In the Claims

This listing of claims will replace all prior versions and listings of claims in the application.

1. (Currently Amended) A peptide that increases the level of estrogen *in vitro* or *in vivo*, wherein the peptide is ~~selected from the group consisting of:~~

~~a)~~ an isolated or substantially pure polypeptide obtainable from *Dioscorea* sp., wherein the polypeptide has an apparent molecular weight of about 32.5 kDA by chromatography, wherein the first twenty-one consecutive amino acids at the N-terminal of the polypeptide consists of SEQ ID NO:1~~;~~

~~b) a fragment of said polypeptide, wherein said fragment exhibits estrogen-increasing activity; and~~

~~c) a variant having at least 85% sequence identity with said polypeptide, wherein said variant exhibits estrogen-increasing activity~~.

2. (Original) A peptide according to claim 1, wherein the peptide increases the level of progesterone *in vitro* or *in vivo*.

3. (Canceled).

4. (Currently Amended) A peptide according to claim 1, wherein the polypeptide originates from *Dioscorea* ~~*Discorea*~~ *Opposita*.

5. (Original) A peptide according to claim 1, which is recombinantly-produced.

6. (Original) A peptide according to claim 1, wherein the peptide has higher activity after incubation at pH 1 than after incubation at pH 0.1 or at pH 2, wherein the activity is increasing the level of estrogen and/or progesterone in an ovarian cell or in a female subject.

7. (Original) A peptide according to claim 6, wherein the peptide has activity after incubation at pH 0.1, wherein the activity is increasing the level of estrogen and/or progesterone in an ovarian cell or in a female subject.

8. (Original) A peptide according to claim 1, wherein the peptide has higher activity after incubation at 80°C than after incubation at 60°C or at 100°C, wherein the activity is increasing the level of estrogen and/or progesterone in an ovarian cell or in a female subject.

9. (Original) A peptide according to claim 8, wherein the peptide has activity after incubation at 100°C, wherein the activity is increasing the level of estrogen and/or progesterone in an ovarian cell or in a female subject.

10. – 20. (Canceled).

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/588,702	08/17/2012	Cho Wing Sze	UHK.165XC1	6857

23557 7590 06/06/2014

SALIWANCHIK, LLOYD & EISENSCHENK
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PO Box 142950
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EXAMINER	
NOAKES, SUZANNE MARIE	

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
06/06/2014	ELECTRONIC

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

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

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

cuspto@slepatents.com

Office Action Summary	Application No. 13/588,702	Applicant(s) SZE ET AL.	
	Examiner SUZANNE M. NOAKES	Art Unit 1656	AIA (First Inventor to File) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS 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 *04/25/2014*.

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

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

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

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

Disposition of Claims*

5)☒ Claim(s) *1,2 and 4-9* is/are pending in the application.

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

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,2 and 4-9* is/are rejected.

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

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

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

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

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

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

4) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The amendments and response filed 25 April 2014 are acknowledged. Claims 3, and 10-20 are canceled. Thus, claims 1, 2 and 4-9 are pending and subject to examination on the merits.

Withdrawal of Previous Rejections

2. The rejection of claims 1-9 under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, written description is withdrawn in view of the amendments to the claims.

3. The indicated allowability of claim 1(a) is withdrawn upon further consideration for the reasons indicated in the rejection below.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

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

5. Claims 1, 2 and 4-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter because based upon an analysis with respect to the claims as a whole, said claim(s) do not recite something significantly different than a judicial exception. That is, said claims are determined to be drawn to a

naturally occurring polypeptide which is a product of nature that is not markedly or substantially different from that which exists in naturally.

The claims are drawn to a peptide that increases the level of estrogen *in vivo* or *in vitro* wherein said peptide is a substantially pure or isolated polypeptide from the species *Dioscorea*, said polypeptide has a MW of 32.5 kDa (ascertained by chromatography) and a N-terminus of SEQ ID NO: 1.

Thus, the claims are considered to be drawn to the judicial exception of a natural product and thus the claims are analyzed as whole in order to determine if they recite something which includes elements that add significantly more to the natural product than the mere isolation or discovery of the natural product itself.

Upon review of the instant claims, the claimed peptides/polypeptides are deemed to solely encompass natural products that exist in nature and which have not been altered in any way so that they are markedly or substantially different. That is, for example, the polypeptide comprising SEQ ID NO: 1 has not been altered in any way which would impart something markedly different from the natural polypeptide comprising SEQ ID NO: 1. As such, the claims are not subject matter which is eligible under the current standards for patentability of 35 U.S.C. § 101.

Applicants are referred to http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf, and specifically to Examples A-E.

Conclusion

6. No claim is allowed. This is a Non-Final Office action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. 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.

