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**Letter No.:-BIO-TECH/2014/**

To,  
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**SUB : Examination Report**

APPLICATION NUMBER : 2132/MUMNP/2007  
DATE OF FILING : 17/12/2007  
DATE OF REQUEST FOR EXAMINATION : 07/05/2009  
DATE OF PUBLICATION : 01/02/2008

With reference to the RQ No. 1110/RQ-MUM/2009 Dated 07/05/2009 in the above mentioned application for Grant of Patent ,  
a) Examination has been conducted under Section 12 and 13 of the Patents Act 1970 , The following objections are hereby communicated

b) Objections :

The subject-matter claimed in claims 1-53 contains the following groups of inventions, which are not linked so as to form a single inventive concept as required u/s 10 (5) of the Patents Act, 1970 (as amended):

Group I: Claims 1-17 and 19-53, which are directed to a system and a method of promoting hair growth;

Group II: Claim 18 (in part), which is directed to a method of enhancing or restoring hair colour;

1 Group III: Claim 18 (in part), which is directed to a method of increasing the thickness of hair;

Group IV: Claim 18 (in part), which is directed to a method of improving the general appearance of hair; and

Group V: Claim 18 (in part), which is directed to a method of reducing or eliminating dandruff.

The claims must be limited to one inventive concept. A *posteriori* analysis has concluded that the composition of claim 1 is known in the prior art. Unity is lacking since there exists no other linking feature, common to all groups, which overcomes the prior art. Thus, claims 1-54 lack unity.

2 System claims 1-15 and 19-33 are considered indefinite, as they do not reasonably apprise those skilled in the art of their scope. It is unclear what applicant intends the term "system" to mean.

The present application claims the subject-matter, which is a traditional knowledge or which is an aggregation or duplication of known properties of traditionally known components such as extracts of *Veratrum* plant, *Buxus* plant, *Holarrhena* plant, *Solanum* plant and *Rauwolfia* plant for the treatment of hair loss and thus, falls within the ambit of Section 3 (p) of the Patents Act, 1970 (as amended). The use of *Veratrum* plant, *Buxus* plant, *Holarrhena* plant, *Solanum* plant and *Rauwolfia* plant for the treatment of Alopecia (i.e. Hair loss) is traditionally known, which can be evident from the following TKDI citations:

(a) Aminuddaullah Abul Farj Ibn Al-Quff Maseehi, Kitaab-al-Umdah-fil-Jeraahat, Part II (13<sup>th</sup> century AD), Deyerah-al-Ma'aarif Usmania, Hyderabad, 1937 AD, which discloses the use of *Veratrum* plant for the treatment of Alopecia;

3 (b) Mohammad Najmul Ghani Khan, Khazaain-al-Advia, Vol III (20<sup>th</sup> century AD), Nadeem Yunus Printer/Sheikh Mohd Basheer & Sons, Lahore, 1926 AD, which discloses the use of *Buxus* plant for the treatment of Alopecia;

(c) Caraka-Samhita - Edited and translated by P. V. Sharma, Vol. II, Chaukhamba Orientalia, Varanasi Edn. 5<sup>th</sup>, 2000, which discloses the use of *Holarrhena* plant for the treatment of Alopecia;

(d) Vrindmadhava - Marathi translated by Datto Vallala Borkar, Yagyeeswara Gopal Dixit, Bookseller, Pune; Edn. 1992, which discloses the use of *Solanum* plant for the treatment of Alopecia; and

(e) Mohammad Akmal Khan - Qaraabaadeen Azam wa Akmal (19<sup>th</sup> century AD), Matba Siddiqi, Delhi, which discloses the use of *Rauwolfia* plant for the treatment of alopecia.



4 The subject-matter of claims 16-18 and 34-51 relates to a method of treatment of human hairs (i.e. treatment of Alopecia), which is statutorily non-patentable subject-matter as per Section 3 (i) of the Act.

5 The subject-matter claimed in the present application is considered as a mere admixture of traditionally known ingredients such as extracts of *Veratrum* plant, *Buxus* plant, *Holarrhena* plant, *Solanum* plant, *Rauwolfia* plant and *Pilocarpus* plants, which is statutorily non-patentable subject matter as per Section 3 (e) of the Act.

6 Claim 54, which is voluntarily added a new claim during National Phase (NP) entry, is vague and unclear, as it defines the subject-matter in terms what is disclosed in the specification. It fails to point out what is included or excluded by the claim language of said claim. As per Section 10 (4) (c) of the Act, a claim is admissible only when it clearly defines the scope of the invention for which protection is sought. Hence, claim 54 is not allowable u/s 10 (4) (c) of the Act.

