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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/915,419	10/29/2010	David Schmidt	052775-0390871	7575
909	7590	03/15/2012	EXAMINER	
Pillsbury Winthrop Shaw Pittman, LLP (NV)			GHALI, ISIS A D	
PO Box 10500			ART UNIT	PAPER NUMBER
McLean, VA 22102			1611	
			NOTIFICATION DATE	DELIVERY MODE
			03/15/2012	ELECTRONIC

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

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

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

docket\_ip@pillsburylaw.com  
margaret.drosos@pillsburylaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 12/915,419	<b>Applicant(s)</b> SCHMIDT, DAVID	
	<b>Examiner</b> Isis Ghali	<b>Art Unit</b> 1611	

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

**Period for Reply**

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

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

**Status**

- 1)  Responsive to communication(s) filed on 13 February 2012.
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 5)  Claim(s) 58-78 is/are pending in the application.
- 5a) Of the above claim(s) 63, 64, 78 is/are withdrawn from consideration.
- 6)  Claim(s) \_\_\_\_\_ is/are allowed.
- 7)  Claim(s) 58-62 and 65-77 is/are rejected.
- 8)  Claim(s) \_\_\_\_\_ is/are objected to.
- 9)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 10)  The specification is objected to by the Examiner.
- 11)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \*    c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/29/2010, 12/22/2010.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_.

### **DETAILED ACTION**

The receipt is acknowledged of applicant's election filed 02/13/2012; IDS filed 12/22/2010; IDS filed 10/29/2010.

Claims 58-78 are pending.

### ***Election/Restrictions***

1. Applicant's election with traverse of invention I, claims 58-77, in the reply filed on 02/13/2012 is acknowledged. Applicant's argument was found persuasive regarding invention I should include claims 58-77. However, species election of left handed molecule and right-handed molecule is maintained. Applicants did not traverse this species election.

2. Claims 63 and 64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/13/2012.

Claims 58-62 and 65-77 are included in the prosecution.

### ***Claim Rejections - 35 USC § 112***

3. 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

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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 58-62 and 65-77 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. Claim 58 recites “apparatus comprising at least one Left- Handed organic material-containing apparatus and at least one Right-Handed organic material-containing apparatus for simultaneous application to a subject's body.....”. The specification lacks adequate written description for the two apparatus applied simultaneously to a subject’s body. Nowhere applicants described two separate apparatus applied simultaneously. The figures show one apparatus (100). Figure 3 shows multi-layered patch sealed in one enclosure forming apparatus (100). The recitation of more than one apparatus without any description in the disclosure does not meet the written description requirement as one of ordinary skill in the art could not recognize or understand the claimed system from the mere recitation of two apparatus. Claims employing limitations at the point of novelty, such as applicants’, neither provide those elements required to practice the inventions, nor “inform the public” during the life of the patent of the limits of the monopoly asserted.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. *Vas-Cath Inc. v Mahurkar*, 19 USPQ 2d 1111. The invention is, for purpose of the “written description” inquiry, whatever is now claimed

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(see page 1117). The specification does not clearly allow person of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 116). One cannot describe what one has not conceived. See *Fiddes v Baird*, 30 USPQ2d 1481, 1483.

The requirement for adequate written description, Applicants' attention is directed to MPEP § 2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F. 3d 1559, 1568 (Fed. Cir. 1997), cert denied, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish list or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F. 3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including inter alia, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F. 3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216,225 (W.D.N.Y. 2003).

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Applicant has failed to provide any written description for "two apparatus applied simultaneously" in the instant specification. As such, it is not apparent that Applicant was actually in possession of, and intended to use, within the context of the present invention, two apparatus at the time the present invention was made.

Finally, the test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See *In re Kaslow*, 707 F 2d 1366, 1375 (Fed. Cir. 1983). See MPEP 2163.06.

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him. See *Genetech*, 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

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

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 58-62 and 65-77 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 58 recites the limitation "apparatus" in the 2<sup>nd</sup> line. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

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

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

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

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

8. Claims 58-62 and 65-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blendermann (US 2002/0156340, currently listed on PTO 892) in view of Blitzer et al. (US 6,475,514, IDS filed 10/29/2010).

