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(21) International Application Number: PCT/AU93/00507 (22) International Filing Date: 1 October 1993 (01.10.93) (30) Priority data: PL 5068 1 October 1992 (01.10.92) AU (71) Applicant (for all designated States except US): DE-NOVO INTERNATIONAL PTY LTD [AU/AU]; 1/7 Cochrane Street, Mitcham, VIC 3132 (AU). (72) Inventors; and (75) Inventors/Applicants (for US only) : BRADLEY, Joan [GB/AU]; BRADLEY, Gilbert [GB/AU]; Unit 6, 19 Graham Road, Rosanna, VIC 3084 (AU). (74) Agents: CORBETT, Terence, G. et al.; Davies Collison Cave, 1 Little Collins Street, Melbourne, VIC 3000 (AU).		(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, LV, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: TOPICAL COMPOSITION AND THE USE OF SAID COMPOSITION IN RESTORING HAIR AND/OR PREVENTING HAIR REMOVAL (57) Abstract The invention relates to a topical composition comprising at least about 85 % by volume of eucalyptus oil, at least about 5 % by volume of rosemary oil and optionally a cosmetically and/or pharmaceutically acceptable additive and methods for preventing hair removal and/or restoring hair involving said topical composition. The invention also relates to a method for the treatment and/or prophylaxis of alopecia, baldness and/or related disorders and a method for treating dandruff, seborrhoea, scalp psoriasis and/or related dermatological disorders involving said topical composition.		

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**TOPICAL COMPOSITION AND THE USE OF SAID COMPOSITION IN
RESTORING HAIR AND/OR PREVENTING HAIR REMOVAL**

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10 The invention relates to a topical composition and the use of said composition in restoring hair and/or preventing hair removal. In particular, the invention relates to the use of the composition in treating alopecia or baldness.

15 Alopecia or baldness is currently treated by topical administration of a drug which contains monoxodil as the active ingredient to the hair and scalp. This drug can only be obtained by prescription and its use requires supervision by a physician. This drug is applied to the hair and scalp twice daily and once treatment ceases, hair continues to fall out. There are also side effects associated with the use of this drug.

20 A requirement accordingly exists for a topical composition for treating alopecia and related disorders which is composed of natural ingredients and which is non-injurious to the patient.

25 According to one aspect of the present invention there is provided a topical composition comprising at least about 85% by volume of eucalyptus oil, at least about 5% by volume of rosemary oil and optionally a cosmetically and/or pharmaceutically acceptable additive.

30 According to another aspect of the present invention there is provided a method for preventing hair removal and/or restoring hair which comprises topical administration of the composition defined above to the hair, scalp and/or skin of a subject in need thereof.

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According to a further aspect of the present invention there is provided a method for the treatment and/or prophylaxis of alopecia, baldness and/or related disorders which comprises topical administration of the composition defined above
5 to the hair, scalp and/or skin of a subject in need thereof.

This method is particularly useful in treating cancer patients suffering hair loss following chemotherapy.

10 According to a still further aspect of the present invention there is provided a method for treating dandruff, seborrhoea, scalp psoriasis and/or related dermatological disorders which comprises topical administration of the composition defined above to the hair, scalp and/or skin of a subject in need thereof.

15 The amount of eucalyptus oil in the composition is preferably about 85 to about 95% by volume, more preferably about 90% by volume. The amount of rosemary oil in the composition is preferably about 5 to about 15% by volume, more preferably about 10% by volume.

20 In a particularly preferred embodiment, the composition comprises about 90% by volume of eucalyptus oil and about 10% by volume of rosemary oil.

The eucalyptus oil may be naturally occurring or synthetically produced. The eucalyptus oil may be obtained from any species of eucalyptus, particularly
25 *Eucalyptus cyanophylla*, *Eucalyptus polybractea* or *Eucalyptus viridis*. *Eucalyptus cyanophylla* and *Eucalyptus polybractea* are also known as "Blue Mallee". *Eucalyptus viridis* is also known as "Green Mallee".

The primary active ingredient in the eucalyptus oil is cineol. The eucalyptus
30 oil is preferably obtained from the Blue Mallee as this eucalyptus contains a high concentration of cineol in the range of about 80 to about 83%.

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The cosmetically and/or pharmaceutically acceptable additive may be present in an amount of not more than about 5%, more preferably about 1%. This additive may be of any suitable type known in the art and may be selected from one or more
5 of alcohols, perfumes, surfactants, thickeners, antioxidants and preservatives. The additives may also include other agents suitable for restoring hair and/or preventing hair removal, such as, for example, biotin or squalene.

The topical composition can be prepared by any suitable method known in
10 the art. Preferably, the composition is prepared by mixing the eucalyptus oil and rosemary oil together. If desired, the composition may be formulated into a lotion, cream, hair tonic, hair cream, shampoo, hair rinse, ointment or soap.

The topical composition is also useful for the general maintenance of hair and
15 is particularly useful as a conditioner.

The methods of the invention involve the topical administration of the composition for a time and under conditions sufficient for the treatment to be effective. The composition is preferably applied daily to the hair, scalp and/skin
20 over a period of several weeks.

The eucalyptus oil and rosemary oil are preferably administered simultaneously in the methods of the invention. However, it will be appreciated that they may also be administered separately or sequentially, if desired.
25

The present invention also extends to a kit comprising:
(a) at least about 85% by volume of eucalyptus oil; and
(b) at least about 5% by volume of rosemary oil,
said components (a) and (b) being held separately for separate, sequential or
30 simultaneous use.

