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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	12189536
Filing Date	2008-08-11
First Named Inventor	Hilton Becker
Art Unit	1632
Examiner Name	Marcia Stephens Noble
Attorney Docket Number	DHB0012US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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	Attorney Docket Number	DHB0012US

	1	S. Shepard et al., "Using Hyaluronic Acid to Create a Fetal-like Environment In Vitro", Annals of Plastic Surgery, 36, 65-69, January 1996	☐

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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] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] 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	12189536
Filing Date	2008-08-11
First Named Inventor	Hilton Becker
Art Unit	1632
Examiner Name	Marcia Stephens Noble
Attorney Docket Number	DHB0012US

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.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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	/Toby D. Hain/	Date (YYYY-MM-DD)	2012-01-09
Name/Print	Toby D. Hain	Registration Number	66105

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.**

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 record s.

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 Acknowledgement Receipt

EFS ID:	11785547
Application Number:	12189536
International Application Number:	
Confirmation Number:	7206
Title of Invention:	HYALURONIC ACID PRODUCT AND METHOD FOR TREATING LACERATIONS AND WOUNDS IN A LIVING BODY
First Named Inventor/Applicant Name:	Hilton Becker
Customer Number:	23413
Filer:	Toby D. Hain
Filer Authorized By:	
Attorney Docket Number:	DHB0012US
Receipt Date:	09-JAN-2012
Filing Date:	11-AUG-2008
Time Stamp:	14:28:23
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) Form (SB08)	65P5283.PDF	612433 15835a19ef25d673ef540bb467cb2cea6db3c9f1	no	4

Warnings:	
Information:	

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

2	Non Patent Literature	65R0989.PDF	3402934 faa860561b45c4e55afd42e7b7f2d6ffec8c71eb	no	5

Warnings:

Information:

Total Files Size (in bytes):	4015367

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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.

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

PTO/SB/30EFS (07-09)
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	12189536	Filing Date	2008-08-11	Docket Number (if applicable)	DHB0012US	Art Unit	1632
First Named Inventor	Hilton Becker			Examiner Name	Marcia Stephens Noble		

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
  Remove the Application from Appeal

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 061130

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	/Toby D. Hain/	Date (YYYY-MM-DD)	2012-01-06
Name	Toby D. Hain	Registration Number	66105

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.

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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:	12189536
Filing Date:	11-Aug-2008
Title of Invention:	HYALURONIC ACID PRODUCT AND METHOD FOR TREATING LACERATIONS AND WOUNDS IN A LIVING BODY
First Named Inventor/Applicant Name:	Hilton Becker
Filer:	Toby D. Hain
Attorney Docket Number:	DHB0012US

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:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	2801	1	465	465
		Total in USD ($)		**465**

Electronic Acknowledgement Receipt

EFS ID:	11775088
Application Number:	12189536
International Application Number:	
Confirmation Number:	7206
Title of Invention:	HYALURONIC ACID PRODUCT AND METHOD FOR TREATING LACERATIONS AND WOUNDS IN A LIVING BODY
First Named Inventor/Applicant Name:	Hilton Becker
Customer Number:	23413
Filer:	Toby D. Hain
Filer Authorized By:	
Attorney Docket Number:	DHB0012US
Receipt Date:	06-JAN-2012
Filing Date:	11-AUG-2008
Time Stamp:	14:49:47
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$465
RAM confirmation Number	1287
Deposit Account	061130
Authorized User	HAIN,TOBY D.

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)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment After Final	65O9626.PDF	95324 3856d2e24464cb3a5e6fb8743765b6a78ff6366e	no	17
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	6584551.PDF	697965 dd7612c1bde029cec20444c5b2fe165467a0d13f	no	3
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30715 17b233a33a3b1d0aabcbba1dd54f422d66783843	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	824004		

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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

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hilton BECKER	)	
	)	Group Art Unit: 1632
Serial No.: 12/189,536	)	
	)	Examiner: Marcia Stephens
Filed: August 11, 2008	)	Noble
	)	Confirmation No.: 7206

For: HYALURONIC ACID PRODUCT AND METHOD FOR TREATING LACERATIONS AND WOUNDS IN A LIVING BODY

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

RESPONSE TO FINAL OFFICE ACTION
UNDER 37 C.F.R. § 1.114, WITH AMENDMENT

Sir:

In response to the Final Office Action dated September 16, 2010, the Applicant requests reconsideration in view of the following amendments and remarks for entry in the above-identified application, which are submitted with a request for continued examination ("RCE").

This response replaces the claim amendments filed on November 16, 2010. Therefore, please DO NOT ENTER the claim amendments filed on November 16, 2011.

In the Specification

Please amend the specification as follows. These changes incorporate amendments to the specification that were presented in the Response filed on June 25, 2010.

Please replace the paragraph beginning on page 2, line 19 as follows:

In essence, an exemplary embodiment[[s]] of the present invention contemplates a water activatable medicinal preparation for treating lacerations and wounds in a human body. The medicinal preparation is an emulsion of finely ground hyaluronic acid dispersed in a human-compatible oil and preferably in a human-compatible, absorbable oil such as squalane oil. In a preferred embodiment of the invention the emulsion contains about 5% to about 20% hyaluronic acid by weight or by volume. In a more preferred exemplary embodiment of the invention, the particles size of the hyaluronic acid is equal to or less than about 20 microns.

Please replace the paragraph beginning on page 2, line 28 as follows:

An exemplary embodiment of the present invention also contemplates a method for treating lacerations and wounds in a living body such as a human being in order to enhance healing and reduce scarring. The method includes the steps of providing a water-activatable emulsion of pure or relatively pure hyaluronic acid in a human-compatible and preferably highly absorbable oil. The hyaluronic acid is preferably ground to a fine particle size of about 20 microns or less and mixed into a dispersion in the human-compatible absorbable oil to produce an emulsion with about 5% to about 20% by weight or volume hyaluronic acid. The emulsion is then applied to the laceration or wound by any means as will be well understood by a doctor or surgeon of ordinary skill in the art and activated with water to form hyaluronic acid gel. Typically, the application of water may be by a fine spray, but other methods may be used. The oil is absorbed by the body while a portion of the water additive remains in contact with the hyaluronic acid and forms a hyaluronic acid gel, which enhances the healing of the laceration and/or wound.

Please replace the paragraph beginning on page 4, line 6 as follows:

FIG. 1 illustrates a first exemplary embodiment of the invention, i.e., a method for treating lacerations or wounds in a living body. The method 20 includes the step 22 of providing a first

mass of a preservative-free hyaluronic acid in pure or relatively pure form and a second mass of a human-compatible and preferably absorbable oil, for example, squalane oil.

Please replace the paragraph beginning on page 5, line 19 as follows:

In step 30, a cosmetic surgeon applies water to the emulsion, for example, by a fine spray or other means. It is presently believed that the absorbable oil rapidly penetrates the skin leaving a portion of the hyaluronic acid particles on the surface, and the water partially solvates or reacts with some of the residual ~~reacts with the~~ hyaluronic acid particles to form a hyaluronic acid gel at the wound site or on the laceration as well as into the dermis. It is also believed that a portion of the hyaluronic acid gel is carried into the patient's dermis while a portion covers the wound area, thereby enhancing ~~to enhance~~ healing.

In the Claims

1. (Currently Amended) A method for treating ~~lacerations and~~ wounds ~~in a living human body~~, comprising:

~~providing a first mass of a hyaluronic acid and a second mass of a human-compatible oil;~~

reducing the particle size of [[the]]hyaluronic acid ~~to produce ultra-fine~~ particles ~~of hyaluronic acid~~;

~~forming an emulsion of the ultra-fine~~dispersing the hyaluronic acid particles in the human-compatible oil to prepare the hyaluronic acid composition consisting of the hyaluronic acid particles and the human-compatible oil in an emulsion, such that the hyaluronic acid particles are pure hyaluronic acid in an inactive state ~~the emulsion being free of water and preservatives~~;

~~applying~~ disposing the hyaluronic acid composition on the wound~~emulsion to the laceration or a wound~~; and

~~forming an hyaluronic acid gel by~~ applying, after disposing the hyaluronic acid composition on the wound, water to the hyaluronic acid composition to activate the hyaluronic acid particles~~emulsion on the laceration or the wound~~.

