage to or heating of surrounding dental tissue by more than about 10°C. *See* Application, paragraph 0012. The cited art neither teaches nor suggests apparatus having the claimed "means for applying an electrical voltage" as now defined. For this additional reason, claim 25 is further patentable over the art of record.

Claims 2-6, 20 and 21 depend from claim 1 and are therefore patentable over the combination of Fontenot and Weiss for at least the reasons given above relative to claim 1. In addition, they recite additional elements that may further distinguish over the prior art of record.

For example, claim 3 further claims "wherein the aqueous conducting fluid does not include a chemical disinfectant such that the electric field kills the microbes without assistance of a chemical disinfectant". Because both Fontenot and Weiss require an antimicrobial agent when killing microbes, they neither teach nor suggest a method in which "the aqueous conducting fluid does not include a chemical disinfectant such that the electric field kills the microbes without assistance of a chemical disinfectant." It is not enough, as implied in the Office Action, to affirmatively perform the act of claim 1 in order to render claim 3 obvious over Fontenot and Weiss. It must be shown that Fontenot and Weiss disclose or suggest performing the specific method step of claim 3, in which the "aqueous conducting fluid does not include a chemical disinfectant". Because Fontenot and Weiss both require a chemical disinfectant to kill microbes, they do not suggest the specific act recited in claim 3.

Claim 5 further claims "wherein the chemical disinfectant comprises aqueous sodium hypochlorite". Weiss discloses extracting teeth and then cleaning the *extracted teeth* with sodium hypochlorite (paragraph 0112). This use of sodium hypochlorite occurs *after* the tooth has been extracted and *before* applying an electric field to the teeth. Weiss then teaches that the sodium hypochlorite is flushed out of the extracted tooth using EDTA solution, followed by introducing calcium hydroxide (pH = 12.5) into the root canal space prior to applying an electric field (*id.*). In contrast, claim 5 utilizes sodium hypochlorite to assist the electric field in killing microbes in a "root canal preparation of a patient" (*i.e.*, while the tooth is still in the patient's mouth).

The Office Action rejects claims 7 and 8 under 35 U.S.C. § 103(a) as being unpatentable over Fontenot in view of Weiss et al., and further in view of Hermanson (US 2007/0105799). Hermanson was only cited as allegedly disclosing the claimed voltages but otherwise fails to teach or suggest the method of claim 1, in which "the electric field interact[s] with and kill[s] microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue". Hermanson only discloses "electroporation" in the context of "electrically-assisted plasmid delivery". Paragraph 0323. Hermanson, like Fontenot and Weiss, utilizes electric energy to help deliver an agent to human cells but fails to teach or suggest the claimed method in which the electric field itself interacts with and kills microbes rather than simply enhancing the effects of an antimicrobial agent.

The Office Action rejects claims 9-17 under 35 U.S.C. § 103(a) as being unpatentable over Fontenot in view of Weiss et al., and further in view of Chornenky et al. (US

2003/0060856). Chornenky was only cited as allegedly disclosing the claimed time and pulse rate ranges but otherwise fails to teach or suggest the method of claim 1 in which "the electric field interact[s] with and kill[s] microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue". Chornenky et al. only discloses "electroporation" in the context of "treatment of benign prostatic hyperplasia". Abstract. Thus, Chornenky et al., like Fontenot and Weiss, utilizes electric energy to primarily interact with human cells (*i.e.*, eukaryotic cells), not microbes (*i.e.*, prokaryotic cells, which are quite different from eukaryotic cells in structure and function), and fails to teach or suggest the claimed methods.

The Office Action rejects claim 18 under 35 U.S.C. § 103(a) as being unpatentable over Fontenot in view of Weiss and Chornenky, and further in view of Sen et al. (US 6,593,130). Sen et al. was only cited as allegedly disclosing the claimed rest time range but otherwise fails to teach or suggest the method of claim 1 in which "the electric field interact[s] with and kill[s] microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue". Sen et al. only discloses "electroporation" in the context of "gene, protein or drug therapy" in an "organ". *See* col. 1, lines 14-18. Thus, Sen et al., like Fontenot and Weiss, utilizes electric energy to help deliver an agent to human cells (*i.e.*, eukaryotic cells) but fails to teach or suggest the claimed method, in which the electric field interacts with and kills microbes (*i.e.*, prokaryotic cells, which are quite different from eukaryotic cells in structure and function).

The Office Action rejects claim 19 under 35 U.S.C. § 103(a) as being unpatentable over Fontenot in view of Weiss, and further in view of Marchitto et al. (US 6,419,642). Marchitto was only cited as allegedly disclosing "using virtually no current" but otherwise fails to teach or suggest the method of claim 1 in which "the electric field interact[s] with and kill[s] microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue". Marchitto only discloses "electroporation" in the context of irradiation enhanced permeation and delivery of substances through skin. *See* Abstract. Thus, Marchitto et al., like Fontenot and Weiss, utilizes electric energy to help deliver an agent to human cells (*i.e.*, eukaryotic cells) but fails to teach or suggest the claimed method, in which the electric field interacts with and kills microbes (*i.e.*, prokaryotic cells, which are quite different from eukaryotic cells in structure and function).

The Office Action rejects claim 22 under 35 U.S.C. § 103(a) as being unpatentable over Fontenot in view of Weiss, and further in view of Riitano. Riitano was only cited as allegedly suggesting "the range of length for the instrument" but otherwise fails to teach or suggest the method of claim 1 in which "the electric field interact[s] with and kill[s] microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue". Riitano et al. does not in fact disclose or relate in any way to application of an electric field to a root canal preparation for any reason, much less to kill microbes, and is therefore irrelevant to the *method* of claim 22.

The Office Action rejects claim 23 under 35 U.S.C. § 103(a) as being unpatentable over Fontenot in view of Weiss, and further in view of Aleksandrovskiy. Aleksandrovskiy was only cited as allegedly disclosing "a range of diameter for the instrument" but otherwise fails to teach or suggest the method of claim 1 in which "the electric field interact[s] with and kill[s] microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue". Aleksandrovskiy does not in fact disclose or relate in any way to application of an electric field to a root canal preparation for any reason, much less to kill microbes, and is therefore irrelevant to the *method* of claim 23.

New claims 26-35 further define and claim aspects of the disclosed invention that distinguishes over the cited art. Support for new claims 26 and 27 is found at paragraph 0031 of the Application. The art of record neither teaches nor suggests the specific method steps of claims 26 and 27, which help create the electric field defined in claim 1

Support for new claims 28 and 29 is found at paragraphs 0032-0033 of the Application. The art of record neither teaches nor suggests the specific method steps of claims 28 and 29, which claim additional aspects of how the electric field of claim 1 operates to kill microbes.

Support for new claims 30-32 is found at paragraph 0034 of the Application. The art of record neither teaches nor suggests the specific method steps of claims 30-32, which claim additional aspects of how the electric field of claim 1 operates to kill microbes, particularly with respect to kill rate *by the electric field*.

Support for new claims 33-35 is found at paragraph 0012 of the Application. The art of record neither teaches nor suggests the specific method steps of claims 33-35, which claim additional aspects of how the electric field of claim 1 operates to kill microbes without substantial heating of surrounding tissue, particularly with respect to the temperature increase, if any, caused by the electric field.

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Dated this 20th day of July 2012.

Respectfully submitted,

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
12/813,565	06/11/2010	

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☐		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	07/20/2012	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 35	Minus	** 25	= 10	X $ =		OR	X $60=	600
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $ =		OR	X $250=	0
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	600

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/DENISE LILES/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/813,565	06/11/2010	Roberto Armanino	7678.1035.1.1	7247

22913 7590 04/20/2012

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EXAMINER	
WILSON, JOHN J	

ART UNIT	PAPER NUMBER
3732	

MAIL DATE	DELIVERY MODE
04/20/2012	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.

Office Action Summary	Application No.	Applicant(s)	
	12/813,565	ARMANINO, ROBERTO	
	Examiner	Art Unit	
	JOHN J. WILSON	3732	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2012*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-25* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-25* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

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 –
>
> (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.

Claims 1, 9-14, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Valle et al., "A new therapeutic protocol for paediatric endodontics: a case report". Valle teaches a method for disinfecting a root canal including the steps of electrically connecting a ground electrode to a patient, page 2, paragraph 5, inserting a monopolar probe into a root canal, see Figs. 6 and 7 on page 4, and applying an electric voltage to create an electric field that interacts with and kills microbes, page 2, paragraph 2, last 7 lines, while not damaging surrounding dental tissue, page 2, paragraph 3. As to claims 9-14, see page 2, paragraph 4. As to claim 25, Valle teaches the structure as claimed in the method as described above.

Claim Rejections - 35 USC § 103

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 negatived by the manner in which the invention was made.

Claims 2-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valle et al., "A new therapeutic protocol for paediatric endodontics: a case report" in view of Pond

(2010/0047735). Valle shows the method as described above, however, does not sow using an aqueous fluid. Pond teaches an electroporation method with a fluid [0058]-[0059] and that the fluid can be water [0039]. It would have been obvious to one of ordinary skill in the art to modify Valle to include the use of an aqueous fluid as taught by Pond in order to better clean and disinfect the canal [0016]. As to claim 6, Valle teaches using a high frequency current, however, does not state the voltage used. Pond teaches using a voltage in the range of 100-5000 V. It would have been obvious to one of ordinary skill in the art to modify Valle to include using a voltage as taught by Pond in order to better clean and disinfect the canal. As to claims 9-19, Pond further teaches that "However, it is understood that any operating parameters that would be used to improve the system would fall within the scope of the present invention." [0061], as such, the parameters in claims 9-19 would have been obvious to the skilled artisan in maximizing the system.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valle et al., "A new therapeutic protocol for paediatric endodontics: a case report" in view of Fontenot et al (2008/0199830). Valle does not show the use of a silver probe. Fontenot teaches using a silver probe [0029] [0060]. It would have been obvious to one of ordinary skill in the art to modify Valle to include the use of silver as shown by Fontenot in order to better create the electric field and disinfect the canal.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Valle et al., "A new therapeutic protocol for paediatric endodontics: a case report" in view of Riitano et al

(2002/0090594). Valle does not show a range of length for the instrument. Riitano teaches instruments used in a root canal and teaches a range of length of 8-35 mm [0136]. It would be obvious to one of ordinary skill in the art to modify Valle to include a length range as taught by Riitano in order to match the size of a root canal. The specific range is an obvious matter of choice in the degree of a known parameter.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Valle et al., "A new therapeutic protocol for paediatric endodontics: a case report" in view of Aleksandrovskiy et al (2006/0286511). Valle does not show a range of diameter for the instrument. Aleksandrovskiy teaches instruments used in a root canal and teaches a range of diameter of .2-1 mm [0010]. It would be obvious to one of ordinary skill in the art to modify Valle to include a diameter range as taught by Aleksandrovskiy in order to match the size of a root canal. The specific range is an obvious matter of choice in the degree of a known parameter.

Claims 1-6, 20, 21, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot et al (2008/0199830) in view of Weiss et al (2004/0101809). Fontenot teaches a method for delivering antimicrobial agents to a root canal [0064], and as such, teaches a method for disinfecting the root canal, the method includes electrically connecting a ground electrode 415, Fig. 13, inserting a monopolar probe 1300 into a root canal, and applying an electric voltage. Fontenot does not state the level of the electric field used with respect to heating of surrounding dental tissue. Fontenot, however, does teach the method can use electroporation [0053]-[0054]. Weiss teaches using an electric field in root canal treatment and teaches the need

to use a field so as to control the heat buildup [0086]-[0087]. It would be obvious to one of ordinary skill in the art to modify the method of Fontenot to include using a field that will prevent heating of tissue in order to prevent excess unintended tissue damage. With respect to the limitation of the field kills microbes or assists in killing microbes, all of the actual claimed steps and structure are shown, and as such, the shown method must inherently be capable of functioning as claimed. This same statement is true for meeting claim 3 because the shown field must be capable of killing microbes without assistance of a chemical disinfectant. As to claim 2, Fontenot teaches using a medicament 1310, however, does not state that it is an aqueous fluid. Fontenot describes using an aqueous medicament with respect to another embodiment [0041]-[0042]. It would be obvious to modify the embodiment of Fig. 13 to include an aqueous fluid as taught Fontenot as indicated above in order to best deliver the medicament to the desired site. As to claim 5, Weiss also teaches the use of sodium hypochlorite [0112]. As to claim 6, Fontenot teaches using 5 volts [0051]. As to claim 20, Fontenot teaches using silver [0029], [0060]. As to claim 21, Fontenot teaches the use of an adhesive pad [0043]. As to claim 24, Fontenot shows a prepared rood canal in Fig. 13. As to claim 25, Fontenot shows a connected electric ground 415, monopolar probe 1300, means for applying voltage 410, and structure used to kill microbes [0064], while as stated above Weiss teaches that such a device should be capable of producing a field that will not damage or substantially heat the tissue.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot et al (2008/0199830) in view of Weiss et al (2004/0101809) as applied above to claim 1, and further in view of Hermanson (2007/0105799). The above combination does not show a range of

volts used. Hermanson teaches an electroporation method that includes using a voltage range of 100-1500 volts. It would be obvious to one of ordinary skill in the art to modify the above combination to include a voltage range as taught by Hermanson in order to use the best voltage for electroporation of the medication. The specific range is an obvious matter of choice in the degree of a known parameter. It is further held, that in view of the teaching of Fontenot, parameters for electroporation such as voltage, current, distance between electrodes, medicament fluid used, are known parameters that one of ordinary skill in the art would find obvious to select in order to achieve expected results.