7 Claims 52-53 refer to instructions for use, which do not define technical features of a kit which is a product. They rather relate to the method of using the kit, thereby rendering the category of the claim unclear. Further, said claims are not sufficiently defined by its essential technical features. It should be noted that an independent claim must contain all the technical features essential for the definition of the invention.

8 Following documents are being relied upon for deciding novelty and/or inventive step of claims 1-53:

D1: WO 01/27135;

D2: EP 0792646;

D3: JP 05-051306;

D4: Grieve, M. Box. A Modern Herbal, [online] 1995 [retrieved on 2006.08.04] Retrieved from the Internet;

D5: JP 09-188606;

D6: Felter, H.W. and Lloyd J.U. King's American Dispensatory, [online] 1898 [retrieved on 2006.08.30] Retrieved from the Internet;

D7: JP 2003-081861;

D8: JP 2001-172130;

D9: Aminuddaaulah Abul Farj Ibn Al-Quff Maseehi, Kitaab-al-Umdah-fil-Jeraahat, Part II (13<sup>th</sup> century AD), Deyerah-al-Ma'arif Usmania, Hyderabad, 1937 AD. D9 discloses the use of *Veratrum* plant for the treatment of Alopecia;

D10: Mohammad Najmul Ghani Khan, Khazaain-al-Advia, Vol III (20<sup>th</sup> century AD), Nadeem Yunus Printer/Sheikh Mohd Basheer & Sons, Lahore, 1926 AD. D10 discloses the use of *Buxus* plant for the treatment of Alopecia;

D11: Caraka-Samhita - Edited and translated by P. V. Sharma, Vol. II, Chaukhamba Orientalia, Varanasi Edn 5th, 2000. D11 discloses the use of *Holarrhena* plant for the treatment of Alopecia;

D12: Vrindmadhava - Marathi translated by Datto Vallala Borkar, Yagyeeswara Gopal Dixit, Bookseller, Pune; Edn. 1992. D12 discloses the use of *Solanum* plant for the treatment of Alopecia; and

D13: Mohammad Akmal Khan - Qaraabaadeen Azam wa Akmal (19<sup>th</sup> century AD), Matba Siddiqi, Delhi. D13 discloses the use of *Rauwolfia* plant for the treatment of Alopecia.

#### NOVELTY:

The present application relates to a system and a method for promoting hair growth. The system comprises one or more extracts from the following steroidal alkaloid-containing plants: *Veratrum*, *Buxus*, *Holarrhena*, *Solanum* and *Rauwolfia* as well as optionally one or more extracts from *Pilocarpus* plants, which facilitate the opening of skin pores or a seaweed extract which provides nutrients to the hair.

Claims 1, 4, 5, 7, 8, 12-17 and 52 are not novel, as being anticipated by D1. D1 discloses that topical compositions comprising plant steroidal alkaloids such as *Veratrum* type alkaloids (veratramine, jervine, cyclopamine, cycloposine and muldamine), *Solanum* type alkaloids (solanidine and tomatidine) and derivatives thereof regulate hair growth.

Claims 1, 12-15 and 17 are not novel, as being anticipated by D2. D2 discloses topical compositions comprising a *Solanum* plant extract, which protects against hair loss and treats dandruff.

Claims 1, 4, 7, 12-17 and 52 are not novel, as being anticipated by D3. D3 discloses compositions comprising a *Rauwolfia* plant extract, which promotes hair production and hair growth.

Claims 1, 4-6, 9, 12-17 and 52 are not novel, as being anticipated by D4. D4 discloses compositions comprising a *Buxus* plant extract, which promotes the growth of hair.

Claims 1, 4-9 and 12-18 are novel, as being independently anticipated any one of D9 to D13, which disclose the use of *Veratrum* plant, *Buxus* plant, *Holarrhena* plant, *Solanum* plant and *Rauwolfia* plant for the treatment of Alopecia (i.e. Hair loss).

#### INVENTIVE STEP:

Claims 1, 2, 4-9, 12-17 and 52 would have been obvious to a person skilled in the art to which they pertain with regards to D5 in view of D1, D2, D3 or D4. D5 discloses that compositions comprising a *Pilocarpus* plant extract (excepting pilocarpine) have a superior hair growing action. It would therefore, be obvious that compositions comprising a *Pilocarpus* plant extract and: steroidal alkaloids from *Veratrum* or *Solanum* (D1); a *Solanum* plant extract (D2); a *Rauwolfia* plant extract (D3); or a *Buxus* plant extract (D4) would promote hair growth.