2. (Currently Amended) The method ~~for treating lacerations and wounds in a human body~~ of claim 1, wherein the human-compatible oil is rapidly absorbable into the skin of a patient.

3. (Currently Amended) The method of claim 1~~for treating lacerations and wounds in a human body of claim 2~~, wherein the human-compatible~~, rapidly absorbable~~ oil comprises squalane oil.

4. (Canceled)

5. (Currently Amended) The method of claim 1~~for treating lacerations and wounds in a human body of claim 4~~, wherein the particle size of the hyaluronic acid particles is less than or equal to 70 microns.

6. (Currently Amended) The method of claim 5~~for treating lacerations and wounds in a human body of claim 4~~, wherein the particle size of the hyaluronic acid particles is less than or equal to 20 microns.

7. (Currently Amended) The method of claim 1~~for treating lacerations and wounds in a human body of claim 6~~, wherein applying water ~~forming the hyaluronic acid gel~~ comprises spraying water onto the hyaluronic acid composition to produce a hyaluronic acid gel~~emulsion~~.

8. (Currently Amended) The method of claim 3~~for treating lacerations and wounds in a human body of claim 7~~, wherein the ~~emulsion comprises the hyaluronic acid ranging from~~ hyaluronic acid particles are present in an amount of about 5 wt% to about 20 wt%, ~~by weight~~ and the squalane oil is present in an amount of about 95 wt% to about 80 wt%, based on the weight of the hyaluronic acid composition~~and squalane oil ranging from 95% to 80% by weight~~.

9. (Currently Amended) A hyaluronic acid composition ~~product~~ to treat ~~lacerations and~~ wounds ~~in a living body~~, ~~comprising~~consisting of:

~~an emulsion of hyaluronic acid and~~ a human-compatible, rapidly absorbable oil; and

hyaluronic acid particles disposed in the human-compatible oil in an emulsion,

wherein the hyaluronic acid particles are pure hyaluronic acid in an inactive state~~, the emulsion being free of water and preservatives~~.

10. (Currently Amended) The hyaluronic acid composition ~~product to treat laceration and wounds in a living body~~ of claim 9, wherein the human-compatible, rapidly absorbable oil comprises squalane oil.

11. (Currently Amended) The hyaluronic acid composition ~~product to treat laceration and wounds in a living body~~ of claim 10, wherein the ~~emulsion comprises hyaluronic acid ranging~~

~~from~~ hyaluronic acid particles are present in an amount of about 5 wt% to about 20 wt%, and the squalane oil is present in an amount of about 95 wt% to about 80 wt%, based on the weight of the hyaluronic acid composition ~~by weight and squalane oil ranging from about 95% to about 80% by weight~~.

12. (Currently Amended) The hyaluronic acid composition ~~product to treat laceration and wounds in a living body~~ of claim 11, wherein the particle size of the hyaluronic acid particles~~in the emulsion~~ is less than or equal to 70 microns.

13. (Currently Amended) The hyaluronic acid composition ~~product to treat laceration and wounds in a human body~~ of claim 12, wherein the particle size of the hyaluronic acid particles~~in the emulsion~~ is less than or equal to 20 microns.

14. (Currently Amended) A method for preparing ~~to prepare~~ a hyaluronic acid composition~~product~~, ~~comprising~~consisting of:

~~providing a first mass of a hyaluronic acid and a second mass of a human-compatible oil;~~

reducing the particle size of [[the]]hyaluronic acid particles to less than 20 microns~~to produce ultra-fine particles of hyaluronic acid~~; and

dispersing the hyaluronic acid~~forming an emulsion of the ultra-fine~~ particles in squalane oil to form the hyaluronic acid composition consisting of squalane oil and hyaluronic acid particles in an emulsion,

wherein the hyaluronic acid particles are pure hyaluronic acid in an inactive state~~the human-compatible oil, the emulsion being free of water and preservatives~~.

15. (Currently Amended) The method ~~to prepare a hyaluronic acid product~~ of claim 14, wherein the ~~product comprises:~~

pure hyaluronic acid is present in an amount of ~~ranging from~~ about 5 wt% to about 20 wt%, and the ~~by weight; and~~

squalane oil is present in an amount of ~~ranging from~~ about 95 wt% to about 80 wt%, based on the weight of the hyaluronic acid composition ~~by weight~~.

16. (Currently Amended) The method ~~for preparing a hyaluronic acid product~~ of claim 14, wherein the hyaluronic acid particles are suspended within the squalane oil, such that bacterial growth is inhibited~~the particle size of the hyaluronic acid is reduced to less than or equal to 20 microns~~.

REMARKS

Claims 1-16 are pending in the present Application. Claims 1-3 and 5-16 have been amended, and claim 4 has been cancelled, leaving claims 1-3 and 5-16 for consideration upon entry of the present amendment.

Claim Amendments

Independent claims 1, 9, and 14 have been amended for clarification and to recite dispersing hyaluronic acid particles in a human compatible oil such the such that the hyaluronic acid particles are pure hyaluronic acid in an inactive state. Support for these amendments can be found at least in claim 3 ("pure hyaluronic acid") and at page 2, lines 19-26 and page 6, lines 1-9 and FIG. 1of the specification as originally filed.

Claims 2, 3, 5-8, 10-13, and 15 have been amended for clarification.

Claim 16 has been amended to recite that the hyaluronic acid particles are dispersed within the squalane oil, such that bacterial growth is inhibited. Support for this amendment can be found at least at page 2, lines 8-15 of the specification as originally filed.

Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks.

Objection to the Specification

The specification was objected to as containing grammatical errors and as allegedly containing new matter. Office Action dated September 16, 2010, p. 13.

The specification has been amended in part to correct grammar and does not introduce new matter. See Amendments to the Specification above.

The Examiner states that "added material which not supported by the original disclosure is as follows: Page 7, lines 6-8, recites, 'the water partially solves some of the residual react with the hyaluronic acid particles'." *Id.*

The amendment of the specification for the paragraph beginning on page 6, line 19 recites, *inter alia*, "water partially solvates or reacts with some of the residual hyaluronic acid." One skilled in the art readily identifies *solvation and reaction* as chemistry inherent among the interactions of hyaluronic acid and water. Moreover, according to MPEP § 2163.07(a), by disclosing in a patent application a device that inherently performs a function or has a property,

operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter (emphasis added). Here, the gylcosoaminoglycan hyaluronic acid necessarily forms an equilibrium with water due to its pKa (pKa = 3), resulting in reversible deprotonation, protonation, and hydrogen bonding, i.e., water partially solvates or reacts with hyaluronic acid. Hence, amendment of the specification is proper under MPEP § 2163.07(a).

Accordingly, reconsideration, withdrawal of the objection to the specification, and allowance of the instant claims are respectfully requested.

Claim Rejections Under 35 U.S.C. § 112

Claims 1-16 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description. The Examiner indicates that claim 1, 9, and 14 recite "the emulsion being free of water" and contends that specification does not provide support for such matter. Office Action dated September 16, 2011, page 11.

Without conceding as to the propriety of the Examiner's rejection, claims 1, 9, and 14 have been amended. Thus, this rejection is moot.

Accordingly, reconsideration, withdrawal of the rejection under 35 U.S.C. § 112 of claims 1-16, and allowance of the instant claims are respectfully requested.

Claim Rejections Under 35 U.S.C. § 102(b)

Claims 9 and 10 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent Publication No. 2003/0113387 applied for by Tsuchida et al. (hereinafter "Tsuchida").

The Examiner alleges that Tsuchida teaches every claimed feature at paragraphs [0019, 0021, and 0027]. Office Action dated September 16, 2010, page 2. The Applicant traverses on the grounds that Tsuchida does not teach at least a composition consisting of a human-compatible, rapidly absorbable oil and pure hyaluronic acid in an inactive state.