Claims 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot et al (2008/0199830) in view of Weiss et al (2004/0101809) as applied above to claim 1, and further in view of Chornenky et al (2003/0060856). The above combination does not show a treatment duration time range or pulse rate range. Chornenky teaches that for an electroporation method, duration and pulses are parameters that need to be considered for treatment [0058]. It would be obvious to one of ordinary skill in the art to modify the above combination to include using a duration and pulse rate range as taught by Chornenky in order to better move the desired material by electroporation. The specific ranges are an obvious matters of choice in the degree of known parameters to the skilled artisan. It is further held, that in view of the teaching of Fontenot, parameters for electroporation such as voltage, current, distance between electrodes, medicament fluid used, duration of treatment or pulse rates are known parameters that one of ordinary skill in the art would find obvious to select in order to achieve expected results.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot et al (2008/0199830) in view of Weiss et al (2004/0101809) and Chornenky et al (2003/0060856) as applied above to claim 12, and further in view of Sen et al (6593130). The above combination does not show a treatment including a rest time range. Sen teaches using a rest time for an electroporation method, column 3, lines 60-64. It would be obvious to one of ordinary skill in the art to modify the above combination to include using a time as taught by Sen in order to improve the electroporation of the material. The specific range is an obvious matte of choice in the degree of a known parameter to the skilled artisan.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot et al (2008/0199830) in view of Weiss et al (2004/0101809) as applied above to claim 1, and further in view of Marchitto et al (6419642). The above combination does not show using virtually no current. Marchitto teaches that it is known in the art of electroporation to use only a small current so as to avoid tissue damage, column 22, lines 47-59. It would be obvious to one of ordinary skill in the art to modify the above combination to include a small current as taught by Marchitto in order to avoid damaging tissue. The limitation virtually is held to be open to interpretation, and as such, a small current is held to be virtually no current. It is further held, that in view of the teaching of Fontenot, parameters for electroporation such as voltage, current, distance between electrodes, medicament fluid used, are known parameters that one of ordinary skill in the art would find obvious to select in order to achieve expected results.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot et al (2008/0199830) in view of Weiss et al (2004/0101809) as applied above to claim 1, and further in view of Riitano et al (2002/0090594). The above combination does not show a range of length for the instrument. Riitano teaches instruments used in a root canal and teaches a range of length of 8-35 mm [0136]. It would be obvious to one of ordinary skill in the art to modify the above combination to include a length range as taught by Riitano in order to match the size of a root canal. The specific range is an obvious matter of choice in the degree of a known parameter. It is further held, that in view of the teaching of Fontenot, parameters such a length and diameter, are known parameters that one of ordinary skill in the art would find obvious to select in order to achieve expected results.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot et al (2008/0199830) in view of Weiss et al (2004/0101809) as applied above to claim 1, and further in view of Aleksandrovskiy et al (2006/0286511). The above combination does not show a range of diameter for the instrument. Aleksandrovskiy teaches instruments used in a root canal and teaches a range of diameter of .2-1 mm [0010]. It would be obvious to one of ordinary skill in the art to modify the above combination to include a diameter range as taught by Aleksandrovskiy in order to match the size of a root canal. The specific range is an obvious matter of choice in the degree of a known parameter. It is further held, that in view of the teaching of Fontenot, parameters such a length and diameter, are known parameters that one of ordinary skill in the art would find obvious to select in order to achieve expected results.

Response to Arguments

Applicant's arguments filed April 6, 2012 have been fully considered but they are not persuasive. The new limitation is met by the newly applied reference to Valle et al. With respect to the rejection under Fontenot and Weiss, and others, it is held that the combination inherently reads on the new limitation because all of the actual claimed steps and structure are met, and as such, they must be capable of functioning in the claimed manner. The noticing that a known method has a new inherent result does not patentable distinguish over the already known method. Further, the field of Fontenot does interact with, and is at least partly responsible for the killing of microbes even if the electroporation is only used to open cell pores for a disinfectant. Further, it is noted that it is not clear from the present disclosure at exactly what point the parameters used for the field only opens pores long enough for materials to pass in without damaging the cells, and at what point, the parameters kill the cells, and as such, it is not clear what claims are commensurate with applicant's arguments. The combined prior art is held to be combinable based on the motivation of electroporation delivering materials, even though, this is not the same as the motivation argued. Where the prior art teaches using the same parameters as claimed, the effect on cells must be the same, even if not stated or recognized by the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than S Any inquiry concerning this communication or earlier communications from the examiner should be directed to EXAMINER whose telephone number is (571)272-6266. The examiner works a part time schedule and can normally be reached on Monday or Thursday from 8 AM to 4:30 PM, or on Friday from 8 AM to 12 PM.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact*** **the examiner's supervisor, SPE, *at* (571) 272-4964**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John J Wilson/
Primary Examiner
Art Unit 3732

Notice of References Cited	Application/Control No. 12/813,565	Applicant(s)/Patent Under Reexamination ARMANINO, ROBERTO	
	Examiner JOHN J. WILSON	Art Unit 3732	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2010/0047735	02-2010	Pond, Gary J.	433/29
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Valle et al, "A new theaputic protocal for paediatric endodontics: a case report", 9-2005, ctsocumoo GIII£ml0- val. 19- II. 2, pp. 210-213, see http://www.d-p-s.uk.com/comfort-zone/downloads/Endox%20Rome%20Paper.pdf.
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12813565	ARMANINO, ROBERTO
	Examiner	Art Unit
	JOHN J WILSON	3732

SEARCHED			
Class	Subclass	Date	Examiner
433	32, 224	1/19/2012	JW
Updated	All	4/18/2012	JW

SEARCH NOTES		
Search Notes	Date	Examiner
Text Search	1/19/2012	JW
Text Search	4/18/2012	JW

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S63	815	electroporation same (kill$3 with (microbe$1 or bacteria$1 or cell$1))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/04/17 12:04
S64	55	(irreversible with electroporation) same (kill$3 with (microbe$1 or bacteria$1 or cell$1))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/04/17 15:05
S65	39	endox	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/04/18 10:39

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12813565	ARMANINO, ROBERTO
	Examiner	Art Unit
	JOHN J WILSON	3732

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/19/2012	04/19/2012							
	1	✓	✓							
	2	✓	✓							
	3	✓	✓							
	4	✓	✓							
	5	✓	✓							
	6	✓	✓							
	7	✓	✓							
	8	✓	✓							
	9	✓	✓							
	10	✓	✓							
	11	✓	✓							
	12	✓	✓							
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	21	✓	✓							
	22	✓	✓							
	23	✓	✓							
	24	✓	✓							
	25	✓	✓							

FILED ELECTRONICALLY

PATENT APPLICATION
Docket No. 7678.1035.1.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:		)
	Roberto Armanino	)
Serial No.:	12/813,565	) Art Unit 3732
Filed:	June 11, 2010	)
Confirmation No.:	7247	)
For:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION	)
Examiner:	John J. Wilson	)
Customer No.:	022913	)

AMENDMENT A AND RESPONSE

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action of January 24, 2012, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A method for disinfecting a root canal preparation of a patient, comprising:

electrically connecting a ground electrode to a body of the patient so as to provide an electrical ground;

inserting a monopolar probe into a root canal preparation of a tooth of the patient; and

applying an electrical voltage between the ground electrode and the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal preparation, the electric field interacting with and ~~and so as to~~ killing microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue.

2. (Original) A method as recited in claim 1, wherein the root canal preparation contains an aqueous conducting fluid when the electrical voltage is applied.

3. (Currently Amended) A method as recited in claim 2, wherein the aqueous conducting fluid does not include a chemical disinfectant such that the electric field kills the microbes without assistance of a chemical disinfectant.

4. (Currently Amended) A method as recited in claim 2, wherein the aqueous conducting fluid comprises a chemical disinfectant that assists the electric field in killing the microbes.

5. (Original) A method as recited in claim 4, wherein the chemical disinfectant comprises aqueous sodium hypochlorite.

6. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage in a range of about 1 volt to about 10,000 volts.

7. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage in a range of about 250 volts to about 2000 volts.

8. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage in a range of about 500 volts to about 1500 volts.

9. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage over a time duration in a range of about 10 nanoseconds to about 30 seconds.

10. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage over a time duration in a range of about 0.001 second to about 5 seconds.

11. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage over a time duration in a range of about 0.01 second to about 4 seconds.

12. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage that is pulsed, wherein individual pulses of the electric voltage have a time duration in a range of about 1 nanosecond to about 1000 milliseconds.

13. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage that is pulsed, wherein individual pulses of the electric voltage have a time duration in a range of about 5 nanoseconds to about 500 milliseconds.

14. (Original) A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage that is pulsed, wherein individual pulses of the electric voltage have a time duration in a range of about 1 millisecond to about 200 milliseconds.

15. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises applying a number of individual pulses in a range of 2 to about 50 million.

16. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises applying a number of individual pulses in a range of about 10 to about 3 million.

17. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises applying a number of individual pulses in a range of about 15 to about 500,000.

18. (Original) A method as recited in claim 12, wherein applying an electrical voltage comprises providing a rest time between individual pulses in a range of about 1 second to about 5 seconds.

19. (Original) A method as recited in claim 1, wherein applying an electrical voltage results in virtually no electrical current flow between the monopolar probe inserted within the root canal preparation and the ground electrode.

20. (Original) A method as recited in claim 1, wherein the monopolar probe inserted within the root canal preparation comprises silver.

21. (Original) A method as recited in claim 1, wherein the ground electrode further comprises an adhesive pad for holding the ground electrode to gingival tissue.

22. (Original) A method as recited in claim 1, wherein the monopolar probe has a length in a range of about 12 mm to about 20 mm.

23. (Original) A method as recited in claim 1 wherein the monopolar probe has a diameter in a range of about 0.06 mm to about 1 mm.

24. (Currently Amended) A method for disinfecting a root canal preparation of a patient, comprising:

providing a root canal preparation of the patient's tooth that contains an electrically conductive fluid;

electrically connecting a ground electrode to gingival tissue of the patient so as to provide an electrical ground;

inserting a monopolar probe into a root canal preparation of a tooth of the patient; and

applying an electrical voltage between the ground electrode and the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal preparation, the electric field interacting with and ~~and so as to~~ killing microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue.

25. (Currently Amended) An apparatus for use in disinfecting a root canal preparation of a patient, comprising:

means for electrically connecting a ground electrode to a body of a patient so as to provide an electrical ground;

a monopolar probe sized and configured for insertion into a root canal preparation of a tooth of a patient; and

means for applying an electrical voltage between the ground electrode and the monopolar probe when inserted within a root canal preparation ~~and in a manner~~ so as to produce an electric field within the root canal preparation that ~~is able to~~ interacts with and kills microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue.

REMARKS

Applicants and Applicant's attorney express appreciation to the Examiner for the courtesies extended during the recent interview held on March 7, 2012. Reconsideration and allowance for the above-identified application are now respectfully requested. Claims 1-25 are pending, wherein claims 1, 3-4 and 24-25 have been amended.