/SUZANNE M NOAKES/
Primary Examiner, Art Unit 1656
03 June 2014

AMENDMENTS TO THE CLAIMS

1-73 (Cancelled)

74. (New) A pharmaceutical product comprising an allergen extract or an allergoid thereof, which comprises at least one extract of mite bodies selected from the following groups a)-b):

a) An extract of Der p mite bodies, wherein the extract of Der p mite bodies is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 70% v/v Der p mite bodies,

b) An extract of Der f mite bodies, wherein the extract of Der f mite bodies is prepared from one fraction or combined fraction(s) of mite cultures said fractions comprising more than 70% v/v Der f mite bodies,

and at least one extract of mite faecal particles selected from the following groups c)-d):

c) An extract of Der p faecal particles, wherein the extract of Der p faecal particles is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 70% v/v Der p faecal particles,

d) An extract of Der f faecal particles, wherein the extract of Der f faecal particles is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 70% v/v Der f faecal particles.

75. (New) The pharmaceutical product according to claim 74 comprising an extract of Der p mite bodies and an extract of Der p faecal particles.

76. (New) The pharmaceutical product according to claim 74 comprising an extract of Der f mite bodies and an extract of Der f faecal particles.

77. (New) The pharmaceutical product according to claim 74 comprising an extract of Der p mite bodies, an extract of Der p faecal particles, an extract of Der f mite bodies and an extract of Der f 2 faecal particles.

78. (New) The pharmaceutical product according to claim 74, wherein the extract of Der p mite bodies is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 95% v/v Der p mite bodies; and/or the extract of Der f mite bodies is prepared from one fraction or combined fraction(s) of mite cultures said fractions comprising more than 95% v/v Der f mite bodies; and/or the extract of Der p faecal particles is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 95% v/v Der p faecal particles; and/or the extract of Der f faecal particles is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 95% v/v Der f faecal particles.

79. (New) The pharmaceutical product according to claim 74, wherein the extract of Der p mite bodies is prepared from one Der p mite body fraction or combined Der p mite body fractions and where extraction of said fraction(s) of mite bodies results in an extract comprising by weight equal amounts of group 1 and group 2 allergen or more group 2 allergen than group 1 allergen and/or the extract of Der f mite bodies is prepared from one Der f mite body fraction or more combined Der f mite body fractions and where extraction of said fraction(s) of mite bodies results in an extract comprising by weight equal amounts by weight of group 1 and group 2 allergen or more group 2 allergen than group 1 allergen.

80. (New) The pharmaceutical product according to claim 74, wherein the extract of Der p mite bodies is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 95% v/v Der p mite bodies; the extract of Der f mite bodies is prepared from one fraction or combined fraction(s) of mite cultures said fractions comprising more than 95% v/v Der f mite bodies; the extract of Der p faecal particles is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 95% v/v Der p faecal particles; the extract of Der f faecal particles is prepared from one fraction or combined fraction(s) of mite cultures said fraction(s) comprising more than 95% v/v Der f faecal particles.

81. (New) The pharmaceutical product according to claim 74, wherein the pharmaceutical product is a sublingual tablet.

82. (New) The pharmaceutical product according to claim 81, wherein the sublingual tablet is a fast dissolving sublingual tablet.

83. (New) A mite body fraction comprising more than 70% v/v mite bodies.

84. (New) The mite body fraction according to claim 83, wherein the mite bodies are Der p mite bodies or Der f mite bodies.

85. (New) A mite faecal particle fraction comprising more than 70% v/v faecal particles.

86. (New) The mite faecal particle fraction according to claim 85, wherein the faecal particles is Der p faecal particles or Der f faecal particles.

87. (New) A method for the manufacture of a mite allergen allergen extract (I) or allergoids thereof for a pharmaceutical product according to claim 74, said allergen extract (I) having a predetermined and controlled amount by weight of allergens selected from Der f 1, Der f 2, Der p 1 and Der p 2 allergens and comprising the following steps:

a) Fractions of Der p mite bodies and/or fractions of Der p mite faecal particles are isolated from Der p cultures of mites, and/or fractions of Der f mite bodies and/or fractions of Der f mite faecal particles are isolated from Der f mite cultures;

b) Optionally combining several fractions of Der p mite bodies, optionally combining several fractions of Der p mite faecal particles, optionally combining several fractions of Der f mite bodies and optionally combining several fractions of Der f mite faecal particles;

c) Extracting allergens from mite body faction(s) obtained in a step a) or a step b) as above and/or extraction of allergens from mite faecal particle fraction(s) obtained in a step a) or a step b) as above; and thereafter

d) Measuring the concentration (w/v) of group 1 and group 2 allergen in mite allergen extracts obtained in a step c) as above; and optionally

c) Mixing one or more extract(s) of mite bodies with one or more extract(s) of faecal particles as obtained in a step c) as above to obtain a mixture of allergen extracts (I) with a predetermined amount by weight of group 1 to group 2 allergen and optionally

f) Converting the extract (I) to an allergoid thereof.