### **Applicant Claims**

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Claim 58 is directed to a system for application to a subject's body to provide a beneficial biological effect for the subject, the apparatus comprising at least one Left-Handed organic material-containing apparatus and at least one Right-Handed organic material-containing apparatus for simultaneous application to a subject's body:

A. the at least one Left-Handed organic material-containing apparatus for application to a first position on a subject's body comprises

- 1 at least one organic material including a Left-Handed molecule;
- 2 at least one substrate for said at least one Organic material; and
- 3 at least one enclosure for said at least one organic material and said at least one substrate; and

B. the at least one Right-Handed organic material-containing apparatus for application to a second position on a subject's body separate and distinct from the first position comprises

- 1 at least one organic material including a Right-Handed molecule;
- 2 at least one substrate for said at least one organic material; and
- 3 at least one enclosure for said at least one organic material and said at least one substrate,

wherein the at least one Left-Handed organic material-containing apparatus and the at least one Right-Handed organic material-containing apparatus together provide the beneficial biological effect.

#### **Determination of the Scope and Content of the Prior Art**



**(MPEP §2141.01)**

Blendermann teaches an article such as a patch to hold nutrients in on the body. The article incorporates at least one nutrient, which is capable of emitting electromagnetic waves that stimulate proprioceptive zones throughout the body, resulting in a therapeutic effect (abstract). The invention relates to a nutrient-holding device which requires a compartment which houses nutrients. These active agents (nutrients, metabolites) have the ability to emit photons (electromagnetic waves) that can stimulate reflex zones located on the surface of the body. These agents deliver natural frequencies and radiations which affect reflex zones located throughout the body surfaces by placement of said device on the surface of various locations on the body (paragraph 0033). The reference teaches using the active agent nutrients encased in a device that holds it on the body at various locations to affect reflex zones by stimulating mechanoreceptors for continuous therapeutic effect (paragraphs 0037, 0053). Appropriate active agents include amino acids including L-carnitine, and bee pollen, which is the honey precursor (paragraphs: 0040-0043). The nutrient holding device comprises waterproof housing made of plastic and adapted to hold the nutrient adjacent to the body in various locations (paragraphs 0051-0052).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims****(MPEP §2141.012)**

Although Blendermann teaches wearing various devices into various locations on the body, however, the reference does not specifically teach simultaneous application of

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right-handed molecules containing apparatus and left handed molecules containing apparatus, or substrate of organic material as claimed by claim 58. The reference does not teach the material of the substrate as claimed by claim 69, the material of the plastic film as claimed by claim 70, adhesive to hold the device to the skin as claimed by claim 71-72, additives for active agents as claimed by claim 75. While Blendermann teaches application of various devices to various locations in the body, however, the reference does not teach application to negative and positive points as claimed by claims 73 and 74. Although Blendermann teaches patch, however, does not specifically teach the layered patch as claimed by claim 76.

Blitzer teaches transdermal patches for administration of nutrient supplement to a subject wherein the patch comprises amino acids including L-carnitine and sugars (abstract; col.2, lines 47-51, 65-67; col.5, lines 7, 24-30; col.8, line 8). The patch comprises backing layer, which reads on the claimed substrate, made of polyester fabric and prevents loss of the active agents (col.9, lines 5-6; co1.11, lines 45-59). The patches are stored in pouches comprising polypropylene (co1.12, lines 27-37). The patch further comprises adhesive to affix and secure the patch to the skin and of the kind removed without discomfort (col.9, lines 55-67). The patch comprises additives such as permeation enhancers including glycols, preservatives including alcohols, and plasticizers, and vehicles to carry active agents (col.9, lines 21-26; co1.13, lines 12-15, 49-52; co1.14, lines 10-12). Figure 1 shows layered patch.

### **Finding of Prima Facie Obviousness Rational and Motivation**

**(MPEP §2142-2143)**

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide patches comprising housing to hold different nutrients on various locations of the body as taught by Blendermann, and further apply the nutrients in formulation containing additives located on a substrate of polyester and attach the housed patch to the skin using adhesive as taught by Blitzer. One would have been motivated to do so because Blitzer teaches that additives can preserve the nutrients, and the substrate prevents loss of nutrients and adhesive secures the device to the skin. One would reasonably expect formulating patches comprising housing to hold different nutrients on various locations of the body wherein the nutrients are provided in preserving formulation and supported by substrate to prevent their loss and the devices are secure to the skin.