As discussed during the Examiner Interview, the claimed methods differ from the cited art in that the claimed methods utilize an electric field to kill microbes (*e.g.*, through electroporation of the cell wall of the microbes in order to keep cell channels open and cause death of the microbe). In contrast, the cited art involves applying a current to human tissue in order to facilitate permeation of active agents into human tissue and cells, including antimicrobial agents. As further discussed, by taking advantage of natural channels through the cell walls of microbes, which can be forced to open and stay open through correct application of an electric field, the present invention promotes death of microbes by application of the electric field itself. And because the electric field can immediately permeate the entire root canal preparation, including any auxiliary canals where microbes might be hidden, the inventive methods can more completely kill microbes that may be hiding in narrow recesses and auxiliary canals within the root canal preparation as compared to purely chemical means for eradicating microbes. It is precisely because antimicrobial compositions are slow to penetrate into narrow recesses, auxiliary canals and pores that the cited art utilizes methodologies that drive chemicals and biological agents into human tissues and cause them to penetrate faster. The present invention solves problems associated with chemical eradication of microbes in a new and nonobvious way.

The Office Action rejects claims 1-6, 20, 21, 24 and 25 under 35 U.S.C. § 103(a) as being unpatentable over Fontenot (US 2008/0199830) in view of Weiss et al. (US 2004/0101809). As discussed during the Examiner Interview, Fontenot discloses devices "for the active *delivery of medicaments* into hard and soft tissues, particularly those of the oral cavity. The devices apply an AC voltage with a DC offset to *drive medicaments into the tissues*." Abstract (emphasis added). Similarly, and as further discussed, Weiss discloses "*mobilizing a medicament into the dentinal wall of a tooth* comprising a charged substance within a cavity of a tooth and subjecting the substance to an electric charge." Abstract (emphasis added). Accordingly, the combination of Fontenot and Weiss involves application of a medicament into the tissue and use of electric power or an electric charge to cause mobilization or movement of the medicament through

tissue, including dental tissue. In both references, as well as the combination thereof, the purpose of the disclosed methods is to improve movement of a *medicament* into human tissue so that the *medicament* is more effective in performing its intended function, such as providing antimicrobial activity. Thus, even if one were to combine Fontenot and Weiss, the combination would neither teach nor suggest the method of claim 1 as amended, which includes:

> electrically connecting a ground electrode to a body of the patient so as to provide an electrical ground;
>
> inserting a monopolar probe into a root canal preparation of a tooth of the patient; and
>
> applying an electrical voltage between the ground electrode and the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal preparation, *the electric field interacting with and killing microbes* within the root canal preparation without damage to or substantial heating of surrounding dental tissue.

As further discussed during the Examiner Interview, the reference in Fontenot to "electroporation" is in connection with increasing the permeability of *human* cells to more quickly diffuse medicaments into the cells. Any reliance in Weiss on "electroporation" (if it exists as at) would be for the same purpose. Fontenot and Weiss fail to teach or suggest applying an electric field across a root canal preparation in a manner so that *the electric field itself* interacts with and kills microbes without damaging or substantially heating surrounding dental tissue. In view of the foregoing, Applicant submits that claim 1 as amended is patentable an unobvious over the combination of Fontenot and Weiss. Independent claims 24 and 25 were similarly amended and are patentable over the combination of Fontenot and Weiss for substantially the same reasons.

Claims 2-6, 20 and 21 depend from claim 1 and are therefore patentable over the combination of Fontenot and Weiss for at least the reasons given above relative to claim 1. In addition, they recite additional elements that may further distinguish over the prior art of record. For example, claim 3 further claims "wherein the aqueous conducting fluid does not include a chemical disinfectant such that the electric field kills the microbes without assistance of a chemical disinfectant". Because both Fontenot and Weiss require an antimicrobial agent when killing microbes, they neither teach nor suggest a method in which "the aqueous conducting fluid

does not include a chemical disinfectant such that the electric field kills the microbes without assistance of a chemical disinfectant".

Claim 4 further claims "wherein the aqueous conducting fluid comprises a chemical disinfectant that assists the electric field in killing the microbes." The combination of Fontenot and Weiss fails to teach or suggest the use of "a chemical disinfectant that *assists the electric field* in killing the microbes" as required by claim 4.

Claim 5 further claims "wherein the chemical disinfectant comprises aqueous sodium hypochlorite". Weiss discloses extracting teeth and then cleaning the *extracted teeth* with sodium hypochlorite (paragraph 0112). Such cleaning with sodium hypochlorite occurs after the tooth has been extracted and *before* applying an electric field to the teeth. Weiss then teaches that the sodium hypochlorite is flushed out of the extracted tooth using EDTA solution, followed by introducing calcium hydroxide (pH = 12.5) into the root canal space prior to applying an electric field (*id.*). In contrast, claim 5 utilizes sodium hypochlorite to assist the electric field in killing microbes in a "root canal preparation of a patient" (*i.e.*, while the tooth is still in the patient's mouth).

The Office Action rejects claims 7 and 8 under 35 U.S.C. § 103(a) as being unpatentable over Fontenot (US 2008/0199830) in view of Weiss et al. (US 2004/0101809), and further in view of Hermanson (US 2007/0105799). As discussed during the Examiner Interview, Hermanson was only cited as allegedly suggesting the claimed voltages but otherwise fails to teach or suggest the method of claim 1 in which "the electric field interact[s] with and kill[s] microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue". As further discussed, Hermanson only discloses "electroporation" in the context of "electrically-assisted plasmid delivery". Paragraph 0323. Thus, Hermanson, like Fontenot and Weiss, utilizes electric energy to help deliver an agent to human cells but fails to teach or suggest the claimed methods.

The Office Action rejects claims 9-17 under 35 U.S.C. § 103(a) as being unpatentable over Fontenot (US 2008/0199830) in view of Weiss et al. (US 2004/0101809), and further in view of Chornenky et al. (US 2003/0060856). As discussed during the Examiner Interview, Chornenky et al. was only cited as allegedly suggesting the claimed treatment duration time ranges and pulse rate range but otherwise fails to teach or suggest the method of claim 1 in which "the electric field interact[s] with and kill[s] microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue". As further discussed, Chornenky

et al. only discloses "electroporation" in the context of "treatment of benign prostatic hyperplasia". Abstract. Thus, Chornenky et al., like Fontenot and Weiss, utilizes electric energy to primarily affect human cells, not microbes, and fails to teach or suggest the claimed methods.

The Office Action rejects claim 18 under 35 U.S.C. § 103(a) as being unpatentable over Fontenot (US 2008/0199830) in view of Weiss et al. (US 2004/0101809) and Chornenky et al. (US 2003/0060856), and further in view of Sen et al. (US 6,593,130). As discussed during the Examiner Interview, Sen et al. was only cited as allegedly suggesting the claimed rest time range but otherwise fails to teach or suggest the method of claim 1 in which "the electric field interact[s] with and kill[s] microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue". As further discussed, Sen et al. only discloses "electroporation" in the context of "gene, protein or drug therapy" in an "organ". *See* col. 1, lines 14-18. Thus, Sen et al., like Fontenot and Weiss, utilizes electric energy to help deliver an agent to human cells but fails to teach or suggest the claimed methods.

The Office Action rejects claim 19 under 35 U.S.C. § 103(a) as being unpatentable over Fontenot (US 2008/0199830) in view of Weiss et al. (US 2004/0101809), and further in view of Marchitto et al. (US 6,419,642). Marchitto et al. was only cited as allegedly suggesting "using virtually no current" but otherwise fails to teach or suggest the method of claim 1 in which "the electric field interact[s] with and kill[s] microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue". Marchitto et al. only discloses "electroporation" in the context of irradiation enhanced permeation and delivery of substances through skin. *See* Abstract. Thus, Marchitto et al., like Fontenot and Weiss, utilizes electric energy to help deliver an agent to human cells but fails to teach or suggest the claimed methods.

The Office Action rejects claim 22 under 35 U.S.C. § 103(a) as being unpatentable over Fontenot (US 2008/0199830) in view of Weiss et al. (US 2004/0101809), and further in view of Riitano et al. (US 2002/0090594). Riitano et al. was only cited as allegedly suggesting "the range of length for the instrument" but otherwise fails to teach or suggest the method of claim 1 in which "the electric field interact[s] with and kill[s] microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue". Riitano et al. does not in fact disclose application of an electric field to a root canal preparation and is therefore essentially irrelevant to the *method* of claim 22.

The Office Action rejects claim 23 under 35 U.S.C. § 103(a) as being unpatentable over Fontenot (US 2008/0199830) in view of Weiss et al. (US 2004/0101809), and further in view of

Aleksandrovskiy et al. (US 2006/0286511). Aleksandrovskiy et al. was only cited as allegedly suggesting "a range of diameter for the instrument" but otherwise fails to teach or suggest the method of claim 1 in which "the electric field interact[s] with and kill[s] microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue". Aleksandrovskiy et al. does not in fact disclose application of an electric field to a root canal and is therefore essentially irrelevant to the *method* of claim 22.

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Dated this 6th day of April 2012.

Respectfully submitted,

/John M. Guynn 36153/

JOHN M. GUYNN
Registration No. 36,153
WORKMAN NYDEGGER
Attorney for Applicant(s)
Customer No. 022913

JMG:kft
3669767_1.DOC

Electronic Acknowledgement Receipt

EFS ID:	12490090
Application Number:	12813565
International Application Number:	
Confirmation Number:	7247
Title of Invention:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION
First Named Inventor/Applicant Name:	Roberto Armanino
Customer Number:	22913
Filer:	John Michael Guynn/Kelli Tyree
Filer Authorized By:	John Michael Guynn
Attorney Docket Number:	7678.1035.1.1
Receipt Date:	06-APR-2012
Filing Date:	11-JUN-2010
Time Stamp:	16:37:26
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		7678_1035_1_1_Amendment.pdf	64513 2e09a6d29622642afbbee6755051de5aaa85ae4e	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	10
Warnings:			
Information:			
	Total Files Size (in bytes):	64513	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

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.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
12/813,565	06/11/2010	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☐ RATE ($)	SMALL ENTITY ☐ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 04/06/2012	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 25	Minus	** 25	= 0	X $ =		OR	X $60=	0
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $ =		OR	X $250=	0
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	0

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/CHRISTINE V. MOORE/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/813,565	06/11/2010	Roberto Armanino	7678.1035.1.1	7247

22913 7590 03/08/2012

Workman Nydegger
1000 Eagle Gate Tower
60 East South Temple
Salt Lake City, UT 84111

EXAMINER	
WILSON, JOHN J	
ART UNIT	PAPER NUMBER
3732	
MAIL DATE	DELIVERY MODE
03/08/2012	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.

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	12/813,565	ARMANINO, ROBERTO	
	Examiner	Art Unit	
	JOHN J. WILSON	3732	

All participants (applicant, applicant's representative, PTO personnel):

(1) *JOHN J. WILSON*. (3)_____.

(2) *JOHN GUYNN*. (4)_____.

Date of Interview: *07 March 2012*.

Type: ☐ Telephonic ☐ Video Conference
☒ Personal [copy given to: ☐ applicant ☒ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1*.

Identification of prior art discussed: *Fontenot, Weiss*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

A proposed amentment, see attachment, to claim 1 was discussed.It was pointed out that the prior art does not use the electric field to kill the microbes directly as this invention. It was stated that the current proposed claim does not appear to bring out this feature in a distinguishing way. Other language will be considered and submitted.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☒ Attachment

12813656ProposedAmendmentForInterview	/John J Wilson/ Primary Examiner Art Unit 3732

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

PROPOSED AGENDA FOR INTERVIEW DATED MARCH 7, 2012
Serial No. 12/813,565
Docket No. 7678.1035.1.1
Examiner John J. Wilson
Fax No. (571) 273-6266

1. (**Proposed Amendment – for discussion only**) A method for disinfecting a root canal preparation of a patient, comprising:

electrically connecting a ground electrode to a body of the patient so as to provide an electrical ground;

inserting a monopolar probe into a root canal preparation of a tooth of the patient; and

applying an electrical voltage between the ground electrode and the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal ~~and so as to~~ sufficient to kill microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue.

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/813,565	06/11/2010	Roberto Armanino	7678.1035.1.1	7247

22913 7590 01/24/2012

Workman Nydegger
1000 Eagle Gate Tower
60 East South Temple
Salt Lake City, UT 84111

EXAMINER	
WILSON, JOHN J	

ART UNIT	PAPER NUMBER
3732	

MAIL DATE	DELIVERY MODE
01/24/2012	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.