88. (New) The method according to claim 87, wherein one or more extract(s) of mite bodies and one or more extract(s) of faecal particles is mixed to obtain a mixture of allergen extracts (I).

89. (New) The method according to claim 87, wherein the mixture of mite allergen extract (I) comprises extract(s) of Der p mite bodies, extract(s) of Der p faecal particles, extract(s) of Der f mite bodies and extract(s) of Der f 2 faecal particles.

90. (New) The method according to claim 87, wherein the pharmaceutical product is a fast dissolving sublingual tablet.

91. (New) A method for treatment and/or prevention of allergy and allergic asthma caused by house dust mites which method comprises administering to a patient in need of such treatment an effective amount of a pharmaceutical product of claim 74.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/701,614	04/22/2013	Heather Michelle Webster	059366/432945	2518

826 7590 06/19/2014

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
ROONEY, NORA MAUREEN	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
06/19/2014	ELECTRONIC

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

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

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

usptomail@alston.com

Office Action Summary	Application No. 13/701,614	Applicant(s) WEBSTER ET AL.	
	Examiner NORA ROONEY	Art Unit 1644	AIA (First Inventor to File) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS 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 *05/08/2014*.

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

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

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

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

Disposition of Claims*

5)☒ Claim(s) *74-91* is/are pending in the application.

5a) Of the above claim(s) *83-91* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *74-82* is/are rejected.

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

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

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

Application Papers

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

11)☒ The drawing(s) filed on *12/03/2012* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☒ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *12/03/2012*.

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

4) ☐ Other: _____.

DETAILED ACTION

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

2. Claims 74-91 are pending.

3. Applicant's election of Group I, claims 74-82 without traverse in the reply filed on 03/10/2014 is acknowledged.

4. Claims 83-91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/10/2014.

4. Claims 74-82 are currently under consideration as they read on a pharmaceutical product comprising mite body and fecal particle extracts.

5. Applicant's IDS document filed on 12/03/2012 has been considered.

Double Patenting

6. Claims 74-82 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-11, 13-15 and 17-29 of copending Application No. 13/314,024. Although the claims at issue are not identical, they are not patentably distinct from each other because claims 1-11, 13-15 and 17-29 in Application 13/314,024 are directed to method of manufacturing and using the instant allergen extracts of instant claims 74-82.

The reference teachings anticipate the claimed invention.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

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

8. Claims 74-82 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter because the claimed invention is not directed to patent eligible subject matter. Based upon an analysis with respect to the claim as a whole, claims 74-82 do not recite something significantly different than a judicial exception. The rationale for this determination is explained below:

Claims 74-82 are directed to naturally occurring products, which are a judicial exception for patent-eligibility under 35 U.S.C. 101 in light of the recent court decisions including *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. __, 133 S. Ct. 2107, 106 USPQ2d 1972 (2013), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. __, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012).

See *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products* (*Guidance*). The Guidance implements a new procedure to address changes in the law relating to subject matter eligibility under 35 U.S.C. § 101 in view of these recent court decisions.

The pharmaceutical products recited in the claims are not markedly different from naturally occurring products. The "markedly different" inquiry focuses on the structural characteristics of the product and not how it was made. It is noted that new laboratory or

engineering techniques are not required and the extent of effort required to make product is not relevant to the inquiry. The examiner gives the claim its broadest reasonable interpretation in light of the specification. Based on the plain and ordinary meaning of Der p and Der f extracts of mite bodies and fecal particles in the art in light of the specification, naturally occurring extracts and allergens are encompassed. The combination of the two naturally occurring extract or allergen products in a single composition does not make them eligible. A marked difference requires a product to be both (1) non-naturally occurring and (2) markedly different in structure. As such, the claimed pharmaceutical products are ineligible.

As such, claims 74-82 are not directed to patent eligible subject matter.

Claim Rejections - 35 USC § 102

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

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

10. Claims 74-76 and 78-80 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication 2010/0024048 (PTO-892; Reference A) and corresponding U.S. Patent 8,312,841 (PTO-892; Reference B).

U.S. Patent Application Publication 2010/0024048 and U.S. Patent 8,312,841 teaches preparing Dermatophagoides pteronyssinus and Dermatophagoides farinae allergenic extracts used in allergy formulations for use in vivo or in vitro. The reference teaches extracts of whole cultures, where allergens from both the mites and mite fecal particles are obtained. The reference