Amended claim 9 recites a hyaluronic acid composition to treat wounds, consisting of: a human-compatible, rapidly absorbable oil; and hyaluronic acid particles disposed in the human-compatible oil in an emulsion, wherein the hyaluronic acid particles are pure hyaluronic acid in an inactive state.

Tsuchida discloses the sodium salt of hyaluronic acid combined with at least an oily component and Sasa albo-marginata extract. Tsuchida, paras. [0019, 0027].

The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. MPEP § 211.03. Thus, Tsuchida cannot properly be relied upon since Tsuchida requires Sasa albo-marginata extract. Further, Tsuchida does not teach pure hyaluronic acid and instead teaches the sodium salt of hyaluronic acid, i.e., Tsuchida teaches sodium hyaluronate. Pure hyaluronic acid does not admit of a sodium salt thereof.

To anticipate a claim, a reference must disclose each and every element of the claim. *Lewmar Marine v. Varient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Tsuchida does not disclose, expressly or inherently, compositions that consist of pure hyaluronic acid without Sasa albo-marginata extract. Claims 9 and 10 are therefore not anticipated by Tsuchida.

For at least the same reasons, claims 9-10 are not obvious over Tsuchida. The disclosure of Tsuchida teaches one of ordinary skill in the art that Sasa albo-marginata extract is an essential feature of the compositions for making antipruritic compositions in Tsuchida. Indeed, Tsuchida discloses:

> The present invention relates to an antipruritic composition and a wound-healing-promoting composition, which comprise an extract from Sasa albo-marginata (Bam-booseae Sasa) as an effective component.

Tsuchida, para. [0001]. Accordingly, every composition of Tsuchida has Sasa albo-marginata extract.. There is certainly no suggestion in Tsuchida to eliminate the Sasa albo-marginata, and one of ordinary skill in the art would have no motivation to do so in view of Tsuchida's teaching above.

For an obviousness rejection to be proper, all elements of the claims must be disclosed in the art; and the Examiner must "identify a reason that would have prompted a person of ordinary skill in the art in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.,* 127 S.Ct. 1727, 1741 (2007). Here, the compositions discloses and claimed by Tsuchida all contain a Sasa albo-marginata extract and impure sodium hyaluronate.. A hyaluronic acid composition that consists of (a legal term of art) pure hyaluronic acid and a human-compatible, rapidly absorbable oil are therefore not obvious over Tsuchida.

Reconsideration and withdrawal of the rejection of claims 9 and 10 are respectfully requested.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1-16 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over being unpatentable over U.S. Publication No. 2005/0220721 applied for by Kablick *et al.* (hereinafter "Kablick") in further view of U.S. Publication No. 2003/0113387 applied for by Tsuchida *et al.* (hereinafter "Tsuchida"), Safety Report, 1 In. J. Tox., 37, Abstract only (1982) (hereinafter "Safety Report"), U.S. Patent No. 5,378,461 to Neigut. (hereinafter "Neigut"), and U.S. Publication No. 2003/0021834 applied for by Petito (hereinafter "Petito").

Independent claim 1 recites a method for treating wounds, comprising:

reducing the particle size of hyaluronic acid particles;

dispersing the hyaluronic acid particles in the human-compatible oil to prepare the hyaluronic acid composition consisting of the hyaluronic acid particles and the human-compatible oil in an emulsion, such that the hyaluronic acid particles are pure hyaluronic acid in an inactive state;

disposing the hyaluronic acid composition on the wound; and

applying, after disposing the hyaluronic acid composition on the wound, water to the hyaluronic acid composition to activate the hyaluronic acid particles.

Independent claim 9 recites a hyaluronic acid composition to treat wounds, consisting of:

a human-compatible, rapidly absorbable oil; and

hyaluronic acid particles disposed in the human-compatible oil in an emulsion,

wherein the hyaluronic acid particles are pure hyaluronic acid in an inactive state.

Independent claim 14 recites a method for preparing a hyaluronic acid composition, consisting of:

reducing the particle size of hyaluronic acid particles to less than 20 microns; and

dispersing the hyaluronic acid particles in squalane oil to form the hyaluronic acid composition consisting of squalane oil and hyaluronic acid particles in an emulsion,

wherein the hyaluronic acid particles are pure hyaluronic acid in an inactive state.

The Examiner alleges that Kablick teaches hyaluronic acid powder that can be combined with squalane allegedly taught by Tsuchida and Safety Report, and Neigut in an emulsion. Office Action dated September 16, 2010, page 6.

Although Kablick teaches a hyaluronic acid, Kablick cannot possibly be combined with any reference that teaches an oil carrier or aqueous solution. Such a combination would render Kablick unsatisfactory for its intended purpose and would change the principle of operation of Kablick. Both of which are expressly forbidden by the MPEP, which states:

> **V. THE PROPOSED MODIFICATION CANNOT RENDER THE PRIOR ART UNSATISFACTORY FOR ITS INTENDED PURPOSE**
>
> If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (Claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. *The court reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged.*).
>
> **VI. THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE**
>
> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.).

Here, the Examiner asserts:

> Applicant's argument is not found persuasive because Kablick teaches irrigating the wound site prior to applying the HA powder to hydrate the HA powder into a gel (p. 1, [0011], and [0032]-[0033]). Thus, contrary to Applicant's assertion, Kablick teaches that hydration of the HA at the wound sight to form a gel in intended and a function of their invention. Thus, adding the elements the secondary references will aid the gel formation and healing properties at the wound sight and will not render the invention inoperably. Further, Kablick teaches that the anti-adhesive properties of the medicament come from the ultra-fine particle size and not the dehydrated aspect of the powder. Therefore, since Kablick teaches that the dry spray will form a gel at the irrigated wound site. The addition of elements that aid in the delivery of the HA, such as squalane oil, will not hinder the wound healing properties of the HA. Thus, contrary to Applicants assertion, nothing in the art of Kablick or the secondary references suggests that the HA and squalane oil can not be used successfully together for wound healing. Thus, there is not teaching away from the combination of the art, as asserted by Applicant. Kablick teaches the wound healing and non-adhesive properties of an ultra-fine particle size HA and subsequent HA hydrogel formation at an irrigated wound site. The secondary references teach the use of squalenes and the advanatages of adding squalene to a topical wound healing medicament. Thus, the combination of the ultra-fine HA particle size with squalane oil would be an obvious variant of the wound healing medicament, and method of make and use of said medicament taught by Kablick.

Office Action dated September 16, 2011, page 10. First, the Applicant has not asserted teaching away but rather that the proposed modification renders Kablick unsatisfactory for its intended purpose and changes the principle of operation of Kablick. Second, according to the claim 1, 9, and 14, the hyaluronic acid consists of pure hyaluronic acid and a rapidly absorbable oil (e.g., squalane) in an emulsion, the emulsion is applied to a wound, and thereafter water is applied to the emulsion. The Applicant's specification, which the claims are supposed to be read in view of, makes clear that water is applied after the emulsion is disposed on the skin so that the oil can rapidly penetrate the skin with hyaluronic acid left on the skin reacting with water that is sprayed on the skin to form a hyaluronic acid gel. Specification, page 6, lines 19-25. However, Kablick is strikingly different in that Kablick's discloses (and invention) is solely the entrainment of hyaluronic acid in a gas stream and delivery of the hyaluronic acid in the gas stream to a wound.

Kablick, para. [0010]. Although, Kablick discloses at para. [0011] that the wound may be irrigated prior to applying the powder to provide liquid for hydrating the powder into a gel, Kablick has only one means of hyaluronic acid delivery, namely: powder delivery via gas. Kablick simply does not disclose, teach, or suggest, an alternative to delivering anything other than a powder by anything other than a gas. Thus, any other reference (to combine with Kablick) that provides a liquid delivery mechanism or hyaluronic acid in a liquid of any sort would change the principle of operation of Kablick's invention. That is Kablick's principle of operation is summed up in Kablick's title "Anti-Adhesion Spraying," which is given meaning in the Kablick's Abstract:

> Dry powders containing bioresorbable hyaluraonic acid ("HA") are applied directly to a desired location in a patient wound to reduce adhesions, without first forming a hydrated gel. HA includes hyaluronic acid that has been modified, cross-linked or combined with other substances. It is important to control the size of the particles in the powder. The powder is essentially dry and blowable powder.