Office Action Summary	Application No.	Applicant(s)	
	12/813,565	ARMANINO, ROBERTO	
	Examiner	Art Unit	
	JOHN J. WILSON	3732	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-25* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-25* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *11 June 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/29/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

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 negatived by the manner in which the invention was made.

Claims 1-6, 20, 21, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot et al (2008/0199830) in view of Weiss et al (2004/0101809). Fontenot teaches a method for delivering antimicrobial agents to a root canal [0064], and as such, teaches a method for disinfecting the root canal, the method includes electrically connecting a ground electrode 415, Fig. 13, inserting a monopolar probe 1300 into a root canal, and applying an electric voltage. Fontenot does not state the level of the electric field used with respect to heating of surrounding dental tissue. Fontenot, however, does teach the method can use electroporation [0053]-[0054]. Weiss teaches using an electric field in root canal treatment and teaches the need to use a field so as to control the heat buildup [0086]-[0087]. It would be obvious to one of ordinary skill in the art to modify the method of Fontenot to include using a field that will prevent heating of tissue in order to prevent excess unintended tissue damage. As to claim 2, Fontenot teaches using a medicament 1310, however, does not state that it is an aqueous fluid. Fontenot describes using an aqueous medicament with respect to another embodiment [0041]-[0042]. It would be obvious to modify the embodiment of Fig. 13 to include an aqueous fluid as taught Fontenot as indicated above in order to best deliver the medicament to the desired site. As to claims 3 and 4, that the medicament can be chemical or not is an obvious matter of choice in

the type of known medicaments used in the art. As to claim 5, Weiss also teaches the use of sodium hypochlorite [0112]. As to claim 6, Fontenot teaches using 5 volts [0051]. As to claim 20, Fontenot teaches using silver [0029], [0060]. As to claim 21, Fontenot teaches the use of an adhesive pad [0043]. As to claim 24, Fontenot shows a prepared rood canal in Fig. 13. As to claim 25, Fontenot shows a connected electric ground 415, monopolar probe 1300, means for applying voltage 410, and structure used to kill microbes [0064], while as stated above Weiss teaches that such a device should be capable of producing a field that will not damage or substantially heat the tissue.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot et al (2008/0199830) in view of Weiss et al (2004/0101809) as applied above to claim 1, and further in view of Hermanson (2007/0105799). The above combination does not show a range of volts used. Hermanson teaches an electroporation method that includes using a voltage range of 100-1500 volts. It would be obvious to one of ordinary skill in the art to modify the above combination to include a voltage range as taught by Hermanson in order to use the best voltage for electroporation of the medication. The specific range is an obvious matter of choice in the degree of a known parameter. It is further held, that in view of the teaching of Fontenot, parameters for electroporation such as voltage, current, distance between electrodes, medicament fluid used, are known parameters that one of ordinary skill in the art would find obvious to select in order to achieve expected results.

Claims 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot et al (2008/0199830) in view of Weiss et al (2004/0101809) as applied above to claim 1, and further in view of Chornenky et al (2003/0060856). The above combination does not show a treatment duration time range or pulse rate range. Chornenky teaches that for an electroporation method, duration and pulses are parameters that need to be considered for treatment [0058]. It would be obvious to one of ordinary skill in the art to modify the above combination to include using a duration and pulse rate range as taught by Chornenky in order to better move the desired material by electroporation. The specific ranges are an obvious matters of choice in the degree of known parameters to the skilled artisan. It is further held, that in view of the teaching of Fontenot, parameters for electroporation such as voltage, current, distance between electrodes, medicament fluid used, duration of treatment or pulse rates are known parameters that one of ordinary skill in the art would find obvious to select in order to achieve expected results.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot et al (2008/0199830) in view of Weiss et al (2004/0101809) and Chornenky et al (2003/0060856) as applied above to claim 12, and further in view of Sen et al (6593130). The above combination does not show a treatment including a rest time range. Sen teaches using a rest time for an electroporation method, column 3, lines 60-64. It would be obvious to one of ordinary skill in the art to modify the above combination to include using a time as taught by Sen in order to improve the electroporation of the material. The specific range is an obvious matte of choice in the degree of a known parameter to the skilled artisan.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot et al (2008/0199830) in view of Weiss et al (2004/0101809) as applied above to claim 1, and further in view of Marchitto et al (6419642). The above combination does not show using virtually no current. Marchitto teaches that it is known in the art of electroporation to use only a small current so as to avoid tissue damage, column 22, lines 47-59. It would be obvious to one of ordinary skill in the art to modify the above combination to include a small current as taught by Marchitto in order to avoid damaging tissue. The limitation virtually is held to be open to interpretation, and as such, a small current is held to be virtually no current. It is further held, that in view of the teaching of Fontenot, parameters for electroporation such as voltage, current, distance between electrodes, medicament fluid used, are known parameters that one of ordinary skill in the art would find obvious to select in order to achieve expected results.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot et al (2008/0199830) in view of Weiss et al (2004/0101809) as applied above to claim 1, and further in view of Riitano et al (2002/0090594). The above combination does not show a range of length for the instrument. Riitano teaches instruments used in a root canal and teaches a range of length of 8-35 mm [0136]. It would be obvious to one of ordinary skill in the art to modify the above combination to include a length range as taught by Riitano in order to match the size of a root canal. The specific range is an obvious matter of choice in the degree of a known parameter. It is further held, that in view of the teaching of Fontenot, parameters such a length and diameter, are known parameters that one of ordinary skill in the art would find obvious to select in order to achieve expected results.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot et al (2008/0199830) in view of Weiss et al (2004/0101809) as applied above to claim 1, and further in view of Aleksandrovskiy et al (2006/0286511). The above combination does not show a range of diameter for the instrument. Aleksandrovskiy teaches instruments used in a root canal and teaches a range of diameter of .2-1 mm [0010]. It would be obvious to one of ordinary skill in the art to modify the above combination to include a diameter range as taught by Aleksandrovskiy in order to match the size of a root canal. The specific range is an obvious matter of choice in the degree of a known parameter. It is further held, that in view of the teaching of Fontenot, parameters such a length and diameter, are known parameters that one of ordinary skill in the art would find obvious to select in order to achieve expected results.

Drawings

The drawings filed June 11, 2010 have been found to be acceptable by the examiner.

Information Disclosure Statement

The IDS filed September 29, 2010 has been considered and an initialed copy is attached.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EXAMINER whose telephone number is (571)272-6266. The

examiner works a part time schedule and can normally be reached on Monday or Thursday from 8 AM to 4:30 PM, or on Friday from 8 AM to 12 PM.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact*** **the examiner's supervisor, SPE,** ***at*** **(571) 272-4964**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John J Wilson/
Primary Examiner
Art Unit 3732

Notice of References Cited	Application/Control No. 12/813,565	Applicant(s)/Patent Under Reexamination ARMANINO, ROBERTO	
	Examiner JOHN J. WILSON	Art Unit 3732	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2008/0199830	08-2008	Fontenot et al.	433/215
*	B	US-2004/0101809	05-2004	Weiss et al.	433/224
*	C	US-2007/0105799	05-2007	Hermanson, Gary G.	514/044
*	D	US-2003/0060856	03-2003	Chornenky et al.	607/40
*	E	US-6,593,130	07-2003	Sen et al.	435/285.2
*	F	US-6,419,642	07-2002	Marchitto et al.	600/573
*	G	US-2002/0090594	07-2002	Riitano et al.	433/224
*	H	US-2006/0286511	12-2006	Aleksandrovskiy et al.	433/215
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)			Application Number	12/813,565
			Filing Date	June 11, 2010
			First Named Inventor	Roberto Armanino
			Art Unit	3732
			Examiner Name	Not yet known
Sheet	1 of 2		Attorney Docket Number	7678.1035.1.1

U.S. PATENTS

Examiner Initials*	Cite No.	Patent Number	Issue Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	4,175,565	11-27-1979	Chiarenza et al.	
	2	4,291,125	09-22-1981	Greatbatch	
	3	4,854,865	08-08-1989	Beard et al.	
	4	5,383,935	01-24-1995	Shirkhanzadeh	
	5	5,462,644	10-31-1995	Woodson	
	6	5,725,377	03-10-1998	Lemler et al.	
	7	6,273,720	08-14-2001	Spalten	
	8	6,413,498	07-02-2002	Malmagro	
	9	6,482,309	11-19-2002	Green et al.	
	10	6,555,055	04-29-2003	Cisar et al.	
	11	6,778,861	08-17-2004	Liebrecht et al.	

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initials*	Cite No.	Publication Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	12	2004/0034395	02-19-2004	Dick	
	13	2006/0144718	07-06-2006	Lambie	
	14	2006/0265026	11-23-2006	Madjar et al.	
	15	2006/0293724	12-28-2006	Kronberg et al.	

EXAMINER SIGNATURE

Examiner Signature	/John Wilson/	Date Considered	01/19/2012

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.W./

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12813565	ARMANINO, ROBERTO
	Examiner	Art Unit
	JOHN J WILSON	3732

SEARCHED			
Class	Subclass	Date	Examiner
433	32, 224	1/19/2012	JW

SEARCH NOTES		
Search Notes	Date	Examiner
Text Search	1/19/2012	JW

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1132	((433/32) or (433/224)).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/01/19 08:46
L3	3	L1 and (electroporation or apoptosis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/01/19 08:49
L4	24	L1 and (electric adj field)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/01/19 08:49
L5	10	L4 and (sodium adj hypochlorite)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/01/19 08:50
S1	591	(433/32).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/20 16:59
S2	87	S1 and (endodontic$1 or (root adj canal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/20 16:59
S3	10	S2 and kill$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/20 16:59

S4	2	("7270661").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/20 17:05
S5	2	("5421727").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/20 17:08
S6	18	(("5964754") or ("6971878") or ("6482088") or ("3916529") or ("1713971") or ("20070207445")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/20 17:11
S7	2	("6482008").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/20 17:12
S8	60	armanino.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/21 08:28
S9	2	S8 and dental	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/21 08:29
S10	560	(433/224).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/27 15:26
S11	14	S10 and (electric adj field)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/27 15:26

S12	80	S10 and (sodium adj hypochlorite)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/27 15:51
S13	25	S12 and electric$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/27 15:51
S14	560	(433/224).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/28 09:10
S15	14	S14 and (electric adj field)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/28 09:10
S16	1	S14 and (electric adj charge)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/28 09:10
S17	2	("4886075").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/28 10:02
S18	20	"1806683"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/28 10:10
S19	726	electroporation same (kill $3 with cell$1)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/28 11:52

S20	1	S19 and (endodontic$1 or (root adj canal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/28 11:53
S21	14	S19 and dental	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/28 11:53
S22	51	electroporation same (kill $3 with bacteria)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/10/28 11:56
S23	58	electroporation same ((kill $3 or destroy$3) with bacteria)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/08 11:41
S24	1	S23 and (endodontic$1 or (root adj canal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/08 11:41
S25	181	apoptosis same ((kill$3 or destroy$3) with bacteria)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/08 11:41
S26	1	S25 and (endodontic$1 or (root adj canal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/08 11:41
S27	164086	electroporation or apoptosis	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/08 11:43

S28	167	S27 and (endodontic$1 or (root adj canal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/08 11:43
S29	164086	electroporation or apoptosis	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/08 15:47
S30	5707	S29 and dental	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/08 15:47
S31	736	electroporation same (kill $3 with cell$1)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/08 15:47
S32	14	S31 and dental	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/08 15:47
S33	2	S32 and volt$1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/08 15:47
S34	3555	electroporation and dental	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/08 15:48
S35	160	S34 and volt$1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/08 15:48

S36	86	S34 and (duration with second$1)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/08 17:01
S37	3555	electroporation and dental	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 08:49
S38	86	S37 and (duration with second$1)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 08:49
S39	33	S37 and (duration with seconds)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 08:50
S40	96887	electroporation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 09:28
S41	17	S40 and (duration with treatment with seconds)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 09:29
S42	14	electroporation same (treatment with seconds)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 09:35
S43	0	electroporation same (rest adj time)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 09:58

