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P-4120

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES

E. S. D.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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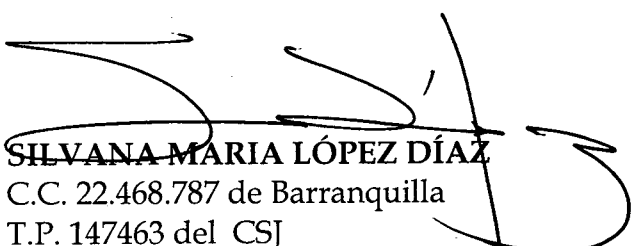
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Ref.: Expediente No. 14-028.636

Solicitud de Diseño Industrial a nombre de
JOHNSON & JOHNSON CONSUMER COMPANIES, INC.

Yo, SILVANA MARIA LÓPEZ DÍAZ, identificada como aparece al pie de mi firma, domiciliada en la Carrera 11 No. 86-53, piso 6, obrando como apoderada de la sociedad **JOHNSON & JOHNSON CONSUMER COMPANIES, INC.**, solicitante del Diseño Industrial de la referencia, dando alcance a la solicitud del 11 de febrero de 2014, me permito aportar copia certificada de la Prioridad No. 13/765,498 del 12 de febrero de 2013.

Señor Superintendente Delegado,


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1/57

ESTADOS UNIDOS DE AMERICA
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7 de febrero de 2014

La presente es para certificar que el anexo es una copia fiel de los registros de la Oficina de Patentes y Marcas de los Estados Unidos, de los documentos de la solicitud de patente identificada más adelante, que cumplieron con los requerimientos para concederse una fecha de presentación de acuerdo con 35 USC 111.

Número de Solicitud: 13/765,498

Fecha de Presentación: 12 de febrero de 2013

EL CÓDIGO DEL PAÍS Y EL NÚMERO DE SU SOLICITUD DE PRIORIDAD, PARA SER USADA EN LA PRESENTACIÓN EXTRANJERA BAJO EL CONVENIO DE PARÍS ES US 13/765,498

Por la autoridad de

Bajo el Secretario de Comercio para la Propiedad Intelectual y el Director de la Oficina de Patentes y Marcas de los Estados Unidos de América

(fdo) M. TARVER

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OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT
APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A
FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: 13/765,498

FILING DATE: February 12, 2013

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY
APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS
CONVENTION, IS US13/765,498

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office



M. TARVER
Certifying Officer

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Electronic Acknowledgement Receipt

EFS ID:	14942520
Application Number:	13765498
International Application Number:	
Confirmation Number:	6443
Title of Invention:	METHODS AND COMPOSITIONS FOR ENHANCING HAIR QUALITY USING BLACKBERRY EXTRACT
First Named Inventor/Applicant Name:	Elizabeth Bruning
Customer Number:	27777
Filer:	Andrea L. Colby/Angela Randall
Filer Authorized By:	Andrea L. Colby
Attorney Docket Number:	JCO5093USNP
Receipt Date:	12-FEB-2013
Filing Date:	
Time Stamp:	18:07:19
Application Type:	Utility under 35 USC 111(a)

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Payment was successfully received in RAM	\$1760
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Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1	Transmittal of New Application	JCO5093UNSP_TrasmittalCover Sheet.pdf	81674 887192d6630210f7f0a389cdd3c8dbbee985 c19a1	no	1
Warnings:					
Information:					
2	Application Data Sheet	JCO5093USNP_ADS_02122013. pdf	1437270 775f81a5bf32b4b3421e9033c85a4d65f1f2 8173	no	8
Warnings:					
Information:					
3	Power of Attorney	POA_JCO5093USNP.pdf	205125 11b63b6671f7605a1c8b16708bbfa206005 56cea	no	3
Warnings:					
Information:					
4		JCO5093USNP_SpecAsFiled.pdf	196590 aa0fb266e73a4c42c0336d497c4be003810 5f558	yes	39
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	36	
	Claims		37	38	
	Abstract		39	39	
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	36929 4e6fa2b25d02a0667c636a0c27252687c42 03d4e	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			1957588		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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UTILITY PATENT APPLICATION TRANSMITTAL (only for new nonprovisional applications under 37 CFR 1.53(b))		Attorney Docket No. JCO5093USNP
		First Inventor Elizabeth Bruning et al.
		Title Methods and Compositions for Enhancing Hair Quality Using Blackberry Extract
		Express Mail Label No. Electronically Filed

