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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/532,802	03/22/2010	Devindra Ramautarsing	313632007800	1647
25225	7590	09/19/2012	EXAMINER	
MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			DAVIS, DEBORAH A	
			ART UNIT	PAPER NUMBER
			1655	
			NOTIFICATION DATE	DELIVERY MODE
			09/19/2012	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):

- EOfficeSD@mofo.com
- PatentDocket@mofo.com
- Drcaldwell@mofo.com

Office Action Summary

Application No.	Applicant(s)	
12/532,802	RAMAUTARSING, DEVINDRA	
Examiner	Art Unit	
DEBORAH DAVIS	1655	

-- 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 ____.
- 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) 1-10,12 and 13 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) 1-10,12 and 13 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:
- Certified copies of the priority documents have been received.
 - Certified copies of the priority documents have been received in Application No. ____.
 - 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

Claims 1-10 and 12-13 are under consideration for examination on the merits.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

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.

Claims 1-10 and 12-13 are 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 1 recites the limitation "said activities" in line 6. There is insufficient antecedent basis for this limitation in the claim.

The metes and bounds of claim 7 with respect to the comparable pharmacological action of the part or extract from one, two, three or four plants from claim 6 as compared to the replaced plants are unclear. It is unclear as to what the comparable part or extract of the replaced plants are. Therefore, the protection sought for this claim is unclear. Applicant is required to particularly point out what the replacement part or extract of a those plants are.

The metes and bounds of claim 8 are unclear because it is not known as to what the synthetic compound encompasses.

Claim Rejections - 35 USC § 102

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 –

(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.

Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by WIPO Publication (WO 2005/076750).

The claims are drawn to a composition comprising an anti-hyperglycaemic agent, an anti-inflammatory, an anti-hyperlipidemic agent, an anti-oxidant, and optionally a gastro-intestinal agent.

The cited WIPO Publication anticipates the claims by disclosing a synergistic herbal formation composition for treating diabetes. The formulation comprising extracts from *Momordica charantia*, *Emblica officinalis*, *Trigonella foenum-gracum*, and *Curcuma longa* as active ingredient. The formulation was administered to rats using distilled water (i.e. pharmaceutically-acceptable excipient) which resulted in reversing the blood sugar level to normalcy (see e.g. abstract, pages 12 and 16). The instant specification describes *Emblica officinalis* as the hyperlipidemic agent, *Curcuma longa* as the antioxidant agent and anti-inflammatory agent, and *Momordica charantia* and *Trigonella foenum-gracum* (see e.g. specification page 9).

Thus, the cited reference anticipates the instant 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 negated by the manner in which the invention was made.

Claims 1-10 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over WIPO Publication (WO 2005/076750), Joel R. L. Ehrenkranz (US 2006/0189512), Dham et al (Current Diabetes Reports, 2006, Vol 6, pages 251-258), Sabu et al. (Pharmaceutical Biology, 2003, Vol. 41, No. 7, pages 500-505), and Mohammad et al. (Key Attributes of TKDL, formulation JA6/323J)

The cited WIPO Publication beneficially teaches a synergistic herbal formation composition for treating diabetes. The formulation comprising extracts from *Momordica charantia*, *Embllica officinalis*, *Trigonella foenum-gracum*, and *Curcuma longa* as active ingredient. The formulation was administered to rats using distilled water (i.e. excipient) which resulted in reversing the blood sugar level to normalcy (see e.g. abstract, pages 12 and 16). The instant specification describes *Embllica officinalis* as the hyperlipidemic agent, *Curcuma longa* as the antioxidant agent and anti-inflammatory agent, and *Momordica charantia* and *Trigonella foenum-gracum* (see e.g. specification page 9).

The cited reference of Ehrenkranz beneficially teaches examples of plant-based substances and/or extracts that have hypoglycemic properties and provide a synergistic effect when combined with phlorizin extract to modify glucose transport in blood and urine and blood insulin levels. The plant extracts having such hypoglycemic properties

include *Curcuma longa*, *Emblica officianalis*, *Enicostemma littorale*, *Gymnema sylvestre*, *Momordica charantia*, *Mucuna pruriens*, *Swertia chirayita*, *Terminalia chebula*, and *Trigonella foenum-graecum* (see e.g. abstract, and paragraph 0030).

