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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,596	09/25/2003	David Schmidt	27439-003	1315

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

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

Office Action Summary	Application No.	Applicant(s)	
	10/669,596	SCHMIDT, DAVID	
	Examiner	Art Unit	
	Isis A. Ghali	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 *21 November 2007*.

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

3)☐ 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

4)☒ Claim(s) *1,3,5,6,10,11,14,16,18,20,22,24,26,34,36,38 and 42* is/are pending in the application.

4a) Of the above claim(s) *36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1,3,5,6,10,11,14,16,18,20,22,24,26,34,38 and 42* is/are objected to.

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

Application Papers

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

10)☐ 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).

11)☐ 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

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

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

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 11/21/2007, and IDS filed 10/04/2007.

Claims 2, 4, 7-9, 12, 13, 15, 17, 19, 21, 23, 25, 27-33, 35, 37, 39-41, 43-57 have been canceled.

Claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 26, 34, 36, 38 and 42 are pending.

This application contains claim 36 drawn to nonelected species with traverse in the reply filed on 02/28/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 26, 34, 38 and 42 are included in the prosecution.

Information Disclosure Statement

1. The information disclosure statement filed 10/04/2007 fails to comply with 37 CFR 1.97(d) because it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered.

2. The information disclosure statement filed 10/04/1007 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

The following rejection has been overcome by virtue of applicant's remarks:

The rejection of claims 16 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite.

The following rejections/objections have been discussed in the previous office action, and are maintained for reasons of record:

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is

requested in correcting any errors of which applicant may become aware in the specification.

4. Applicant has not indicated revision of the specification neither made any correction, therefore the objection made to check the specification has been maintained.

Claim Rejections - 35 USC § 102

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

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

6. Claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 38 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,475,514 ('514).

US '514 discloses transdermal patches for administration of nutrient supplement to a subject wherein the patch comprises amino acids (abstract; col.2, lines 47-51;, 65-67). The amino acids included hydroxyproline that is claimed by applicant by claim 6 as left-handed molecule, further including alanine, valine, phenylalanine, etc. (col.6, lines 65-67; col.7, lines 1-2, 60-67). The patch further includes L-carnitine (col.8, line 8). The patch comprises backing layer, which reads on the claimed substrate, made of polyester fabric (col.9, lines 5-6; col.11, lines 45-59). The patches are stored in pouches

comprising polypropylene (col.12, lines 27-37). The patch further comprises adhesive to affix the patch to the skin (col.9, lines 55-57), and the matrix has polymer foam framework (col.18, lines 10-14), and both of the adhesive layer and foam framework read on the enclosure that prevents the organic material from contact subject's body as required by instant claim 1. The patch comprises additives such as permeation enhancers including glycols, preservatives including alcohols, and plasticizers (col.13, lines 12-15, 49-52; col.14, lines 10-12). The capability of the left-handed molecule of causing beneficial effect as claimed by claim 5 and improving subject stamina as claimed by claim 42 are inherent function of the specific molecule.

Response to Arguments

7. Applicant's arguments filed 11/21/2007 have been fully considered but they are not persuasive. Applicant traverses this rejection by arguing that the reference does not disclose that the enclosure prevents organic material from direct contact with subject's body as instantly claimed by amended claim 1. Further '514 describes a transdermal pouch that releases its contents into, and makes direct contact with, the subject body.

In response to this argument, applicant's attention is directed to the fact that it is also well established that the claims are given the broadest interpretation during prosecution. The scope of the present claims is directed to product comprising specific organic materials in an enclosure so that the organic materials do not directly contact the skin. US '514 teaches product comprising the claimed organic materials and further teaches that the matrix including the organic materials has polymer foam framework

(col.18, lines 10-14), and further comprises adhesive to affix the matrix to the skin (col.9, lines 55-57), and both of the foam framework and adhesive layer read on the enclosure that prevents the organic material from contact subject's body as required by instant claim 1. Therefore, all the elements of claims are met by the references, and also the function required by the enclosure is met by the adhesive polymer foam framework because both of them prevent the matrix comprising the organic materials from direct contact with the skin.

Claim Rejections - 35 USC § 103

8. 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.

9. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '514 in view of US 5,651,973 ('973).

The teachings of US '514 are discussed as set forth in this office action.

However, US '514 does not teach the patch is embodied in a bracelet as claimed by claim 26.

US '973 teaches transdermal patch that is attached to the back of suitable article such as wrist band or bracelet in order to eliminate the contact between irritating elements in the patch and the skin (col.11, lines 20-25).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide patch comprising plurality of amino acids including hydroxyproline and L-carnitine as disclosed by US '514, and attach the patch to a bracelet as disclosed by US '973, motivated by the teaching of US '973 that when the patch is attached to a bracelet it eliminates skin irritation, with reasonable expectation of having patch comprising amino acids and attached to a bracelet to effectively deliver amino acids to the wearer without irritating the skin.

10. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '514 in view of 6,558,695 ('695).

The teachings of US '514 are discussed as set forth in this office action.

Although US '514 teaches additives, however, US '514 does not teach the specific additives as claimed by claim 34.

US '695 teaches transdermal patch comprising glycerin because it acts as irritation mitigating agent and eliminates the possibility of skin irritation (abstract; col.15, lines 14-20).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide patch comprising amino acids including hydroxyproline, L-carnitine, and additives as disclosed by US '514, and replace the additives with glycerin, or further add glycerin to the additives as disclosed by US '695, motivated by the teaching of US '695 that glycerin acts as irritation mitigating agent and eliminates the possibility of skin irritation, with reasonable expectation of having patch

comprising amino acids and glycerin to effectively deliver amino acids to the wearer without irritating the skin.

Response to Arguments

11. Applicant's arguments filed 11/21/2007 have been fully considered but they are not persuasive.

The Examiner would like to clarify that US 6,558,695 (‘695) is the reference used for rejected claim 34, and the number was unintentionally typed wrong.

Applicant traverses the USC 103 rejections by arguing that the cited references, alone or in combination with one another, do not teach or suggest all the features of the claimed invention because both the '973 and the '695 describe trans-dermal delivery systems, these patents do not cure the defects of the '514 patent with regard to claim 1.

In response to applicant's argument that the US ‘973 and US ‘695 are directed to transdermal patches, it is noted that the present claims are not directed to any specific devices, and the claims are directed to the generic limitation "apparatus" that encompasses transdermal devices. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir.1993). Additionally, US ‘973 is relied upon for the solely teachings of bracelet been used to provide active materials to subject, and US ‘695 is relied upon for the solely teaching of glycerin can be provided as additive to the organic materials delivered to subject. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable

expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2002/0072501 teaches L-carnitine to increase energy.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. 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, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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