Regarding the claimed limitation of “simultaneous application of left handed containing apparatus and right handed containing apparatus”, and the limitation of “application to negative and positive points of the body”, Blendermann teaches application to various location to the body, and applicant failed to show unexpected result obtained from simultaneous application of left handed molecule and right handed molecules and the specific sites of application. Further these limitations are directed to an intended use of the apparatus, and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

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Layered apparatus claimed by claim 76 is taught by Blitzer. All the elements taught by the claim are known and conventional in the transdermal art.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571)272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis Ghali/  
Primary Examiner, Art Unit 1611

IG

<b>Notice of References Cited</b>	Application/Control No. 12/915,419	Applicant(s)/Patent Under Reexamination SCHMIDT, DAVID	
	Examiner Isis Ghali	Art Unit 1611	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A US-2002/0156340	10-2002	Blendermann, Edward Ludwig	600/15
	B US-			
	C US-			
	D US-			
	E US-			
	F US-			
	G US-			
	H US-			
	I US-			
	J US-			
	K US-			
	L US-			
	M US-			

**FOREIGN PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N				
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**NON-PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)				
	U				
	V				
	W				
	X				

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

**Search Notes**



Application/Control No.

12/915,419

Examiner

Isis Ghali

Applicant(s)/Patent under Reexamination

SCHMIDT, DAVID

Art Unit

1611

**SEARCHED**

Class	Subclass	Date	Examiner

**INTERFERENCE SEARCHED**

Class	Subclass	Date	Examiner

**SEARCH NOTES  
(INCLUDING SEARCH STRATEGY)**

	DATE	EXMR
Inventor name search IDS review WEST all data bases	3/7/2012	IG

<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  Form PTO-1449	Docket Number	Application Number
	052775-0390871	12/915,419
	Applicant(s)	
	David Schmidt	
	Filing Date	Group Art Unit
	October 29, 2010	

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	REF	DOCUMENT NO.	DATE MM- YYYY	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A	5,597,976	01-1997	Schroeder			
	B						
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	G						
	H						
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**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages, Etc.)

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	Y	
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	BB	

EXAMINER	//isis Ghali//	DATE CONSIDERED	03/08/2012
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.			



<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  Form PTO-1449	Docket Number	Application Number
	052775-0390871	Herewith
	Applicant(s)	
	David Schmidt	
	Filing Date	Group Art Unit
October 27, 2010	1615	

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	REF	DOCUMENT NO.	DATE MM-YYYY	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A	20020072501	06-2002	Cyr et al.			
	B	20030118615	06-2003	Blendermann			
	C	6,558,695	05-2003	Luo et al.			
	D	6,475,514	11-2002	Blitzer et al.			
	E	5,651,973	07-1997	Moo-Young et al.			
	F	5,393,350	02-1995	Schroeder			
	<del>G</del>	<del>5,597,975</del>	<del>04-1997</del>	<del>Schroeder</del>			
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**FOREIGN PATENT DOCUMENTS**

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**OTHER DOCUMENTS. (Including Author, Title, Date, Pertinent Pages, Etc.)**

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EXAMINER	/Isis Ghali/	DATE CONSIDERED	03/08/2012
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.			

<b><i>Index of Claims</i></b>  	<b>Application/Control No.</b>  12915419	<b>Applicant(s)/Patent Under Reexamination</b>  SCHMIDT, DAVID
	<b>Examiner</b>  ISIS GHALI	<b>Art Unit</b>  1611

✓	<b>Rejected</b>
=	<b>Allowed</b>

-	<b>Cancelled</b>
÷	<b>Restricted</b>

N	<b>Non-Elected</b>
I	<b>Interference</b>

A	<b>Appeal</b>
O	<b>Objected</b>

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

CLAIM		DATE							
Final	Original	03/08/2012							
	58	✓							
	59	✓							
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	77	✓							
	78	N							