The cited reference of Dham et al. beneficially teaches that an Ayurvedic medicine to treat diabetes. The medicine contains *emblica*, *Curcuma longa*, *Trigonella foenum-graecum*, *Terminalia belerica*, and *Terminalia chebula* as active ingredients (see e.g. page 256, column 2, paragraph 3).

The cited reference of Sabu et al. beneficially teaches that methanol extracts of *Momordica charantia*, *Trigonella foenum-graecum*, and *Vernonia anthelmintica* were found to reduce serum glucose levels in diabetic rats significantly when orally administered (see e.g. page 505, column 1).

The cited reference of Mohammad et al. beneficially teaches a formulation comprising *Holarrhena antidysenteric* that is useful in the treatment of Diabetes mellitus (see entire page No. 10).

The cited reference of McAnuff et al. beneficially teaches that diosgenin significantly lowered blood glucose in diabetic rats (see e.g. Table 1, page 19, and Results). Diosgenin is a known chemical constituent which can be extracted from the plant *Jateorhiza palmate*. Therefore one would use extracts from *Jateorhiza palmate* containing diosgenin to treat diabetes.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose of treating diabetes. One of

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ordinary skill in the art would be motivated to administer the drug to a person in need thereof since each drug is known in the art to successfully treat diabetes. The adjustment of conventional working conditions with respect to determining the amounts by weight of each plant part or extract would have been judicious selection and routine modification well within the purview of an artisan skilled in the pharmaceutical arts. It would also be obvious for the following reasons: In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Supreme Court reaffirmed "the conclusion that when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *Id.* at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273,282 (1976)). The Supreme Court also emphasized a flexible approach to the obviousness question, stating that the analysis under 35 U.S.C. § 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418; see also *id.* at 421 ("A person of ordinary skill is... a person of ordinary creativity, not an automaton."). The Supreme Court thus implicitly endorsed the principle, stated in *In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980) (citations omitted), that: It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose of treating diabetes by lowering blood glucose levels. [T]he idea of combining them flows logically from their having been individually taught in the prior art.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mana et al. beneficially teaches that *Holarrhena antidysenteric* as an antidiabetic drug (see e.g. Summary).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH DAVIS whose telephone number is (571)272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. 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.

Deborah A. Davis
Patent Examiner, AU 1655

/Christopher R Tate/
Primary Examiner, Art Unit 1655

Notice of References Cited	Application/Control No. 12/532,802	Applicant(s)/Patent Under Reexamination RAMAUTARSING, DEVINDRA	
	Examiner DEBORAH DAVIS	Art Unit 1655	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2006/0189512	08-2006	Ehrenkranz, Joel R. L.	514/003
	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	WO 2005076750 A2	08-2005	World Intellect	KUMAR, ARUN RAJA	
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	McAnuff et al. "Hepatic Function Enzymes and Lipid Peroxidation in Streptozotocin-induced Diabetic Rats Fed Bitter Yam (Dioscorea Polygonoides) Steroidal Sapogenin Extract", Biotechnology Centre, University of the West Indies.
	V	Sabu et al., "Antioxidant Activity of Indian Herbal Drugs in Rats with Aloxan-induced Diabetes", Pharmaceutical Biology, 2003, Vol 41, No. 7, pp. 500-505.
	W	Dham et al, "The Role of Complementary and Alternative Medicine in Diabetes", Current Diabetes Reports, Vol. 6, 2006, pages 251-258.
	X	Mohammad et al. "Key Attributes of TKDL, formulation JA6/323J", Khazaain-al-Advis, Vol III, NAdeem Yunus Printer/Sheikh Mohd, Basheer & Sons, Lahore, 1926 AD.

*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.

Notice of References Cited	Application/Control No. 12/532,802	Applicant(s)/Patent Under Reexamination RAMAUTARSING, DEVINDRA	
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	A US-			
	B US-			
	C US-			
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	K US-			
	L US-			
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FOREIGN PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N				
	O				
	P				
	Q				
	R				
	S				
	T				

NON-PATENT DOCUMENTS

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
U	Mana et al., "Antidiabetic Effect of Hollarrhena Antidysenterica Seeds on Streptozotocin Induced Diabetic Rats", Pharmacology online 1: 426-431 (2011).
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.