Emphasis added. Moreover, Kablick's independent claims further support the Applicant's position:

> 1. An essentially dry blowable powder comprising bioresorbable HA, said powder being characterized in that at least 90% of powder particles have a maximum dimension between 5 .mu.m and 1 mm.
>
> 7. A method of reducing undesirable adhesions during wound healing, comprising applying the powder of claim 1 into a location in a wound where adhesion reduction is desired, said powder being applied to be present in a mass per area sufficient to reduce adhesions as the wound heals.
>
> 8. A method of reducing undesirable adhesions in a wound comprising applying a dry, blowable powder into a location in said wound where adhesion reduction is desired, said powder being applied to be present in a mass per area sufficient to reduce said adhesions, said powder comprising bioresorbable HA, CMC, or both.
>
> 25. Apparatus for delivering powder to a wound, said apparatus comprising a powder reservoir connected to an incoming airflow conduit and an exiting airflow conduit, said conduits being connected to said reservoir to entrain powder in airflow that enters through said incoming conduit and exits through said exiting airflow conduit, said reservoir comprising the powder of claim 1.
>
> 35. Apparatus comprising a dry, blowable powder to be introduced into a location in said wound where adhesion reduction is desired, said powder comprising HA

> or CMC, said apparatus further comprising a reservoir to contain said powder and exit orifices to apply the powder to said location.
>
> 36. A method of making the powder of claim 1 comprising, in any sequence, providing a solid material comprising HA, milling solid material comprising HA, and sieving solid material comprising HA to select material characterized in that at least 90% of powder particles have a maximum dimension between 5 μm and 1 mm.

Thus, Kablick only teaches, discloses, or suggests application of a dry powder to a wound from the powder entrained in an airflow. If Kablick's powder of hyaluronic acid was instead placed in an oil, as the Examiner contends, Kablick's principle of operation would be changed so that a dry powder is not entrained in an airflow. Additionally, Kablick would be unsatisfactory for its intended purpose since powder would not be deliverable to a wound.

Thus for at least this reason, Kablick cannot be combined with Tsuchida, Safety Report, Neigut, or Petito because each reference discloses a liquid carrier.

Moreover, Tsuchida cannot be combined with Kablick because, as discussed above with respect to the rejection of claim 9, every composition of Tsuchida has Sasa albo-marginata extract. There is no suggestion in Tsuchida (or any other cited reference) to eliminate the Sasa albo-marginata, and one of ordinary skill in the art would have no motivation to do so in view of Tsuchida's teachings. Similarly, Neigut only discloses a composition that has minimally Vitamin A, Vitamin E, and a coenzyme Q with an oil. Neigut, col. 4, lines 27-41. Such compositions of Tsuchida or Neigut must contain much more than an oil. Thus, a combination of Tsuchida and/or Neigut with Kablick would not provide a composition consisting of pure hyaluronic acid and a rapidly absorbable oil (in addition to impermissibly rendering Kablick inoperable for its intended purpose and impermissibly changing Kablick's principle of operation).

Furthermore, none of the references disclose, teach, or suggest, and one skilled in the art would not be prompted, to make a composition consisting of pure hyaluronic acid and an oil; to dispose the hyaluronic acid composition consisting of pure hyaluronic acid in a rapidly absorbable oil as an emulsion on a wound; and then to apply, after disposing the hyaluronic acid composition on the wound, water to the hyaluronic acid composition to activate the hyaluronic

acid particles. Certainly, Kablick's disclosure of pre-irrigating the wound prior to blowing a powder in an airflow onto a wound cannot be construed as applying water after disposing an emulsion consisting of pure hyaluronic acid and a rapidly absorbable oil to a wound. Neither Tsuchida, Petito, Neigut, nor the Safety Report cure this deficiency, and one skilled in the art would not be prompted to modify Kablick since that would impermissibly render Kablick inoperable for its intended purpose and impermissibly change Kablick's principle of operation.

For at least these reasons, Kablick, Tsuchida, Neigut, Petito, and the Safety Report, alone or in combination, fail to disclose or suggest the claimed features. For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). In the absence of any disclosure or suggestion of the recited features, claims 1-3 and 5-16 are not obvious over Kablick, Tsuchida, Neigut, Petito, and the Safety Report.

Reconsideration, withdrawal of the rejection under 35 U.S.C. § 103 of claims 1-16, and allowance of the instant claims are respectfully requested.

Conclusion

It is believed that the foregoing remarks fully comply with the Office Action and that the claims herein should now be allowable to the Applicant. Accordingly, reconsideration and allowance are requested.

The Applicant hereby petitions for any necessary extension of time required under 37 C.F.R. 1.136(a) or 1.136(b) or any other necessary fees(s), which may be required for entry and consideration of the present Response and RCE.

If any fees are due in connection with this Reply, or otherwise, the Applicant's attorneys authorize that such fee be charged to Deposit Account No. 06-1130. Please credit any overpayments to Deposit Account No. 06-1130.

Respectfully submitted,

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/189,536	08/11/2008	Hilton Becker	P3980US00

CONFIRMATION NO. 7206

58027
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POWER OF ATTORNEY NOTICE

OC00000050587781

Date Mailed: 10/28/2011

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/13/2011.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/agizaw/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/189,536	08/11/2008	Hilton Becker	DHB0012US

CONFIRMATION NO. 7206

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POA ACCEPTANCE LETTER

OC000000050587852

Date Mailed: 10/28/2011

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/13/2011.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/agizaw/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

POWER OF ATTORNEY

Commissioner for Patents
P.O. Box 1450
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Sir:

Hilton Becker, as named inventor, I hereby appoint the practitioners associated with customer number:

23413

with full power to prosecute the following patents and/or patent applications identified below including all revivals, refilings, continuations, continuations-in-part, divisions and reissues thereof, and to transact all business in the Patent and Trademark Office connected herewith.

Attorney Docket Number	Status	APPLICATION/GRANT NO.	FILE/ISSUE DATE
DHB0001US	PUBLISHED	12/552353	9/2/2009
DHB0001USP	PUBLISHED	12/556050	9/9/2009
DHB0001USP2	PUBLISHED	12/766821	4/23/2010
DHB0002US2	PUBLISHED	12/496365	7/1/2009
DHB0006US	GRANTED	7081136	7/25/2006
DHB0007US	GRANTED	6183514	2/6/2001
DHB0008US2	PENDING	13/157044	6/9/2011
DHB0009US	PENDING	61/509369	7/19/2011
DHB0012US	PENDING	12/189536	8/11/2008
DHB0013US	GRANTED	5507808	4/16/1996

The undersigned hereby grants said practitioners the power to insert on this Power of Attorney any further identification that may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office.

Inventor hereby further directs that all correspondence and telephone calls in connection with these patents and/or patent applications be addressed to the said

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and that all patents and/or patent applications be associated with Customer No. 23413.

By: _____
Hilton Becker
Inventor

Date: 10/4/11

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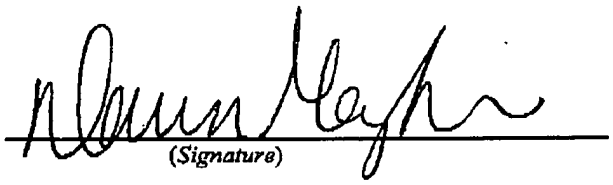
CERTIFICATE OF TRANSMISSION BY FACSIMILE (37 CFR 1.8)		
	Application Number:	12/189,536
	Filing Date:	08-11-2008
	Inventor(s)	Hilton Becker
	Group Art Unit:	1632
	Examiner Name:	NOBLE, MARCIA STEPHENS
	Attorney Docket Number:	DHB0012US

I hereby certify that this Revocation and Appointment of Power of Attorney and Change of Correspondence Address is being facsimile transmitted to the United States Patent and Trademark Office (Fax. No. 571-273-8300) on 10/13/11

Dawn Mayhew
(typed or printed name of person signing certificate)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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/189,536	08/11/2008	Hilton Becker	P3980US00	7206

58027 7590 08/22/2011

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NOBLE, MARCIA STEPHENS	
ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
08/22/2011	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):

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Appeal No: 2011-012272
Application: 12/189,536
Appellant: Hilton Becker

Board of Patent Appeals and Interferences
Docketing Notice

Application 12/189,536 was received from the Technology Center at the Board on August 15, 2011 and has been assigned Appeal No: 2011-012272.