S44	273	electroporation same rest	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 09:58
S45	2	electroporation same (rest with pulses)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 09:59
S46	7324	electroporation same (current)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 10:08
S47	64	electroporation same (current with (minimum or minimiz$3))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 10:10
S48	0	electroporation same (current near (minimum or minimiz$3))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 10:56
S49	2	electroporation same (current near (eliminat $3))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 10:57
S50	591	(433/32).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 11:51
S51	87	S50 and (endodontic$1 or (root adj canal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 11:51

S52	63	S51 and length	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 11:51
S53	566	(433/224).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 12:03
S54	168	S53 and (length with mm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 12:03
S55	32	S50 and (diameter with mm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 12:38
S56	2	("20060286511").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 12:42
S57	32	("20040034395" | "20060144718" | "20060265026" | "20060293724" | "4175565" | "4291125" | "4854865" | "5383935" | "5462644" | "5725377" | "6273720" | "6413498" | "6482309" | "6555055" | "6778861").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/09 16:47

EAST Search History (Interference)

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12813565	ARMANINO, ROBERTO
	Examiner	Art Unit
	JOHN J WILSON	3732

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/19/2012								
	1	✓								
	2	✓								
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	4	✓								
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/813,565	06/11/2010	Roberto Armanino	7678.1035.1.1

CONFIRMATION NO. 7247

PUBLICATION NOTICE

22913
Workman Nydegger
1000 Eagle Gate Tower
60 East South Temple
Salt Lake City, UT 84111

OC000000046064996

Title:METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION

Publication No.US-2011-0039226-A1
Publication Date:02/17/2011

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

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Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)			Application Number	12/813,565
			Filing Date	June 11, 2010
			First Named Inventor	Roberto Armanino
			Art Unit	3732
			Examiner Name	Not yet known
Sheet	1 of 2		Attorney Docket Number	7678.1035.1.1

U.S. PATENTS

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	2	4,291,125	09-22-1981	Greatbatch	
	3	4,854,865	08-08-1989	Beard et al.	
	4	5,383,935	01-24-1995	Shirkhanzadeh	
	5	5,462,644	10-31-1995	Woodson	
	6	5,725,377	03-10-1998	Lemler et al.	
	7	6,273,720	08-14-2001	Spalten	
	8	6,413,498	07-02-2002	Malmagro	
	9	6,482,309	11-19-2002	Green et al.	
	10	6,555,055	04-29-2003	Cisar et al.	
	11	6,778,861	08-17-2004	Liebrecht et al.	

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initials*	Cite No.	Publication Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	12	2004/0034395	02-19-2004	Dick	
	13	2006/0144718	07-06-2006	Lambie	
	14	2006/0265026	11-23-2006	Madjar et al.	
	15	2006/0293724	12-28-2006	Kronberg et al.	

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)				
			Application Number	12/813,565
			Filing Date	June 11, 2010
			First Named Inventor	Roberto Armanino
			Art Unit	3732
			Examiner Name	Not yet known
Sheet	2 of 2		Attorney Docket Number	7678.1035.1.1

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments to Deposit Account No. 23-3178

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	Rick D. Nydegger	Date	September 29, 2010
Name/Print	Rick D. Nydegger	Registration Number	28,651

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Electronic Acknowledgement Receipt

EFS ID:	8526090
Application Number:	12813565
International Application Number:	
Confirmation Number:	7247
Title of Invention:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION
First Named Inventor/Applicant Name:	Roberto Armanino
Customer Number:	22913
Filer:	Rick D. Nydegger/Angela Young
Filer Authorized By:	Rick D. Nydegger
Attorney Docket Number:	7678.1035.1.1
Receipt Date:	29-SEP-2010
Filing Date:	11-JUN-2010
Time Stamp:	16:07:46
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed (SB/08)	IDS_filed_29Sep2010.pdf	157083 15569666deda6ab3cbafb99c99eefc1c2457d774	no	2

Warnings:	
Information:	

This is not an USPTO supplied IDS fillable form

Total Files Size (in bytes):	157083

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

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.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/813,565	06/11/2010	3732	1350	7678.1035.1.1	25	3

CONFIRMATION NO. 7247

22913
Workman Nydegger
1000 Eagle Gate Tower
60 East South Temple
Salt Lake City, UT 84111

FILING RECEIPT

OC000000042204229

Date Mailed: 06/23/2010

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Roberto Armanino, Genova, ITALY;

Assignment For Published Patent Application

Ultradent Products, Inc., South Jordan, UT

Power of Attorney: The patent practitioners associated with Customer Number 022913

Domestic Priority data as claimed by applicant

This appln claims benefit of 61/232,920 08/11/2009

Foreign Applications

If Required, Foreign Filing License Granted: 06/21/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/813,565**

Projected Publication Date: 02/17/2011

Non-Publication Request: No

Early Publication Request: No

Title

METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION

Preliminary Class

433

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where

the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	7678.1035.1.1
	Application Number	
Title of Invention	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information:

Applicant 1

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	ROBERTO		ARMANINO	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Genova	State/Province		Country of Residence	IT

Citizenship under 37 CFR 1.41(b) IT

Mailing Address of Applicant:

Address 1	Salita Serra Riccò 5/11
Address 2	

City	Genova	State/Province	
Postal Code	16164	Country	IT

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	22913		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION		
Attorney Docket Number	7678.1035.1.1	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		Sub Class (if any)	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	4	Suggested Figure for Publication (if any)	3

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	7678.1035.1.1
	Application Number	
Title of Invention	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S. C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	022913		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	non provisional of	61/174562	2009-06-11
Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	non provisional of	61/232920	2009-08-11

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

			Remove
Application Number	Country[1]	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			○ Yes ◉ No

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	7678.1035.1.1
	Application Number	
Title of Invention	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION	

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

Assignee 1

If the Assignee is an Organization check here. ☒

Organization Name	Ultradent Products, Inc.		
Mailing Address Information:			
Address 1	505 West 10200 South		
Address 2			
City	South Jordan	**State/Province**	UT
Country	US	Postal Code	84095
Phone Number		Fax Number	
Email Address			

Additional Assignee Data may be generated within this form by selecting the **Add** button.

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/John M. Guynn 36153/			Date (YYYY-MM-DD)	2010-06-11
First Name	John	Last Name	Guynn	Registration Number	36153

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

COMBINED DECLARATION and POWER OF ATTORNEY
(Utility, Design, National Stage of PCT)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type:

(Check one applicable item below)

[x] utility patent application
[ ] design patent application
[ ] national stage of PCT patent application

INVENTORSHIP IDENTIFICATION

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (*if only one name is listed below*) or an original, first and joint inventor (*if plural names are listed below*) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION

SPECIFICATION IDENTIFICATION

the specification of which:

(*complete (a), (b), or (c)*)

(a) [x] is attached hereto.

(b) [ ] was previously filed, as United States Patent Application Serial No. _____.

(c) [ ] was described and claimed in PCT International Application No. _____, filed on _____, and as amended under PCT Article 19 on _____ and/or under PCT Article 34 on _____ (*if any*).

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified application, including the claim(s), as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information that is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

FOREIGN PRIORITY CLAIM
(35 USC § 119(a)-(d))

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) [x] no such applications have been filed.
(e) [ ] such applications have been filed as follows.

Note: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below, and make the priority claim.

PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	FILING DATE (month, day, year)	PRIORITY CLAIMED UNDER § 119 or § 365
			[ ] YES NO [ ]
			[ ] YES NO [ ]
			[ ] YES NO [ ]
			[ ] YES NO [ ]

U.S. PRIORITY CLAIM
(35 USC § 120)

I hereby claim the benefit under 35 USC § 120 of any United States application(s) or § 365(c) of any PCT international application designating the United States of America listed below, if any, and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information that is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international application filing date of this application.

U.S. or PCT PATENT APPLICATION NO.	FILING DATE (month, day, year)	PATENT NO. (if applicable)

PROVISIONAL APPLICATION CLAIM
(35 USC § 119(e))

I hereby claim the benefit under 35 USC § 119(e) of any United States Provisional application listed below, if any.

U.S. PROVISIONAL APPLICATION NO.	FILING DATE (month, day, year)
61/174,562	June 11, 2009
61/232,920	August 11, 2009

POWER OF ATTORNEY

I hereby appoint as my attorneys and/or patent agents all attorneys and/or patent agents listed under the following Customer Number, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Customer No. 022913

All correspondence and telephonic communications should be directed to:

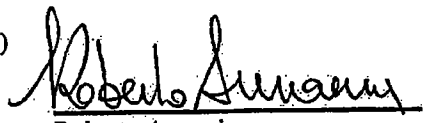
John M. Guynn
WORKMAN NYDEGGER
1000 Eagle Gate Tower
60 East South Temple
Salt Lake City, Utah 84111
Telephone (801) 533-9800
Facsimile (801) 328-1707

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

Date: 09/06/2010

Signature: 
Name: Roberto Armanino
Address: Salita Serra Riccò 5/11
16164 Genova Italy
Citizenship: Italy

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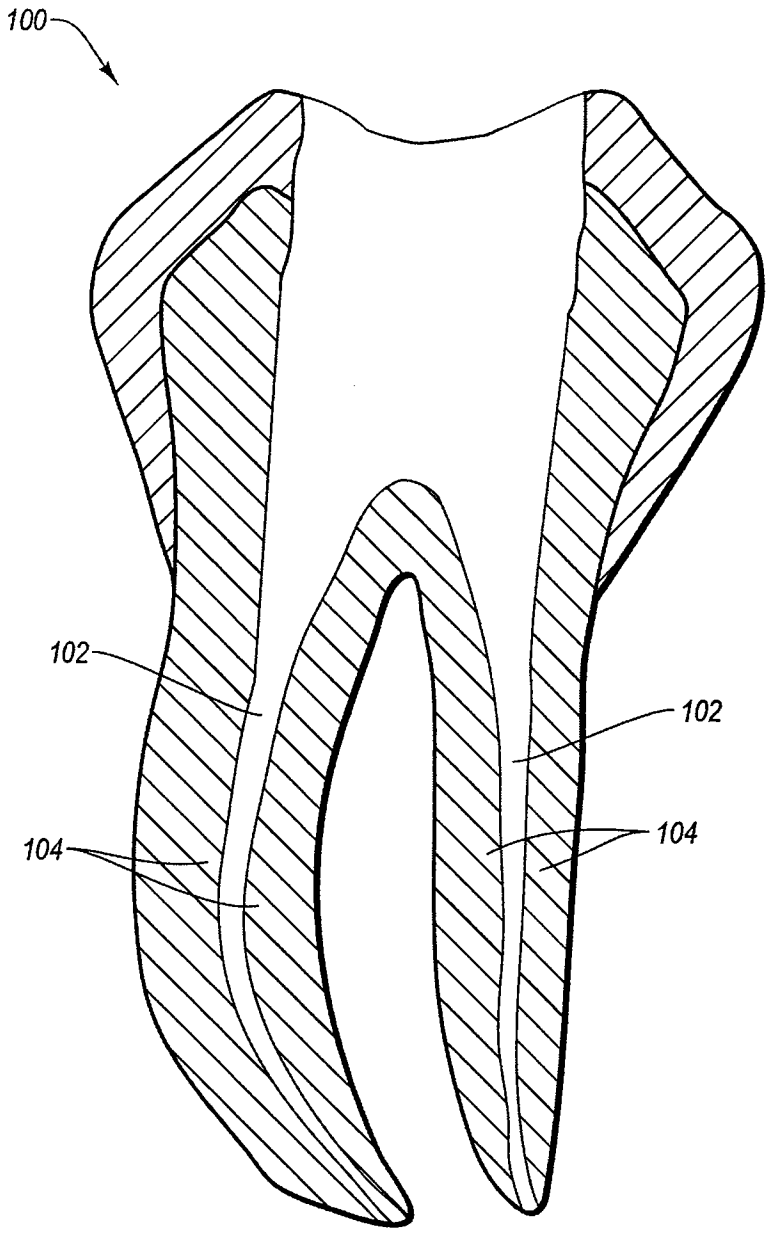