Claims 1, 2, 4-9, 12-18 and 52 would have been obvious to a person skilled in the art to which they pertain with regards to D6 in view of D1, D2, D3 or D4. D6 discloses that a *Jaborandi* extract (which is a *Pilocarpus* extract) causes hair to become darker in colour and is useful in alopecia to promote the growth of hair. It would therefore, be obvious that compositions comprising a *Pilocarpus* (or *Jaborandi*) plant extract and: steroidal alkaloids from *Veratrum* or *Solanum* (D1); a *Solanum* plant extract (D2); a *Rauwolfia* plant extract (D3); or a *Buxus* plant extract (D4) would restore hair colour and promote hair growth.



Claims 1, 3-10, 12-17 and 52 would have been obvious to a person skilled in the art or science to which they pertain with regards to D7 in view of D1, D2, D3 or D4. D7 discloses that a hair tonic comprising an extract of marine algae promotes the growth of hair. It would therefore, be obvious that composition comprising an extract of marine algae and steroidal alkaloids from *Veratrum* or *Solanum* (D1); a *Solanum* plant extract (D2); a *Rauwolfia* plant extract (D3); or a *Buxus* plant extract (D4) would promote hair growth.

Claims 1, 3-9, 12-18 and 52 would have been obvious to a person skilled in the art or science to which they pertain with regards to D8 in view of D1, D2, D3 or D4. D8 discloses that a composition comprising a seaweed extract has hair quality improving action as well as hair-growth promoting action. It would therefore, be obvious that compositions comprising a seaweed extract and steroidal alkaloids from *Veratrum* or *Solanum* (D1); a *Solanum* plant extract (D2); a *Rauwolfia* plant extract (D3); or a *Buxus* plant extract (D4) would improve the general appearance of hair and promote hair growth.

9 The expression "wherein system" in claims 5-9 and 21-25 should read "wherein said system".

Claims 2, 19-25, 32-36, 38-43, 50 and 51 are broader in scope than what is disclosed in the specification. To comply with this requirement, the claims must specify that the seaweed is *Fucus* seaweed. The term seaweed encompasses various species, which are not included in the present description.

11 Claims 27 and 45 are unclear. The expression "seaweed" should read "seaweed extract".

12 Claim 28 is unclear as the term "*Veratrum* plant" lacks proper antecedent basis in claim 22.

In Form-1, Applicants have cancelled out Para 9 (iii) declaration [i.e. the invention as disclosed in the specification used the biological material from India and necessary permission from the competent authority shall be submitted by us before the grant of patent to me/us]. However, the source and geographical origin of the plants used in the present invention is not disclosed in the specification, which is required to be disclosed as per Section 10 (4) (ii) (D) of the Act. While doing so, a separate heading/paragraph at the beginning of the description in the complete specification shall be added that the biological material used in the alleged invention is not from India and should clearly specify the country of source and geographical origin of the same.

14 Proof of right to make the application for patent u/s 7 (2) of the Act submitted to this office on 21/01/2009, which is not filed within the period prescribed under Rule 10 of the Patents Rules, 2003 (as amended). Thus, it is not taken on record.

15 Power of Attorney in favor of the agent shall be filed.

16 If any amendments is made in any page of the specification that page should be freshly typed and filed in duplicate along with a marked copy clearly highlighting the corrections/amendments made. However, a care should be taken that no new matter is added in the specification as originally filed.

17 Kindly note that you should submit the documents only after complying with the above requirements.

18 Details regarding the search and/or examination report including claims of the application allowed, as referred to in Rule 12(3) of the Patent Rule, 2003, in respect of same or substantially the same invention filed in all the major Patent offices along with appropriate translation where applicable, should be submitted within a period of Six months from the date of receipt of this communication as provided under section 8(2) of the Indian Patents Act.

19 Details regarding application for Patents which may be filed outside India from time to time for the same or substantially the same invention should be furnished within Six months from the date of filing of the said application under clause(b) of sub section(1) of section 8 and rule 12(1) of Indian Patent Act.

You are requested to comply with the objections by filing your reply by way of explanation and/or amendments within 12 months from the date of issue of FER failing which your application will be treated as "Deemed to have been abandoned" under section 21(1) of the Act. The last Date is 12/01/2015.

d) You are advised to file your reply at the earliest so that the office can further proceed with application and complete the process within the prescribed period.

(Dr. Dinesh P. Patil)

Asst. Controller of Patents & Designs

NOTE : All Communications to be sent to the Controller of Patents at INTELLECTUAL PROPERTY BUILDING S. M. Road, Antop Hill Mumbai-400 037.

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