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

The mailing address for the Board is:

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The facsimile number of the Board is 571-273-0052. Because of the heightened security in the Washington D.C. area, facsimile communications are recommended. Telephone inquiries can be made by calling 571-272-9797 and referencing the appeal number listed above.

By order of the Board of Patent Appeals and Interferences.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 12/189,536
Filing Date: August 11, 2008
Appellant(s): BECKER, HILTON

Hilton Becker
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/17/2011 appealing from the Office action mailed 9/16/2010 and Advisory Action mailed 12/3/2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

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

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-16.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

US 2005/0220721	Kablick et al.	10-2005
US 2003/0113387	Tsuchida et al.	6-2003
5,378,461	Neigut	1-1995
US 2003/0021834	Petito et al.	1-2003

Safety Report. In. J. Tox. 1(2):37-56, abstract only, 1982.

(9) Grounds of Rejection

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

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 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kablick (US 2005/0220721 pub date:10/6/2005) in further view of Tsuchida (US 2003/0113387 pub date:6/19/2003), Safety Report (In. J. Tox. 1(2):37-56, abstract only, 1982), Neigut (US 5,378,461 patent date:1/3/1995) and Petito (US 2003/0021834 pub date:1/30/2003).

The instant claims are drawn to a method of treating lacerations and wounds in a living human body comprising: providing a first mass of hyaluronic acid (HA) and a second mass of a human-compatible oil; reducing the particle size of the HA to produce ultra-fine particles of HA; forming an emulsion of the ultra-fine particles in the human-compatible oil, the emulsion being free of water and preservatives; applying the emulsion to a laceration or wound; and forming an HA gel by applying water to the emulsion on the laceration or the wound (claims 1-8). The instant claims are also drawn to a HA product to treat lacerations and wounds in a living body, comprising: an emulsion of HA and a human-compatible, rapidly absorbable oil, the emulsion being free of water and preservatives (claims 9-13). The instant claims are also drawn to a method to prepare a HA product comprising: providing a first mass of HA and a second mass of a human-compatible oil; reducing the particle size of the HA to an ultra-fine particle of HA; and forming an emulsion of the ultra-fine particles in the human-

compatible oil, the emulsion being free of water and preservatives (Claims 14-16). Narrowing embodiments of the dependent claims specify that the human-compatible oil is squalane oil, the particle size is less than 70 to 20 microns, and the masses of HA and squalane oil are 5% to 20% by weight and 95% to 80% by weight, respectively.

Kablick teaches providing pure HA in a powder form (p. 2, [0027] and [0028]). Kablick teaches reducing the HA particle size using standard milling and sieving techniques (p. 3, [0032]-[0034]) to produce a powder wherein 90% of the powder particles have dimensions between 5 microns and 1mm (p. 1 [0006], lines 9-11 and [0007]). Kablick teaches that it is important to control the size of the particles in the powder because the ultra-fine particle powder serves as an adhesion barrier and thus reduces adhesions at a wound site (p. 1 [0006] and [0007]). Kablick teaches applying the ultra-fine powder to a wound site at a sufficient concentration to reduce adhesions (p. 1, [0007]). Kablick further teaches irrigating the wound site prior to applying the HA powder to hydrate the HA powder into a gel (p. 1, [0011], and [0032]-[0033]). Thus, Kablick teaches a method of treating a wound comprising providing a first mass of HA, reducing the particle size of the HA, applying the HA to a wound, and forming a HA gel by applying water to the wound, as claimed. Kablick also teaches an HA product comprising HA and a method of making an HA product, comprising a first mass of HA and reducing the particle size of the HA to produce ultra-fine particles of HA, as claimed.

Kablick does not teach forming an emulsion with the ultra-fine HA powder in a human-compatible oil, such as squalane oil. However, at the time the invention was

made, squalane was commonly being used in topical compositions for wound healing and cosmetics (Tsuchida p. 2, [0021] and Safety Report abstract). Further, squalane oil is advantageous to use in topical compositions because it is a natural component of human sebum, non-toxic, and non-irritating (See Safety Report abstract). Further, Neigut teaches that the use of a squalane oil carrier is advantageous because it is a very effective transport medium in topical wound healing applications with a high rate of skin penetration and reduces moisture loss at the applications site (col 5, lines 61-64, col 6, line 41), thus providing motivation to use squalane oil in a tropical application for wound healing.

Kablick also does not teach that the HA is present in a concentration of 5% to 20% by weight. However, Petito teaches the concentration of HA in a topical application sufficient for wound healing is 0.01 to 65% (p. 6, [0065]). Kablick also does not teach that the squalane oil is present at between 80 and 95% by weight. However, it would be obvious to an artisan of ordinary skill that squalane oil carrier would need to be 80 to 95% by weight if the HA is being used in a concentration of 5%-20% by weight, as taught by Petito.

The combination of prior art cited above in all rejections under 35 U.S.C. 103 satisfies the factual inquiries as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Once this has been accomplished the holdings in KSR can be applied (*KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. 389, 82 USPQ2d 1385 (2007): "Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

In the present situation, rationales A, B, E, F and G are applicable. It would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to make an emulsion of the HA powder, taught by Kablick, and squalane oil, as taught by Tsuchida, Safety Report, Neigut, and Petito, to use in a method of treating a wound site, a HA product, and a method of making a HA product, taught by Kablick, with a reasonable expectation of success. An artisan would be motivated to make and use an emulsion of HA and squalane oil because Kablick demonstrates the usefulness of HA for wound healing and squalane is commonly used for topical wound healing compositions, as taught by Tsuchida and Safety Report, Further, squalane is a natural component of human sebum, is non-toxic, and is non-irritating, as taught by Safety

Report, and is an effective transport medium that easily penetrates the skin and retains moisture at the wound site, as taught by Neigut.

Thus, the teachings of the cited prior art in the obviousness rejection above provide the requisite teachings and motivations with a clear, reasonable expectation. The cited prior art meets the criteria set forth in both Graham and KSR.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claims 1, 9, 14, and their dependents, recite, “the emulsion being free of water”. The specification, as originally filed, does not provide implicit or explicit support for this recitation. The specification teaches an HA product comprising a HA having an ultra-fine particle size mixed with a human-compatible oil, such as squalane, wherein the HA product is preservative free. The specification does not provide explicit or implicit support for the emulsion being free of water as claimed. Thus, the recitation of "the emulsion being free of water" constitutes new matter.

(10) Response to Argument

Response to Arguments Traversing the 35 U.C.S. § 103(a) Rejection

Appellant's arguments have been carefully and fully considered and not found persuasive.

Appellant asserts that Kablick does not teach HA in a human compatible oil, such as squalane oil, and Neigut does not cure this deficiency because there is no reason, described by Neigut, to use squalane oil as a carrier with HA particulate. Appellant states that Neigut teaches squalane oil as a carrier for active agents that dissolve in oil. As such, since these active agent dissolve in squalane oil, it can effectively deliver the dissolved active agents into tissue. In contrast, Appellant states that HA does not dissolve in squalane oil but rather remains in particulate form as an emulsion and thus the squalane oil would not transport the HA into the tissue. Thus, Appellant concludes that an artisan would not choose squalane oil as a carrier for HA because HA would not dissolve in squalane and thus the squalane would not serve as an effective transport medium that causes penetration of HA into the tissue.