FIG. 1

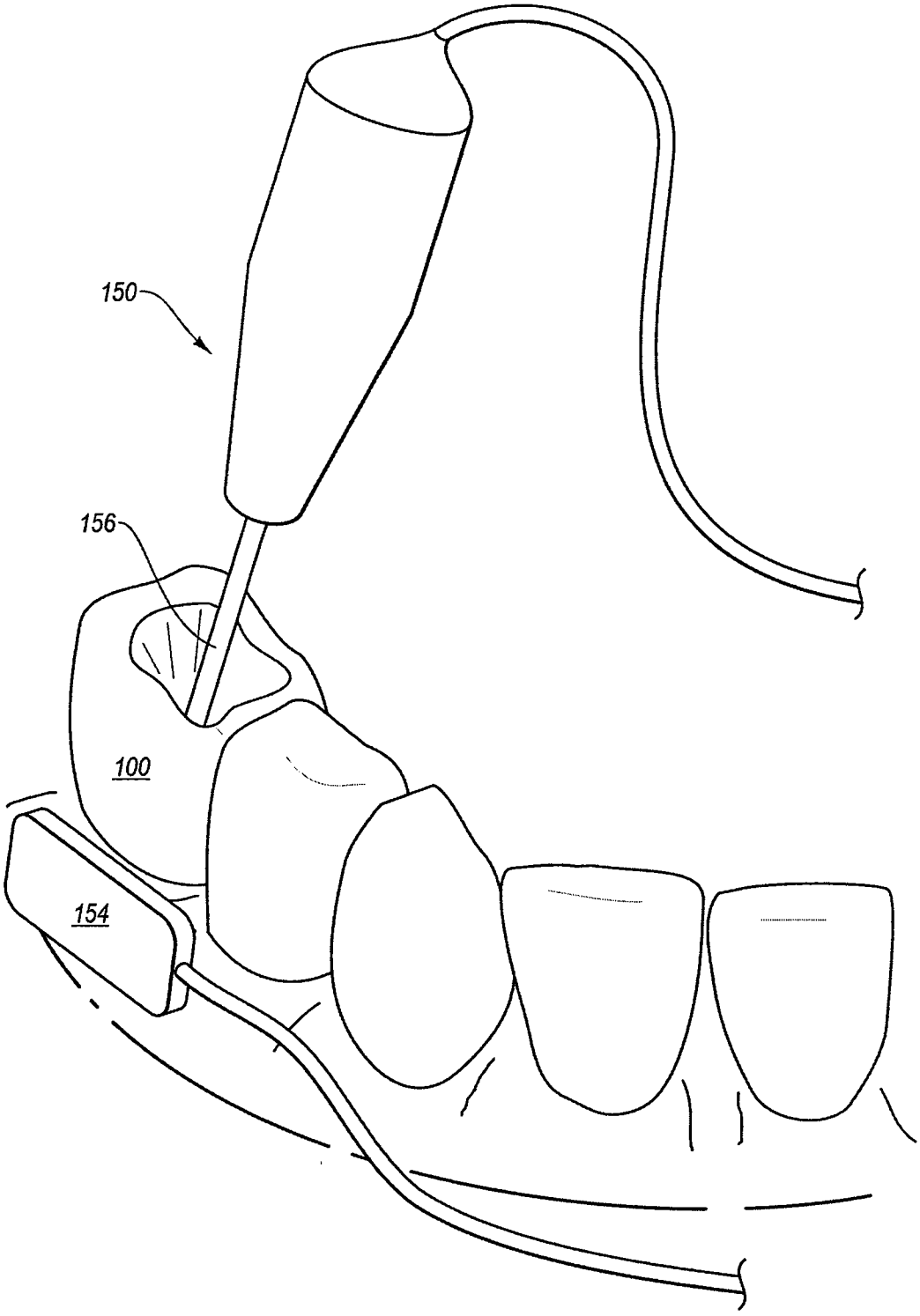

FIG. 2

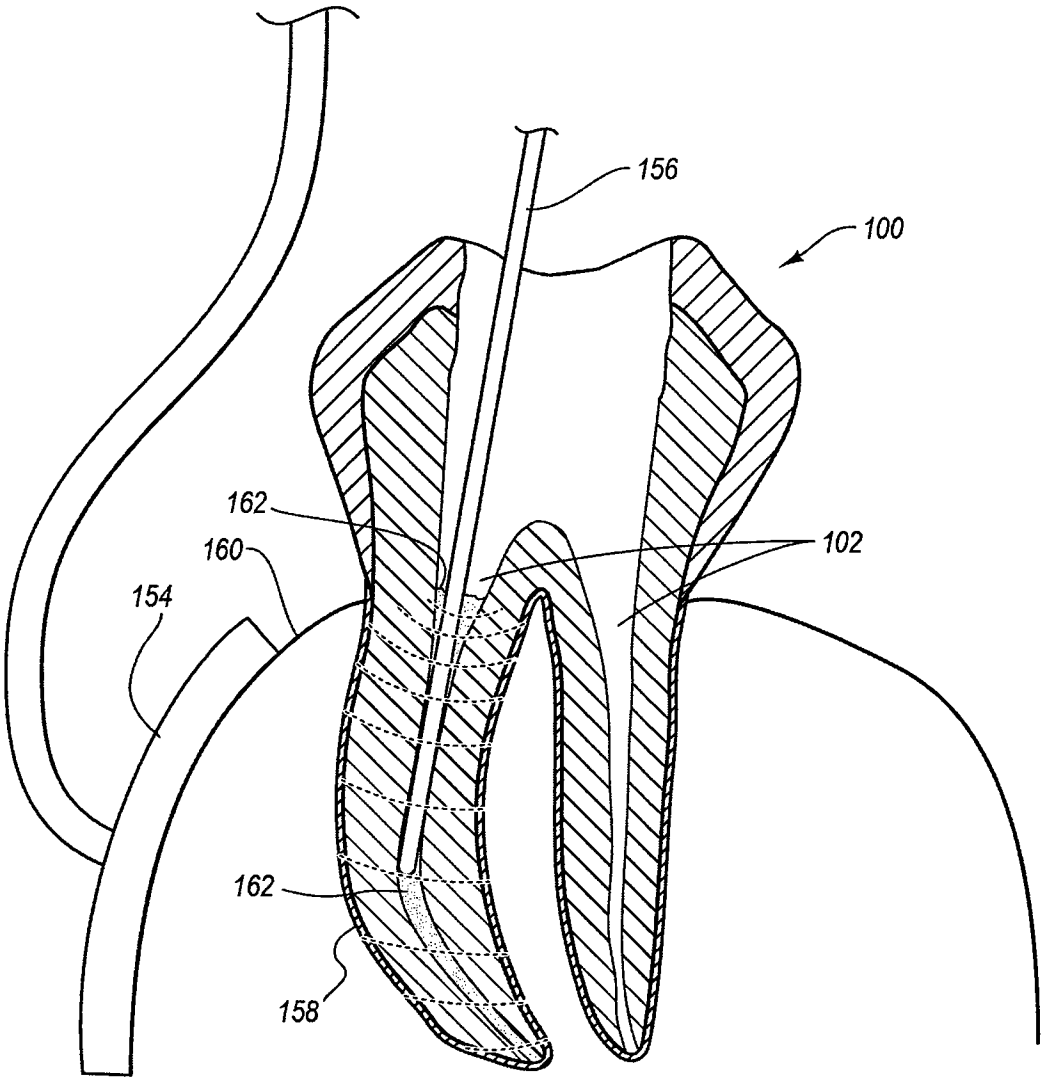

FIG. 3

FIG. 4

FILED ELECTRONICALLY

PATENT APPLICATION
Docket No. 7678.1035.1.1

UNITED STATES PATENT APPLICATION

of

ROBERTO ARMANINO

for

METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION

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METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PRREPARATION

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of earlier filed United States Provisional Application Number 61/174,562, filed June 11, 2009, and also United States Provisional Application Number 61/232,920, filed August 11, 2009, the disclosures of which are incorporated herein in their entirety.

BACKGROUND OF THE INVENTION

1. The Field of the Invention

[0002] The present invention relates to procedures for preparing a root canal of a tooth for receiving a sealer and/or filler material. More particularly, the invention relates to methods for disinfecting a root canal prior to introduction of a sealer and/or filler material therein.

2. The Relevant Technology

[0003] When a root canal of a living tooth becomes infected or abscessed, discomfort and, in many cases, severe pain can result. In the early days of dentistry the only solution was to extract the tooth. More recently, however, dental practitioners have developed techniques to successfully remove the pulp material that forms the nerve of the tooth, which has become infected, and therefore save the teeth while preventing the spread of infection to the patient. After careful preparation of the canal that contained the infected nerve and other pulp material, the canal is refilled with an inert filling material, such as gutta percha, and/or a curable sealer or filler material. This process allows the patient to retain the tooth.

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[0004] To achieve a successful root canal restoration, the dental practitioner must carefully, and as completely as possible, remove the infected pulp material. The pulp removal process typically includes shaping the root canal with one or more endodontic instruments so that it can be effectively and successfully filled and sealed with an inert material to reduce the possibility of further infection.

[0005] Cleaning and shaping the root canal in preparation for receiving a sealing and/or filling material is achieved by the use of metal endodontic instruments that include cutting surfaces for removing tissue in the root canal. Since root canals are seldom straight, often having bends and twists, at least some endodontic instruments are flexible so as to allow the instrument to follow the curvature of the root canal. Currently preferred materials of construction include stainless steel and super-elastic alloys, *e.g.*, nickel-titanium (Ni-Ti) alloys.

[0006] In addition, even once the diseased pulp and nerve tissue have been removed, it is generally necessary to disinfect remaining surfaces and lateral canals of the root canal so as to kill existing bacteria, as well as to prevent later growth of bacteria and/or other microbes, which could lead to further degradation or even loss of the entire tooth. Typically, the practitioner chemically disinfects the root canal preparation, for example, by introducing aqueous sodium hypochlorite into the root canal, followed by rinsing the canal with pure water. Once disinfected and rinsed, the canal is dried prior to filling and sealing. Even with such chemical disinfection, there is still a risk that a significant bacterial population can remain and propagate over time (*e.g.*, within lateral pores or canals that branch off the main root canal), thereby causing risk of further infect and pain to the patient. Improved disinfection techniques would be advantageous as they would reduce the frequency of or even eliminate sealed root canals later developing infection.

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BRIEF SUMMARY OF THE PREFERRED EMBODIMENTS

[0007] The present invention is directed to a method for disinfecting a root canal preparation during an endodontic procedure. The disclosed methods generally involve the application of an electric field in a manner that kills any bacteria that may remain in a root canal after an endodontic procedure while minimizing heat and/or damage to surrounding dental tissue.

[0008] According to one embodiment, the apparatus employed during the disclosed procedures includes a monopolar electrode probe which is sized and configured for insertion into a root canal of a tooth (*e.g.*, having a length of about 15 mm and a diameter of about 0.5 mm), a ground electrode that is electrically connectable to a patient, and a power source for providing an electrical voltage between the monopolar electrode probe and the ground electrode.

[0009] One exemplary method comprises the steps of: (1) electrically connecting the ground electrode to a patient so as to provide an electrical ground that will complete the circuit with the monopolar electrode probe; (2) inserting the monopolar electrode probe into a root canal preparation of a patient; and (3) applying an electrical voltage between the ground and the inserted probe so as to produce an electric field within the root canal preparation, between the probe and the periodontium, killing any microbes still present without significantly damaging or heating surrounding dental tissue (*e.g.*, periodontium, alveolar bone, or adjacent dentin).

[0010] In 1942, Suzuki (Experimental Studies on Ionophoresis, J. Jpn. Stomatol. 16 (1942), pp. 411–417. 4 I) demonstrated that the periodontium of each tooth exhibits substantially identical resistance at any given location, calculated between it and, for example, a ground electrode attached to oral tissue or held in the patient's hand. In other words, the periodontium acts as an equipotential membrane surrounding the roots of a person's teeth.

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The resistance value was proposed by I. Sunada (New Method for Measuring the Length of the Root Canal, Journal of Dental Research 41 (1962), 375–87) and J. Dahlin (Electrometric Measuring of the Apical Foramen, A New Method for Diagnosis and Endodontic Therapy. Quintessence International 10, (1979), pp. 13–22).

[0011] As a result, it has now been discovered that by applying a voltage between the probe and the ground electrode (*e.g.*, in the hand of the patient or attached to the gingiva), an electric field can be generated between the inner root canal system and the periodontium. Where the ground electrode is held in the patient's hand, the rest of the patient's body between the hand and the periodontium simply acts as a large electrical conductor. Since the electric field strength increases as the distance between the electrodes is reduced, and because of the relatively low conductivity of the dentin, it is believed that this is the reason why such an electric field can be generated without damage to surrounding tissue while still killing any microbes that may be present in the root canal.

