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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 13/649,460 | 10/11/2012 | Jaw-Ji Tsai | 67204-002001 | 2950 |
| 69713 | 7590 | 12/17/2013 | EXAMINER | |
| OCCHIUTI & ROHLICEK LLP | | | PACKARD, BENJAMIN J | |
| 321 Summer St. | | | ART UNIT | PAPER NUMBER |
| Boston, MA 02210 | | | 1612 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 12/17/2013 | ELECTRONIC |

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

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

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

INFO@ORPATENT.COM

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DETAILED ACTION

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

Response to Election/Restrictions

Applicant's election without traverse of Group II, claims 7-18 in the reply filed on 08/26/13 acknowledged.

Claims 1-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3rd Party Submission

Examiner notes the presence of a 3rd party submission, which references are discussed in the rejection below.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 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.

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 pre-AIA 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.

Claims 7-18 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Abu Bakr Mohammad (Kitaab-al-Haawi-fil-Tibb, Vol XXI, Part I, pgs 4-7, 1968), Mohmmad Azam Khan (Muheet-e-Azam, Vol I, pgs 8-11, 1896), Agathiayr (Agasthiyar 2000 Vol III, pgs 12-17, 1963), Liang et al (US Pregrant Pub 2002/0031559), and Chae et al (KR 2009084159 A).

Abu Bakr Mohammad teaches Mentha Piperita is used for the treatment of bronchial asthma through oral administration.

Mohmmad Azam Khan teaches Prunus Dulcis is used for treatment of dry cough and bronchial asthma through oral administration.

Agathiayr teaches the use of Nelumbo Nucifera for treatment of rhinitis through oral administration.

Liang et al teaches treatment of allergic rhinitis by administering compositions comprising Euryale Ferox, Disoscorea, Poria Cocos, and Schizonepeta Tenuifolia (¶

13). Further, Fritillaria (§ 52) and Panax Quinquefolium are also taught to be beneficial (§ 58).

Chae et al discloses the use of Diospyros Kaki for treatment of asthma or rhinitis (English abstract).

One of ordinary skill in the art would have been motivated to have combined the agents of the references in order to provide a final composition useful for the same purpose (treating allergic rhinitis, asthma, or dry cough). This position is consistent with well-established precedent holding that it is prima facie obvious to combine compositions known to be individually useful together so as to provide a third composition for the same use. See, e.g., In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980).

Further, it would have been obvious to one of ordinary skill in the art to optimize the amount of each active in order to find the most effective combination and then to adjust the dosage to find the effective dose.

When testing, it would reasonably be expected that a mouse model would be used prior to human trials.

Obvious-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double

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patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

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Claims 7-18 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,958,162 in view of Abu Bakr Mohammad (Kitaab-al-Haawi-fil-Tibb, Vol XXI, Part I, pgs 4-7, 1968), Mohmmad Azam Khan (Muheet-e-Azam, Vol I, pgs 8-11, 1896), Agathiayr (Agasthiyar 2000 Vol III, pgs 12-17, 1963), Liang et al (US Pregrant Pub 2002/0031559), Chae et al (KR 2009084159 A). Although the claims at issue are not identical, they are not patentably distinct from each other because the patent claims are directed to the alcohol extract of the components and lack some of the extracts. The secondary references teach the addition of the various missing components as discussed above.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN PACKARD whose telephone number is (571)270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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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.

/BENJAMIN PACKARD/
Primary Examiner, Art Unit 1612

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|-----------------------------------|---------------------------------------|--|-------------|
| Notice of References Cited | Application/Control No. 13/649,460 | Applicant(s)/Patent Under Reexamination TSAI, JAW-JI | |
| | Examiner BENJAMIN PACKARD | Art Unit 1612 | Page 1 of 1 |

U.S. PATENT DOCUMENTS

| * | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Name | Classification |
|---|--|-----------------|--------------|----------------|
| * | A US-2002/0031559 | 03-2002 | Liang et al. | 424/725 |
| | B US- | | | |
| | C US- | | | |
| | D US- | | | |
| | E US- | | | |
| | F US- | | | |
| | G US- | | | |
| | H US- | | | |
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| | K US- | | | |
| | L US- | | | |
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| * | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Country | Name | Classification |
|---|--|-----------------|-----------------|-----------------|----------------|
| | N KR 2009084159 A | 08-2009 | Korea, Republic | CHAE J H et al. | |
| | O | | | | |
| | P | | | | |
| | Q | | | | |
| | R | | | | |
| | S | | | | |
| | T | | | | |

NON-PATENT DOCUMENTS

| * | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|
| U | Abu Bakr Mohammad (Kitaab-al-Haawi-fil-Tibb, Vol XXI, Part I, pgs 4-7, 1968). |
| V | Mohmmad Azam Khan (Muheet-e-Azam, Vol I, pgs 8-11, 1896). |
| W | Agathiyar (Agasthiyar 2000 Vol III, pgs 12-17, 1963). |
| 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.