Appellant's argument is not found persuasive because the Appellant's assertion is based on the assumption that Neigut and the prior art only teach and/or suggest that squalane is solely an effective transport medium with oil soluble agents and is solely useful in a medicament for its ability to deliver oil soluble agents into the skin. Neigut,

Tsuchida, and Safety Report demonstrate that this assumption is inaccurate and a narrow interpretation of the art for two reasons. First, the skin penetrating property of a squalane carrier, taught by Neigut, is also advantageous with a particulate active agent, such as the HA powder taught by Kablick, because the skin penetrating effect of squalane brings the particulate in close contact with the wound site. Since the HA medicament, taught by Kablick, functions by contacting the wound site and water at the wound site, an artisan of ordinary skill in the art would have a reasonable expectation that the penetrating property of squalane will effectively bring and hold the HA of Kablick in contact with the wound site, which would be advantageous to the effectiveness of the HA medicament. Second, Appellant is overlooking the other described properties of squalane that make it an effective carrier for topical medicaments as taught by Neigut. Neigut teaches squalane is also a natural emollient, improves skin respiration, and reduces moisture loss (col 6, lines 37-41), all advantageous properties for topical wound healing compositions. Further, Neigut teaches that squalane is effectively used in topical medicaments for treating skin wounds, such as skin damage (see abstract; col 1, line 10-20). Thus, contrary to Appellant's assert, Neigut teaches that squalane is used in the prior art for topical wound healing compositions and that squalane is an effective transport medium for multiple reasons, not solely for its skin penetrating properties with oil solvents. Further, it is noted that Neigut is not the sole art provided in the rejection to demonstrate that squalane is commonly used in topical wound healing medicaments because Tsuchida teaches the use of squalane and HA in a wound healing medicament and Safety Report teaches that it is commonly used because it is non-toxic, natural, and

non-irritating (See rejection above). Thus, the combine teachings of Neigut, Tsuchida, and Safety Report, provide ample evidence that squalane is commonly used in topical wound healing medicaments and provides multiple advantageous properties as a transport medium in addition to its property of delivering oil soluble agents through the skin. An artisan of ordinary skill would understand from the teachings of Neigut, Tsuchida, and Safety Report that squalane is used in the prior art as a carrier for topical wound healing agents and that it is natural, improves skin respiration, and reduces moisture, in addition to aiding skin penetration of oil-based agents, all advantageous properties for a topic all wound healing agent. As such, contrary to Appellant's assertion, an artisan of ordinary skill would just as likely choose squalane, as taught by Neigut, Tsuchida, and Safety report, from a finite number of art-established carriers to predictably combine with the HA medicament taught by Kablick, because Neigut teaches that squalane would provide advantageous properties of improving skin respiration at the wound site, bringing and holding the HA in contact at the wound site, and retaining moisture at the wound site, all of which would be advantageous to the HA product of Kablick. Thus, Appellant's argument is not found persuasive.

Appellant asserts that an artisan would not combine the teaching of Neigut with Tsuchida, Petito, and Kablick because Tsuchida and Petito teach aqueous solutions of HA, and an aqueous HA solution will not mix with squalane oil. Appellant's argument is not found persuasive because Tsuchida and Petito were not provided in the rejection to teach the literal combination of an aqueous HA solution with squalane oil, as Appellant asserts. Tsuchida was provided to demonstrate that HA and squalane are used in the

prior art in would healing medicaments. Petito was provided to demonstrate that in other wound healing medicament HA has been used and that it is used at the concentrations claimed in the instant application. Thus, from a combined understanding of the arts of Neigut, Tsuchida, and Safety Report, an artisan of ordinary skill would reasonable understand that both HA and squalane have been used on multiple occasions in the prior art in wound healing medicaments. From Petito, an artisan would reasonably understand that HA is effective in the concentrations as claimed. The artisan of ordinary skill is highly skilled in the understandings of medicament chemistry. As such, an artisan of ordinary skill would not discern from the teaching of Tsuchida and Petito that they should use the aqueous form of HA with squalane oil, as Appellant suggests. An artisan of ordinary skill would reasonably discern that these teachings are useful as a demonstration that HA and squalane are useful in wound healing medicaments and determining the effective HA concentrations. Thus, contrary to Appellant's assertion, an artisan of ordinary skill would combine the teaching of Neguit with Tsuchida and Petito and Kablick for their relevant teachings and for a literal combination of every aspect of these arts.

First, Kablick explicitly teaches irrigating the wound site prior to applying the HA powder to hydrate the HA powder into a gel (p. 1, [0011], and [0032]-[0033]). Thus, contrary to Appellant's assertion, Kablick explicitly teaches the formation of hydrated gel.

Appellant asserts that the claims require first forming a hydrated gel before applying the HA to the wound site. Appellant asserts that Kablick therefore does not

teach the instant claims because Kablick teaches applying a dry HA powder directly to a wound site without first forming a hydrated gel. Appellant's argument is not found persuasive. Appellant's claims recite, "applying the emulsion to a laceration or a wound; and forming a hyaluronic acid gel by applying water to the emulsion on the laceration or the wound" (See last two lines of claim 1). Thus, contrary to Appellant's assertion, the claims do not require that the hydrated gel be made first before applying the HA emulsion because the claims explicitly state applying the emulsion and then state forming a hydrated gel by applying water to the emulsion on the laceration of wound. The claims do not specify when the water has to be applied to the wound site to form a gel. They only specify that the HA emulsion has to be applied to the laceration or wound before the step of forming the hydrate gel. Thus, the breadth of the claims encompasses applying water to the wound site before or after applying the emulsion. Kablick teaches applying water before applying the HA powder to form a hydrated gel upon application of the HA powder. Thus, Kablick does teach the limitations of the claims because the breadth of the claims encompasses the application of water to the wound site before or after the application of the emulsion to the wound site. It is further noted that even if the claim did specify that the water had to be applied after the emulsion was placed on the laceration or wound, an artisan of ordinary skill would understand from the teachings of Kablick that a the hydrated gel is formed by adding water to the powder, thus it would have been obvious to an artisan that placing water on the wound site before or after applying the HA powder will equally form a hydrated HA

gel and thus are obvious equivalents. Thus, contrary to Appellant's assertion, Kablick provides ample teaching of forming a hydrated gel as claimed.

Appellant asserts that Petito can not be combined with Kablick because Petito delivers an aqueous HA solution to a wound site, which will destroy the dry HA powder delivery used by Kablick. Appellant's argument is not found persuasive because Petito is not being provided in the rejection to teach a delivery method of HA. Petito is being provided to demonstrate that the claimed concentration of HA have been taught in the prior art as effective concentration in wound healing medicaments. Again, the skill of the ordinary artisan is high. Thus, an artisan of ordinary skill would not use these teachings as a literal combined recipe to make the invention, as suggested by Appellant. The artisan is quite capable of discerning the relevant teachings of the art of Kablick and the relevant teaching of Petito and combining the teachings in a compatible and useful manner. An artisan would understand that Petito provides an effective HA concentration that can be used in the method of HA. An artisan would not try to do a literal combination of an aqueous and non-aqueous HA product to deliver in the same manner as Kablick because an ordinary artisan would discern that this is not a useful manner of combining these two arts. Thus, contrary to Appellant's arguments, an artisan of ordinary skill would combine the relevant teaching of Petito with the relevant teachings of Kablick, using their level of skill in the art, to produce an obvious variant of Kablick and to arrive at the instant invention with a reasonable expectation of success.

Appellant also asserts that Tsuchida and Neigut can not be combined with Kablick because Tsuchida delivers an aqueous HA solution and Neigut delivers an oil-

based solution to a wound site, which will destroy the dry HA powder delivery used by Kablick. Again, Appellant's arguments are not found persuasive because Tsuchida and Neigut are not being provided to combine three different delivery methods. An artisan of ordinary skill has a high level of skill in the art and would understand the relevance of each of these arts is not to combine their different delivery methods but that these three arts combined teach that HA and squalane are commonly and successfully used in topical wound healing medicament. So an artisan of ordinary skill in the art would reasonably expect from the prior art teaching of Tsuchida and Neigut that the medicament of Kablick could effectively be used as an emulsion of HA and squalene applied directly to the wound site with a reasonable expectation that the emulsion with cause wound healing in a manner taught by Kablick. Further, Neigut provides teachings of advantageous properties for the use of squalane in a wound healing medicament. Thus, Neigut provides motivation to make the emulsion of HA and squalane. Thus, contrary to Appellant’s assertion, the relevant teachings of Tsuchida and Neigut can be combined with Kablick to teach the instant invention as claimed.