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In the composition and method of the invention, the eucalyptus oil acts as a cleansing agent to clean the sebaceous glands thereby permitting the eucalyptus oil to act on the root hair canal.

- 5 The invention will now be further described with reference to the following Examples. These Examples are not intended to limit the invention in any way.

The eucalyptus oil used in the Examples was obtained from the Blue Mallee.

10 **Example 1**

A topical composition containing about 90% eucalyptus oil and about 10% rosemary oil was applied to the scalp and hair of a subject suffering from baldness, massaged thoroughly into the scalp and hair and allowed to dry. It was shown that by repeating this application daily over several weeks, significant new hair growth
15 was observed on the scalp of the subject.

Example 2

Similar results as described in Example 1 were observed when a topical composition containing about 90% eucalyptus oil and about 10% rosemary oil was
20 applied to the scalp and hair of a subject.

Comparative Example 1

A topical composition containing about 75% eucalyptus oil and about 25% rosemary oil was applied to the scalp and hair of a subject suffering from baldness
25 in the same manner as described in Example 1. However, no significant new hair growth was observed on the scalp of the subject.

Comparative Example 2

Similar results as described in Comparative Example 1 were observed when
30 a topical composition containing about 60% eucalyptus oil and about 40% rosemary oil was applied to the scalp and hair of a subject.

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CLAIMS:

1. A topical composition comprising at least about 85% by volume of eucalyptus oil, at least about 5% by volume of rosemary oil and optionally a
5 cosmetically and/or pharmaceutically acceptable additive.
2. A topical composition according to Claim 1, wherein the amount of eucalyptus oil is about 85 to about 95% by volume.
- 10 3. A topical composition according to Claim 1 or Claim 2, wherein the amount of eucalyptus oil is about 90% by volume.
4. A topical composition according to any one of the preceding claims, wherein the amount of rosemary oil is about 5 to about 15% by volume.
15
5. A topical composition according to any one of the preceding claims, wherein the amount of rosemary oil is about 10% by volume.
6. A topical composition according to any one of the preceding claims,
20 wherein the eucalyptus oil is naturally occurring or synthetically produced.
7. A topical composition according to any one of the preceding claims, wherein the eucalyptus oil may be obtained from *Eucalyptus cyanophylla*, *Eucalyptus polybractea* or *Eucalyptus viridis*
25
8. A topical composition according to any one of the preceding claims, wherein the cosmetically and/or pharmaceutically acceptable additive is present in an amount of not more than about 5%.
- 30 9. A topical composition according to any one of the preceding claims, wherein the cosmetically and/or pharmaceutically acceptable additive is present in an amount of about 1%.

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10. A topical composition according to Claims 8 or Claim 9, wherein the cosmetically and/or pharmaceutically acceptable additive is selected from one or more of alcohols, perfumes, surfactants, thickeners, antioxidants, preservatives and agents suitable for restoring hair and/or preventing hair removal.

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11. A topical composition according to Claim 10, wherein the agents suitable for restoring hair and/or preventing hair removal are biotin or squalene.

10 12. A topical composition according to any one of the preceding claims, wherein the composition is formulated into a lotion, cream, hair tonic, hair cream, shampoo, hair rinse, ointment or soap.

13. A kit comprising:
15 (a) at least about 85% by volume of eucalyptus oil; and
(b) at least about 5% by volume of rosemary oil,
said components (a) and (b) being held separately for separate, sequential or simultaneous use.

20 14. A method for preventing hair removal and/or restoring hair which comprises topical administration of the composition according to any one of Claims 1 to 12 to the hair, scalp and/or skin of a subject in need thereof.

25 15. A method for the treatment and/or prophylaxis of alopecia, baldness and/or related disorders which comprises topical administration of the composition according to any one of Claims 1 to 12 to the hair, scalp and/or skin of a subject in need thereof.

30 16. A method according to Claim 15, which is used in treating cancer patients suffering hair loss following chemotherapy.

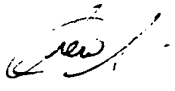
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17. A method for treating dandruff, seborrhoea, scalp psoriasis and/or related dermatological disorders which comprises topical administration of the composition according to any one of Claims 1 to 12 to the hair, scalp and/or skin of a subject in need thereof.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 93/00507

A. CLASSIFICATION OF SUBJECT MATTER Int. Cl. ⁵ A61K 007/06 According to International Patent Classification (IPC) or to both national classification and IPC												
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC: A61K 007/06 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU: IPC as above Electronic data base consulted during the international search (name of data base, and where practicable, search terms used) DERWENT: eucalypt: and rosemary												
C. DOCUMENTS CONSIDERED TO BE RELEVANT												
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.										
X	AU,A,75906/87 (BRADLEY) 3 March 1988 (03.03.88) See whole document	1-17										
A	FR,A,2378512 (LEVY LOZATA) 25 August 1978 (25.08.78) See pages 1 and 2	1-17										
A	Derwent Abstract Accession No. 87-084841/12, Class D21, SU,A,1247011 (AEROZOL TRUST) 30 July 1986 (30.07.86) Abstract	1-17										
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Date of the actual completion of the international search 12 November 1993 (12.11.93)		Date of mailing of the international search report 1 DEC 1993 (1.12.93)										
Name and mailing address of the ISA/AU AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. (06) 2853929		Authorized officer  S. CHEW Telephone No. (06) 2832248										