[0012] Advantageously, the applied voltage is sufficiently low so that preferably virtually no electrical current flows between the ground and the electrode probe, but high enough to generate an electric field capable of eradicating the microbial population (*e.g.*, through electroporation of the cell walls of the microbes and/or apoptosis). Virtually no current flow results in substantially no heating of surfaces or materials within the root canal (*e.g.*, surrounding dental tissue is heated by less than about 10°C, or less than about 5°C, or less than about 2°C or essentially no heating) only the generation of a disruptive electric field that is sufficient to selectively target and kill microbes without damaging surrounding dental tissue.

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[0013] The inventive method provides for simple, effective, rapid and substantially complete disinfection of a root canal preparation, after which the practitioner may proceed to complete the endodontic procedure (*e.g.*, drying, filling and sealing of the root canal).

[0014] These and other advantages and features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0015] To further clarify the above and other advantages and features of the present invention, a more particular description of the invention will be rendered by references to specific embodiments thereof, which are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. The invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0016] Figure 1 illustrates a root canal preparation of a tooth in which the pulp and nerve tissue have been removed; and

[0017] Figure 2 is a perspective view of a patient's mouth in which the ground electrode is connected to the gingiva and the monopolar electrode probe is inserted by the practitioner within the root canal preparation of Figure 1 while an electrical voltage potential is applied;

[0018] Figure 3 is a close up cross-sectional view of the root canal with the monopolar electrode probe inserted within the root canal while an electric field is generated as a result of the difference in electrical potential of the monopolar electrode probe and the periodontium; and

[0019] Figure 4 is a perspective view of a patient in an alternative method similar to that shown in Figure 2 but in which the ground electrode is held within the hand of the patient.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

I. Introduction

[0020] The present invention is directed towards methods for disinfection of a root canal preparation during an endodontic procedure. The disclosed methods generally involve the application of an electric field in a manner that kills any bacteria that may remain in a root canal after an endodontic procedure while minimizing heat and/or damage to surrounding dental tissue.

[0021] According to one embodiment for carrying out the disclosed methods, a monopolar electrode probe sized and configured for insertion into a root canal of a tooth is inserted within the root canal preparation. A ground electrode is electrically connected to the patient (*e.g.*, to the patient's hand). The ground is electrically connected to the monopolar electrode probe through the patient's body, and an electrical voltage is applied between the probe and the ground, resulting in virtually no current flow between the monopolar and ground electrodes, but still generating an electric field in the root canal and optionally surrounding dental tissue. The electric field kills microbes within the root canal of the tooth and optionally within adjacent dentin without significant heating or damaging surrounding dental tissues.

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II. Exemplary Apparatus and Methods

[0022] Figure 1 illustrates a tooth 100 in which one or more root canals 102 of a tooth have been prepared by removing necrotic pulp and nerve material from root canal(s) 102 in preparation for filing and sealing of the root canal(s) 102. Bacteria and other microbes are typically present within root canal 102 and on adjacent dentin surfaces 104, both as a biofilm and in planktonic formats. Once the root canal 102 has been cleared of necrotic

diseased nerve tissue and other relatively large debris particles, an aqueous wash may be introduced into root canal(s) 102 to aid in removal of any residual debris. Using state of the art methods, such a wash may comprise a chemical disinfecting wash solution (*e.g.*, aqueous sodium hypochlorite) that is introduced into the root canal(s) 102 to aid in removal of any residual debris and optionally to disinfect the root canal. While such applications are helpful in eradicating a microbial population, the aqueous chemical disinfecting solution may often not completely kill bacteria and other microbes present within the root canal(s) 102, particularly due to the microanatomy of the dentin where lateral micro-fissures, cracks or other micro-channels may be present. The disinfecting wash solution may not, in all cases, be able to fully penetrate into all regions of the root canal(s), including lateral canals and fissures, where infection may be hiding. As a result, infection and microbes may continue to lurk even after diligent cleaning and disinfecting of the root canal(s).

[0023] As such, according to the present invention, methods of disclosed embodiments include a process by which bacteria and other microbes within the root canal(s) 102 are eradicated by generation of an electric field within the root canal 102. Although nothing forecloses their use in the context of the disclosed methods, it may be unnecessary to apply a chemical disinfecting wash in all cases, or even in any cases, although such a wash may be applied so as to provide chemical disinfection in conjunction with methods for disinfection using an electric field. Preferably, the root canal 102 is washed with an aqueous EDTA solution (*e.g.*, 0.5 M EDTA) in order to open dentinal tubules by at least partially removing the smear layer plugs produced during cleaning and abrading of the root canal 102. The EDTA wash may be followed by a wash of water and/or an aqueous saline solution in preparation for the electric field disinfection. Depending on the total electrical resistance of the root canal system, the use of a saline solution may be advantageous, as it can provide

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ions within the liquid occupying the root canal 102(s) while applying an electric field, which is believed to aid in propagating and locally increasing the strength of the generated electric field within the root canal and associated dentinal tubules. Once the root canal 102 has been washed (and optionally disinfected using an antiseptic solution), it is ready for in vivo generation of the disinfecting electric field.

[0024] Figure 2 is a perspective view of a patient's teeth in which an electric field disinfection apparatus 150 is being used to provide for electric field disinfection of the root canal(s) 102 of tooth 100. Figure 3 is a cross-sectional view of the tooth 100 and disinfection apparatus of Figure 2. Apparatus 150 includes an electrical power source (not shown), a ground electrode 154, and a monopolar electrode probe 156. As seen in Figure 3, probe 156 is advantageously sized and configured for insertion into root canal 102. It is advantageously elongate and may be needle shaped in some cases. According to one embodiment, the monopolar electrode probe 156 can have a length between about 5 mm and about 30 mm, preferably between about 10 mm and about 25 mm, and more preferably between about 12 mm and about 20 mm. According to one embodiment, the diameter of probe 156 may be less than about 2 mm, preferably between about 0.06 mm and about 1 mm, more preferably between about 0.1 mm and about 1 mm, and most preferably between about 0.25 mm and about 0.75 mm.

[0025] Ground electrode 154 can be attached to patient 125, for example, to the gingiva 160 adjacent tooth 100 (Figure 3). Attachment may be accomplished by an adhesive pad surrounding the electrode. Such an adhesive pad aids in holding and electrically connecting the ground electrode 154 to gingival tissue 160. In another embodiment, the ground electrode may be configured to be held within the hand of the patient (Figure 4). A method in which the ground electrode is held within the patient's hand may reduce the chance of a

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burn, as an electrode configured to be gripped by or otherwise attached to the hand or other large surface are of that patient's body has substantially greater surface compared to tissues within the patient's mouth. Moreover, if the adhesive pad connected to ground electrode 154 fails to provides adequate adhesion to the moist gingival tissue, a burn may result. In any case, the ground electrode can be electrically connected to the patient by virtually any desired means to provide an electrical "ground" relative to the probe 156 when a voltage differential is applied between ground electrode 154 and probe 156 so as to complete the electrical circuit.

[0026] An electrical voltage potential is then applied by the power source between ground electrode 154 and probe 156. The applied voltage is advantageously sufficiently low that virtually no current flows between ground electrode 154 and probe 156. Rather, an electric field is advantageously generated between electrode probe 156 and the periodontum 158, which is electrically connected to ground electrode 154 through the patient's electrically conductive body (*e.g.*, conductive fluids, such as blood). Because of the equipotential characteristics of periodontium 158, it is believed that the electric field only extends between probe 156 and periodontium 158. In other words, the periodontium 158 may act as the ground.

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[0027] The appropriate applied voltage may depend on the duration of voltage application, whether the voltage is continuous or pulsed, is direct current or alternating current, and if pulsed the nature of the waveform employed (*e.g.*, sine wave, square wave, etc.), as well as the waveform frequency. Voltage may also depend on other variables, for example, on the specific materials and configurations of the ground electrode 154, electrode probe 156, the distance between the electrodes, and the compositional characteristics of water (*e.g.*, aqueous solution 162) or other fluid within the root canal. By way of example, the applied

electrical voltage may be between about 1 volt and about 10,000 volts, preferably between about 10 volts and about 10,000 volts, more preferably between about 250 volts and about 2000 volts, and most preferably between about 500 volts and about 1500 volts. In addition to being low enough to prevent significant current flow (*e.g.*, to prevent sparking or arcing, which can result in heat generation and/or tissue damage), the voltage can be sufficiently high to produce an electric field with sufficient strength to eradicate the microbe population that may be present within a root canal preparation or other dental preparation.

[0028] The voltage can be applied for a duration sufficient to generate an electric field that is effective in causing electroporation and/or apoptosis and eradication (*e.g.*, at least a 2 log reduction, preferably at least a 3 log reduction, more preferably at least a 4 log reduction) of bacteria (both planktonic and biofilm) within the root canal preparation. According to one embodiment, the voltage may be pulsed during application of the voltage. For example, the total duration of applied voltage (whether pulsed or unpulsed) may be between about 10 nanoseconds and about 30 seconds, preferably between about 0.001 second and about 5 seconds, and more preferably between about 0.01 second and about 4 seconds. Even more preferred durations may be between about 1 second and about 5 seconds, and most preferably may be between about 2 seconds and about 4 seconds.

[0029] In the case where the voltage is pulsed, individual pulse durations can typically be between about 1 nanosecond and about 1000 milliseconds (ms), preferably between about 5 nanoseconds and about 500 ms, and more typically between about 1 ms and about 100 ms. Preferred individual pulse duration values may be between about 10 ms and about 1000 ms, more preferably between about 50 ms and about 500 ms, and most preferably between about 100 ms and about 200 ms.

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[0030] Furthermore, the number of pulses in the case of application of a pulsed voltage may be between about 2 and about 50 million, typically between about 10 and about 3 million, and more typically between about 15 and about 500,000. Most preferred pulse numbers may be between about 2 and about 50, more preferably between about 10 and about 30, and most preferably between about 15 and about 25.

[0031] One particular example discovered by the inventor to provide suitable results involves the application of 1000 volts over a duration of about 2.8 seconds, with an individual square wave pulse duration of about 140 ms, a pulse number of about 20 pulses, and a rest time between pulses of about 3 seconds. Preferably, rest times between such pulses can range between about 0.5 second and about 10 seconds, more preferably between about 1 and about 5 seconds.

[0032] Such operating parameters have been found by the inventor to be sufficient to result in destruction of bacteria. Although it is believed, according to one theory, that electroporation and/or apoptosis of the bacteria and/or other microbe cell walls may be the mechanism by which killing of the bacteria and other microbes is achieved, the inventor is not bound to this theory, and it is possible that other factors may contribute to or be responsible for the discovered microbe-killing ability of the disclosed methods.

[0033] According to one theory, it is believed that the electric field disrupts the integrity of the cell wall, opening pores through the wall and into the interior of the cell. Another theory is that the electric field induces apoptosis, which may trigger an inner biological mechanism of the microbe, resulting in the death of the cell. In any case, the disclosed methods result in killing of the microbes, although the particular mechanism by which the electric field leads to death may not be fully known. According to one theory, an osmotic shock may occur while the membrane breaks down, and the inner environment of the cell is irreversibly

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damaged. According to another theory, free radicals either generated by the electric field and/or already present within the root canal are able to more easily penetrate through the protective cell wall as a result of cell wall degradation. Under such a theory, any sodium hypochlorite or other residual chemical disinfectant within the root canal should more easily penetrate and kill bacteria cells present in planktonic and/or biofilm formats, leading to an even greater log reduction of the microbial population and a synergistic effect between the electric field and chemical disinfectant. In the case where the method involves application of short pulses, it is believed that the electric field may not be sufficient to cause cell wall breakdown but rather generates the activation of inner cell mechanisms that lead to apoptosis of the cell. In any case, the method has been found effective in eradicating microbes within a root canal or other dental preparation.

[0034] Because of the electric field, the concentration of a chemical disinfectant that may otherwise be required to eradicate the bacteria is considerably lower compared to disinfecting the root canal without generation of an electric field. For example, the inventor has found that essentially or almost zero disinfectant concentration may be sufficient, as electric fields can result in eradication of the bacteria by itself (*e.g.*, to yield at least a 2 log, 3 log, or 4 log reduction). The presence of any added chemical disinfectant may serve to increase the log reduction as compared to applying the electric field by itself (*e.g.*, at least a 3 log reduction, 4 log reduction, or 5 log reduction may be achieved when an electric field is employed simultaneously with chemical disinfection). No matter the actual mechanism, it has been found that exposing the root canal and surrounding lateral voids and structures to an electric field as described above surprisingly and advantageously results in eradication of the microbes present, without any need for chemical disinfection, or when using

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significantly lower concentrations and/or amounts of chemical disinfectant (*e.g.*, less than about 50%, or less than about 75%, or even less than about 90%).