Appellant asserts that Examiner is improperly selecting certain features but not others features to discount Appellant's arguments. Appellant submits that references must be read and interpreted in their entirety. Appellant states that limiting a reference to a few select passages and disregarding the balance of the reference cannot be tolerated in establishing a prima facie case of obviousness. Appellant thus asserts given all the combined factors taught, there is no reason to modify Kablick with any of the secondary references. Appellant's argument is not found persuasive. It is

acknowledged and agreed a reference needs to be considered and interpreted in its entirely. Examiner further agrees that it would be inappropriate to use a teaching out of context of the reference and in a manner that disregards another teaching in that reference. However, this standard does not require every aspect of a teaching must be literally combined with every aspect of another reference to make a prima facie case of obviousness. “Considering” and “interpreting” a reference in its entirely means understanding the reference as a whole and understanding the reference in the context of all the teaching in that art. Further, the standard and statutes allow for multiple ways of combining the prior art in addition to literal combinations of the art teachings, such as substitutions, deletions, even "obvious to try" under predictable circumstance. Nothing in Kablick, Tsuchida, Safety Report, Neigut, and Petito teach that the active healing ingredient, HA, can not be used in a squalene carrier or has to be in an aqueous solution to make it effective as a wound healing agent. Thus, nothing in the entirety of these combined arts would suggest that adding squalane to the HA particulates of Kablick would not function in the methods or product of Kablick. As such, Examiner has properly considered and interpreted these arts in their totality and has used the relevant teachings in a manner that is consistent with the teachings of each art and the combine state of the art, to properly provide a case of obviousness with the teaching of Kablick, Tsuchida, Safety Report, Neigut, and Petito.

Appellant asserts that even if the art could be combined, Examiner has not provided a persuasive reason to combine the arts of Kablick, Tsuchida, Safety Report, Neigut, and Petito. Appellant’s arguments are not found persuasive because the

Examiner has provided multiple reasons to combine these prior arts. The Examiner has stated that the art can be combined under the rationale of combining prior art elements according to known methods to yield predictable results, as allowed by KSR. More particularly, Kablick demonstrates that HA is a known medicament for wound healing, Neigut and Safety Report, and Tuchida demonstrate that squalane is a known carrier for wound healing medicaments. Thus the HA of Kablick and be combined with the squalane of Neigut and Safety Report, and Tuchida using emulsion production methods known in the art and applied to a topical wound as taught by Kablick to predicable make a wound healing HA product as claimed and treat a wound as claimed. Examiner has stated that the arts can be combined under the rationale of simple substitution of one known element for another to obtain predictable results, as allowed by KSR. In particular, the HA powder delivery, taught by Kablick, can be simply be substituted by an HA/squalane emulsion made by combining Kablick, Tsuchida, Neigut, and Safety Report, by known means to predictably arrive at a method of treating a wound that applies the emulsion to the wound, as taught in Kablick, with a reasonable expectation of success. Examiner has stated that the art can be combined under the rationale of "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success, as allowed by KSR. In particular, an artisan could choose squalane, as taught by Tsuchida, Neigut, and Safety Report, from a finite number of prior art establish carriers used in topic wound healing medicaments to predictable use in a medicament with dry HA powder, taught by Kablick, with a reasonable expectation of successfully yielding a medicament that treats wounds as

claimed. Examiner has also stated that the art can be combined under the rationale of some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention, as allowed by Grahm vs Deer and KSR. In particular, Examiner has stated an artisan would be motivated to combine the HA powder, taught by Kablick, with a squalane oil, as taught by Neigut, Tsuchida, and Safety Report, because Neigut and the Safety Report teaches that squalane is an effective transport medium for topical wound healing medicaments that would provide improved skin respirations and will retain moisture and the HA at the wound site, all of which would be advantageous to the effectiveness of the HA at the wound site in the method of Kablick. Thus, contrary to Appellant's assertion, Examiner has provided ample reasoning for combining these prior art teachings.

Appellant asserts that the claims require an “emulsion free of water”. Appellant asserts that the combined art of Kablick, Tsuchida, Safety Report, Neigut, and Petito would not be free of water because Tsuchida and Petito teach aqueous HA solutions. Appellant's arguments are not found persuasive because again Tsuchida and Petito were not provides for teaching an aqueous solution but rather the use of HA in wound healing medicaments in prior art. Nowhere does the rejection suggest combining the aqueous solution of Tsuchida or Petito with the squalane of Neigut and the Safety report. The rejection suggests the combination of the dry powder HA of Kablick with the squalane as taught by Tsuchida, Neigut, and Safety Report. As such, Appellant’s argument is not persuasive.

Appellant asserts that Kablick also does not teach an emulsion free of water because Kablick teaches that the HA is in a dry powder particular form and further states that "dry" means having water content low enough to permit effective entrainment of the particles in a stream of flowing gas, for example less than 25% water by weight (par [0006]). Appellant asserts that 25% water by weight means that the HA powder contains water. Appellant's argument is not found persuasive because Kablick states "less than 25% water by weight". Thus, Kablick is contemplating a range of water content that would be considered a dry HA powder. "Less than 25% water by weight" encompasses a HA particulate comprising 0% water by weight to a maximum of 25% water by weight. As such, Kablick contemplates a dry HA powder that has 0% water by weight in the recited range and as such teaches a dry HA powder that is "free of water". Thus, contrary to Appellant's assertion, Kablick does teach an emulsion free of water because the range of water permitted in the HA particular taught by Kablick includes 0% water by weight which is a particulate free of water.

Appellant asserts that Neigut and Safety Report teach squalane but not an HA or an emulsion. Appellant's arguments are not found persuasive. Neigut and Safety Report were not provided in the rejection to teach HA or a specific emulsion. These two references were used to demonstrate that squalane has been used with other active agents, including HA, as carriers in topical wound healing agents. Thus, it would have been obvious to an artisan of ordinary skill at the time of the invention, that if they combined squalane with the HA particulate taught, by Kablick, this combination would

predictably arrive at an emulsion of HA and squalane. Thus, Appellant's argument is not persuasive.

Appellant asserts the teachings of Neigut teach away from the claimed invention because Neigut teaches dissolving coenzyme in squalane so that the finished product does not contain particles. However, the claimed product and the methods using the product have a final composition of an emulsion which comprises HA particles. Appellant further states Kablick only teaches particulate HA and Neigut teaches that the finished product does not contain particles. From this, Appellant concludes that the arts teach away from the instant invention. Appellant's argument is not found persuasive because Appellant is not considering the more general teachings of Neigut but rather a specific example of an oil dissolvable coenzyme that is to be delivered into the skin. Appellant is also isolating the teachings of Neigut from the context of the rejection that uses the combined teaching of Neigut, Tsuchida, and Safe Report, which teach that squalane has been used with a variety of active agents, not just oil soluble agents. Therefore, in the case of the coenzyme/squalane composition, Appellant states that an artisan of ordinary skill would understand that this agent is to be dissolved completely with no particulate matter remaining because the intent for this particular agent is for the squalane to deliver it into the skin. An ordinary artisan would also understand from the teachings of Neigut, in addition to Tsuchida and Safety Report, that squalane can also be used as a carrier for other non-oil soluble wound healing agents to be delivered topically. Thus, contrary to Appelllant's assertion, neither Neigut, Kalick, nor any of the other arts provided in the rejection teach away from the claimed invention. Further,

neither Neigut nor Kablick teach away from the instant invention because neither Neigut nor Kablick teach or suggest that squalane will not function with a particulate or a water soluble active agent, such as HA. Indeed the art of Tsuchida and Safety Report suggest that squalane can be used in a medicinal composition with aqueous HA or non-oil soluble agents for wound healing. Therefore, since Neigut and Kablick do not provide evidence that squalane can not be used or is not functional with particulate or water soluble agent, such as HA and the art of Tsuchida and Safety Report imply that particulates, water soluble agents, and other agents can be used and function with squalane, neither Neigut, Kablick, nor any of the arts provided in the rejection teach away from the instant claims, and Applciant's argument is not persuasive.