[0035] The electrodes 154 and 156 may be formed of any suitable electrically conductive material. Examples of suitable materials include platinum, gold, silver, copper, aluminum, stainless steel, and other metals and alloys. In one embodiment, the monopolar electrode probe 156 that is inserted within the root canal 102 comprises silver, which may also result in release of silver ions during generation of the electric field within the root canal. Silver ions can exhibit an anti-microbial effect, and such an embodiment may act to further reduce the population of microbes within the root canal during the disinfection procedure.

Example 1

[0036] Extracted teeth were collected and de-coronated. The root canal systems of each tooth were shaped to achieve a size ISO 25 at the apex. The apices where sealed from outside the tooth with a composite resin to avoid direct flow of current from the apex. Each tooth was tightly enveloped in aluminum foil, and a wire was connected. All samples were included in a transparent resin block, with the free end of the wire out. The periphery surrounding the upper access to the root canal system was sealed with composite. All samples were inoculated repeatedly with a culture of *E. faecalis.* Before treatment, liquid inside the root canal system of all the samples was removed from the root canal using absorbent paper points and then placed in a microcentrifuge tube, diluted and plated for determination of viability and number of colony forming units per mL (cfu/mL).

[0037] Each root canal system was filled again with sterile 0.1M saline solution. The ground electrode of the generator was connected to the wire extending out of the resin block, and the probe connected with the active electrode was inserted into the root canal system.

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Under these conditions, 10 pulses of electrical power were applied using the electrodes. Afterwards, liquid inside the root canal system was removed with from the root canal using absorbent paper points and then placed in a microcentrifuge tube, diluted, and plated for determination of viability and number of cfu/mL.

[0038] Each root canal system was lightly shaped with an endodontic file, rinsed with 0.1M sterile saline solution, shaped again, rinsed with sterile saline solution again, and then dried. The purpose of this instrumentation was to eliminate any biofilm presumably present on the interior surface of the root canal due to the long inoculation time of the samples. During this procedure, sterile saline solution irrigation (0.1M) was used to wash out debris. The use of saline solution by itself avoided chemical antibacterial activity. At this point, the dentinal tubules deep within the dentin structure still retained their bacteria biofilm.

[0039] Subsequent to drying the canal, a 0.5M EDTA solution was applied for 30 seconds in order to eliminate smear plugs due to the filing or abrading action inside the openings of the dentinal tubules. EDTA is not believed to have any significant antimicrobial effect at the concentration used. Afterwards, the root canal system was rinsed with 0.1M sterile saline solution again. Under these conditions, 10 pulses of electrical power were applied using the electrodes, and afterwards the liquid inside the root canal system was dried with paper points then placed in a microcentrifuge tube, diluted and plated for determination of viability and number of cfu/mL.

[0040] After the foregoing steps, the root canal was filled with saline and sterile gate #4 was used to collect shavings of dentin, which were dried with paper points and then placed in a microcentrifuge tube, diluted and plated to determine number of cfu/mL. The outcomes after two sets of 10 pulses and instrumentation was a kill rate of 98.7% (about a 2 log

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reduction) in the root canal system, and a kill rate of 99.9% (a 3 log reduction) in the dentin shavings. The operating parameters were as shown in Table I below.

Table I

Parameter	Value
Voltage	1000 V
AC/DC	AC
AC Frequency	315 KHz
Number of Pulses	20
Pulse Duration	140 ms
Total Duration	2.8 seconds
Rest Time between Pulses	3 seconds

[0041] The foregoing test and outcome show how electric fields can be effective in eradicating an otherwise difficult-to-treat infective condition. Dentin is an example of a tissue that can be very difficult to disinfect due to its tubular microstructure. The interior of a tooth is made of dentin, a substance organized in a multi-tubular structure. Typically, dentinal tubules extend from the root canal to the external surface of the root. The microtubules extend generally perpendicularly to the axis of the canal. Such tubules have a diameter of about 2 microns and, seen from inside the canal, have a generally regular disposition, appearing somewhat like a honeycomb. Dentinal tubules, once colonized by a bacterial biofilm, comprise a biological structure that is nearly impossible to sterilize in vivo. According to current endodontic protocol, it is acceptable to leave an amount of

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bacteria living inside of the microstructure. Such state of the art methods rely on "entombing" and eventual death of the microbial population over time using endodontic cement rather than complete eradication of the microbes in the first instance. The experiment conducted above shows that the concept of achieving substantially complete eradication by electric field generation is achievable.

[0042] The needle probe inserted in the root canal system is an electrode that generates an electric field that has a correspondent in the periodontium that acts as the second (*i.e.*, ground) electrode such that the entirety of the dentin wall can be within the influence of the electric field. This allows killing substantially all of the bacteria residing both within the dentin and the root canal. There are no significant side effects within tissue beyond the periodontium because electric field effects beyond the periodontium are greatly diminished.

[0043] The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

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CLAIMS

1. A method for disinfecting a root canal preparation of a patient, comprising:

electrically connecting a ground electrode to a body of the patient so as to provide an electrical ground;

inserting a monopolar probe into a root canal preparation of a tooth of the patient; and

applying an electrical voltage between the ground electrode and the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal and so as to kill microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue.

2. A method as recited in claim 1, wherein the root canal preparation contains an aqueous conducting fluid when the electrical voltage is applied.

3. A method as recited in claim 2, wherein the aqueous conducting fluid does not include a chemical disinfectant.

4. A method as recited in claim 2, wherein the aqueous conducting fluid comprises a chemical disinfectant.

5. A method as recited in claim 4, wherein the chemical disinfectant comprises aqueous sodium hypochlorite.

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6. A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage in a range of about 1 volt to about 10,000 volts.

7. A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage in a range of about 250 volts to about 2000 volts.

8. A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage in a range of about 500 volts to about 1500 volts.

9. A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage over a time duration in a range of about 10 nanoseconds to about 30 seconds.

10. A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage over a time duration in a range of about 0.001 second to about 5 seconds.

11. A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage over a time duration in a range of about 0.01 second to about 4 seconds.

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12. A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage that is pulsed, wherein individual pulses of the electric voltage have a time duration in a range of about 1 nanosecond to about 1000 milliseconds.

13. A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage that is pulsed, wherein individual pulses of the electric voltage have a time duration in a range of about 5 nanoseconds to about 500 milliseconds.

14. A method as recited in claim 1, wherein applying an electrical voltage comprises applying an electrical voltage that is pulsed, wherein individual pulses of the electric voltage have a time duration in a range of about 1 millisecond to about 200 milliseconds.

15. A method as recited in claim 12, wherein applying an electrical voltage comprises applying a number of individual pulses in a range of 2 to about 50 million.

16. A method as recited in claim 12, wherein applying an electrical voltage comprises applying a number of individual pulses in a range of about 10 to about 3 million.

17. A method as recited in claim 12, wherein applying an electrical voltage comprises applying a number of individual pulses in a range of about 15 to about 500,000.

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18. A method as recited in claim 12, wherein applying an electrical voltage comprises providing a rest time between individual pulses in a range of about 1 second to about 5 seconds.

19. A method as recited in claim 1, wherein applying an electrical voltage results in virtually no electrical current flow between the monopolar probe inserted within the root canal preparation and the ground electrode.

20. A method as recited in claim 1, wherein the monopolar probe inserted within the root canal preparation comprises silver.

21. A method as recited in claim 1, wherein the ground electrode further comprises an adhesive pad for holding the ground electrode to gingival tissue.

22. A method as recited in claim 1, wherein the monopolar probe has a length in a range of about 12 mm to about 20 mm.

23. A method as recited in claim 1 wherein the monopolar probe has a diameter in a range of about 0.06 mm to about 1 mm.

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24. A method for disinfecting a root canal preparation of a patient, comprising:

providing a root canal preparation of the patient's tooth that contains an electrically conductive fluid;

electrically connecting a ground electrode to gingival tissue of the patient so as to provide an electrical ground;

inserting a monopolar probe into a root canal preparation of a tooth of the patient; and

applying an electrical voltage between the ground electrode and the monopolar probe inserted within the root canal preparation so as to produce an electric field within the root canal and so as to kill microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue.

25. An apparatus for use in disinfecting a root canal preparation of a patient, comprising:

means for electrically connecting a ground electrode to a body of a patient so as to provide an electrical ground;

a monopolar probe sized and configured for insertion into a root canal preparation of a tooth of a patient; and

means for applying an electrical voltage between the ground electrode and the monopolar probe when inserted within a root canal preparation and in a manner so as to produce an electric field within the root canal that is able to kill microbes within the root canal preparation without damage to or substantial heating of surrounding dental tissue.

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ABSTRACT OF THE DISCLOSURE

Methods employing an electric field for disinfection of a root canal preparation during an endodontic procedure. A monopolar electrode probe sized and configured for insertion into a root canal of a tooth is inserted within the root canal preparation. A ground electrode is electrically connected to the patient to complete the circuit with the monopolar electrode probe. An electrical voltage is applied between the probe and ground, resulting in virtually no current flow between the electrodes, but rather the generation of an electric field within the root canal and adjacent dental tissues. The electric field kills microbes within the root canal system of the tooth without significant heating or damage to surrounding dental tissue.

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Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION
First Named Inventor/Applicant Name:	Roberto Armanino
Filer:	John Michael Guynn/Sandy Perkins
Attorney Docket Number:	7678.1035.1.1

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility application filing	1011	1	330	330
Utility Search Fee	1111	1	540	540
Utility Examination Fee	1311	1	220	220
Pages:				
Claims:				
Claims in excess of 20	1202	5	52	260
Miscellaneous-Filing:				
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1350**

Electronic Acknowledgement Receipt

EFS ID:	7793461
Application Number:	12813565
International Application Number:	
Confirmation Number:	7247
Title of Invention:	METHOD EMPLOYING ELECTRIC FIELDS TO SELECTIVELY KILL MICROBES IN A ROOT CANAL PREPARATION
First Named Inventor/Applicant Name:	Roberto Armanino
Customer Number:	22913
Filer:	John Michael Guynn/Sandy Perkins
Filer Authorized By:	John Michael Guynn
Attorney Docket Number:	7678.1035.1.1
Receipt Date:	11-JUN-2010
Filing Date:	
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Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1350
RAM confirmation Number	7321
Deposit Account	233178
Authorized User	GUYNN,JOHN M.

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	ApplicationDataSheet.pdf	240665 137240cf9dd6b6035ba14ac7d8c1bdcee649b0d9	no	4
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
2	Oath or Declaration filed	Declaration.pdf	146928 c1d1d3ae782e9009518ea26dc4284ebd7ec8fb04	no	4
Warnings:					
Information:					
3	Drawings-only black and white line drawings	Drawings.pdf	100416 a55d77f26685e5c46e8121857698c9d429f15d94	no	4
Warnings:					
Information:					
4		Application.pdf	1009546 206db86001165d5be9dabec8958abce55ebdaa97	yes	24

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	18
Claims	19	23
Abstract	24	24

Warnings:	
Information:	
5 Fee Worksheet (PTO-875) — fee-info.pdf — 36767 — ae4b39c0d34d276bb400c36afdc5d5887842ba33 — no — 2	
Warnings:	
Information:	
Total Files Size (in bytes):	1534322

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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.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (12-04)

Approved for use through 7/31/2006. OMB 0651-0032

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Date: 06/11/2010

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: **12/813,565**

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	LARGE ENTITY RATE ($)	LARGE ENTITY FEE ($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	330
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	540
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	220
TOTAL CLAIMS (37 CFR 1.16(i))	25 minus 20 =	5	X $26		OR	X $52	260
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	0	X $110			X $220	0
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $270 ($135 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			195			390	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1350

APPLICATION AS AMENDED – PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	X =		OR	X =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X =		OR	X =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					N/A		OR	N/A	
						TOTAL ADD'T FEE		OR	TOTAL ADD'T FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	X =		OR	X =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X =		OR	X =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					N/A		OR	N/A	
						TOTAL ADD'T FEE		OR	TOTAL ADD'T FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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