In conclusion, the instant 103(a) rejection has been maintained because the prior art of Kablick, Tsuchida, Neigut, Safety Report, and Petito teach the elements of the claimed invention and provide motivation to combine the art prior. Appellant's arguments have not been persuasive in demonstrating that these prior arts fail to render the claimed invention obvious. As such the instant claims are rendered obvious by the prior art and the rejection of record is maintained.

Response to Arguments Traversing the 35 U.C.S. § 112, 1st New Matter Rejection

Appellant's arguments have been carefully and fully considered and have not been found persuasive.

Appellant states that there is no explicit requirement for limitations introduced by amendments to satisfy the written description requirement and the specification provide adequate support for “the emulsion being free of water and preservatives". Appellant refers to page 2, lines 22-27 as implicit support for "the emulsion being free of water". Appellant states that this recitation clearly implies a water free emulsion because to produce a preservative free form of HA, the emulsion must be free of water, otherwise bacterial growth will occur.

Appellant's argument is not found persuasive. Page 2, lines 22-27 recites:

“HA is water soluble. However, once dissolved in water, due to its high nutritive value, it is rapidly prone to bacterial contamination and ingrowth. Therefore, preservative must be added to prevent bacterial growth. This growth inhibiting effect is undesirable for the healing of wounds or abraded skin.”

This recitation does not explicitly or implicitly disclose an “emulsion being free of water” because this disclosure is open-ended, describes a problem with the use of preservatives in aqueous HA solutions for wound healing, not the use of water, and leaves the artisan to decide the remedy for this problem. Further, this disclosure does not imply that the absence of water is suggested as the solution or a required means of obviating the problem with preservatives and bacterial growth in an aqueous HA solution. This recitation solely implies that preservatives used to inhibit bacterial growth in HA solutions is an inherency to wound healing and leaves it open to art-known means to alleviate this problem. As such, these recitations fail to provide implicit or explicit support for an "emulsion being free of water".

Appellant further states that the specification states, "that there is a need for a relatively pure hyaluronic acid that is free of preservatives and at the same time free of harmful bacteria" (p. 3, lines 10-12). Appellant therefore asserts it is unreasonable to suggest water may be added to hyaluronic acid without preservatives according to the present invention. This argument is not found persuasive because the unreasonableness of adding water to HA without preservatives is a statement of opinion and interpretation, not fact or evidence of implicit disclosure of “emulsion being free of water. This is evidenced by the fact that another artisan of ordinary skill may read the disclosures on page 2, lines 22-27 and page 3, lines 10-12 and come to the conclusion that one can provide a pure HA preservative free emulsion, not by omitting water, but rather by irradiating the emulsion. Given that an artisan can interpret these disclosures as having multiple solutions, such as omitting water or irradiating the emulsion, it is apparent that these open-ended disclosures referred to by Appellant do not provide implicit support for an "emulsion being water free”. Thus, Appellant’s arguments are not found persuasive.

Appellant refers to Fig. 1, page 3, line 16, and page 4, line 1, as support for an "emulsion being free of water". Appellant states that these recitations disclose a medicinal preparation of an emulsion of HA dispersed in a human-compatible oil, whereby the medicinal preparation is activated by HA. Appellant further states that if the preparation comprised water the HA would be activated. Therefore, Appellant asserts these recitations imply an emulsion free of water to assure the HA is in an inactive form. Appellant’s argument is not found persuasive because Appellant is

reading limitations into this disclosure that are not present. These recitations solely state that the HA is activated by water. The specification does not further state or imply that the HA can not be present in the emulsion in the active or aqueous form. To the contrary, the specification states, "The hyaluronic acid is preferably ground to a fine particle size about 20 microns or less and mixed into a dispersion the human compatible absorbable oil to produce an emulsion…," (page 4, lines 3-5). This recitation of "preferably" open-endedly suggests that the HA can be in other forms (aqueous, active, inactive, etc…) than particulate but the preferred embodiment is particulate. Therefore, this recitation implies that contrary to Appellants assertion the emulsion can comprise active or aqueous forms of HA be reciting preferably". None of these recitations state or suggest that the emulsion is required to be free of water or that the HA needs to be in inactive state. Further, nowhere in the specification does it state or suggest such limitations. Thus, these recitations do not implicitly or explicitly support that the "emulsion is free of water", and Appellants argument is not found persuasive.

Appellant refers to the page 4, lines 3-8 as evidence of support of "emulsion being free of water". This recitations states, "The hyaluronic acid is preferably ground to a fine particle size of about 20 microns or less and mixed into a dispersion in the human compatible absorbable oil to produce an emulsion about 5% to 20% by weight or volume hyaluronic acid. The emulsion is then applied to the laceration or wound by any means as will be well understood by an artisan and activated with water to form hyaluronic acid gel". Nothing in this recitation explicitly or implicitly requires the lack of water in the emulsion. The disclosure describes a "preferred" embodiment that uses a

fine HA particulate in an oil to produce an emulsion. This does not require that the emulsion lack water. It solely means that the HA was provided in the emulsion as a fine particulate. Further the disclosure states that emulsion is applied and activated to form an HA gel. This does not state that the HA is specifically in an inactive state by being water free and activated by adding water. It solely states that water activates the emulsion to very specifically form an HA gel. It does not imply or describe the activity state of the HA in the emulsion or imply that the emulsion is ever free of water. As such, these recitations do not provide implicit or explicit support for an "emulsion being free of water".

Appellant asserts refers to page 7, lines 6-7 as support for an "emulsion being free of water". This citations states, "In the preferred embodiment of the invention the emulsion contains between 5-20% hyaluronic acid and 95% to about 80% Squalane oil wherein the percentage given is percent by weight and/or approximately the same percentage by volume". Appellant concludes from this disclosure that the HA product is water free because when the product is 5% HA and 95% squalene, then the product has no water.

This argument is not found persuasive because the disclosed invention relies on the use of commercial grade HA particulate which most often has water residues and thus is not "free of water". Most artisans, when preparing reagents, use dry commercially available components in making their reagents with an understanding that more often than not, these dry components have some moisture residue. However, an artisan will calculate and add this dry ingredient by weight to a reagent being prepared

as if the water residues were not present, as evidenced by Kablick (par [0006]). The specification discloses that “Medical grade hyaluronic acid is available in average particle sizes ranging from about 20 to about 700 microns," (See p. 5, lines 11-13) and thus intends for the use of commercially available medical grade HA particulate in 5-20% by weight in the emulsion. The specification does not explicitly or implicitly state that the HA particulate has to be absent of water residues. The specification further does not implicitly and explicitly describe a means of making these HA particulate starting materials "free of water". Thus, even though specification recites an HA product comprising about 5% to 20% by weight HA particulate by weight and the remaining content of the HA product being about 95% to 80% weight, an artisan of ordinary skill would not interpret this disclosure as explicitly or implicitly disclosing that the HA particulate or the emulsion is “free of water” because most commonly in the art the artisan uses commercial grade dry particulates as starting materials with the understanding that these particulates have water residues and are not free of water. The specification solely discloses the use of commercially available HA particulate, as is consistent with common use in the art, and relies on commonly known means to prepare the HA product. As such, an artisan would not infer that the emulsion is completely free of water residue, as Appellant asserts, because most commonly in the art moisture residues are present in commercially supplied dry starting materials and the specification does not specifically disclose that the starting materials or end product of the HA emulsion would be free of water. As such, Appellant's argument is not found persuasive.

In conclusion, Examiner was unable to discern any disclosures in the specification that would explicitly or implicitly support an “emulsion being free of water”, and Appellant failed to persuasively provide evidence of explicit or implicit support for the recitation of an “emulsion being free of water”. As such, this recitation fails to provide adequate written description and thus constitutes new matter.

(11) Related Proceeding(s) Appendix

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

Respectfully submitted,

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