APPLICATION ELEMENTS See MPEP Chapter 600 concerning utility patent application contents.	ADDRESS TO: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
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1. ☒ Fee Transmittal Form (e.g., PTO/SB/17) (submit an original and a duplicate for fee processing) 2. ☐ Applicant claims small entity status. 3. ☒ Specification [Total Pages - 39] (Preferred arrangement set forth below) - Descriptive Title of the Invention - Cross Reference to Related Applications - Statement Regarding Fed sponsored R&D - Reference to sequence listing, a table, or a computer program listing appendix - Background of the Invention - Brief Summary of the Invention - Brief Description of the Drawings (if filed) - Detailed Description - Claim(s) - Abstract of the Disclosure 4. ☐ Drawing(s) (35 USC 113) [Total Sheets] 5. Oath or Declaration [Total Pages] a. ☐ Newly executed (original or copy) b. ☐ Copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional with Box 18 completed) i. ☐ DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b). 6. ☒ Application Data Sheet. See 37 CFR 1.76	7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix) 8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary) a. ☐ Computer Readable Form (CRF) b. ☐ Specification Sequence Listing on: i. ☐ CD-ROM or CD-R (2 copies); or ii. ☐ paper c. ☐ Statement verifying identity of above copies ACCOMPANYING APPLICATION PARTS 9. ☐ Assignment Papers (cover sheet & document(s)) 10. ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney (when there is an assignee) 11. ☐ English Translation Document (if applicable) 12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations 13. ☐ Preliminary Amendment 14. ☐ Return Receipt Postcard (MPEP 503) (Should be specifically itemized) 15. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed) 16. ☐ Request and Certifications under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent. 17. ☒ Other – Power of Attorney
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18. ☐ If a CONTINUING APPLICATION, check appropriate box and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76: ☐ Continuation ☐ Divisional ☐ Continuation-in-Part (CIP) of prior application No.: , filed . Prior application information: Examiner Group Art Unit: For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation <u>can only</u> be relied upon when a portion has been inadvertently omitted from the submitted application parts.	
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19. CORRESPONDENCE ADDRESS	
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21. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED	
NAME	Andrea L. Colby
SIGNATURE	/Andrea L. Colby/
DATE	February 12, 2013

**METHODS AND COMPOSITIONS FOR ENHANCING HAIR QUALITY
USING BLACKBERRY EXTRACT**

5 **FIELD OF THE INVENTION**

This invention relates to topical compositions and methods for inducing hair growth and improving hair quality utilizing extracts from the Blackberry plant (*Rubus fruticosus*).

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BACKGROUND OF THE INVENTION

Genetic disposition as well as the natural aging process and/or disease contribute to hair loss and slower hair growth in both males and females.

15 Approximately 50% of the population displays this trait to some degree by the age of 50, and thinning of the hair can begin between 12 and 40 years of age independent of gender. Thus, agents able to stimulate hair growth as well as prevent and slow down or reduce

20 hair loss could be beneficial not only to cure alopecia but to affect positively the psychosocial events associated with hair disorders. Studies reveal psychosocial impact with hair loss to include body image dissatisfaction associated with negative stereotypes,

25 such as feeling older, weaker and less attractive.

Drugs, including Minoxidil (Rogaine), Finasteride (Propecia) and Dutasteride (Avodart) are approved treatments for hair loss. However, they may require medical prescription, and are active only on a certain

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percent of the population. Moreover, some of these drugs are not permitted to be used by females due to hormonal effects. For example, premenopausal women should not take Finasteride due to the risk of male pseudo-hermaphroditism to the fetus. Finasteride has been found to lower artificially the results of the prostate-specific antigen (PSA) test, the standard screening test for prostate cancer which can delay the detection and the treatment of the disease.

Minoxidil is a topically applied drug that is effective in inducing hair growth for a subset of patients and will re-grow hair only on top of the scalp. Further, it has limited effect on older people. Minoxidil may slow the rate of hair loss in five out of ten male patients.

Other medical treatments available to treat hair loss include drastic surgical techniques such as scalp reduction, scalp flaps or follicular unit transplantation. These surgeries carry the risk of complications such as elevation of hairline associated with donor region, possibility of necrosis and unnatural appearance of hair growth direction, anesthesia and post-op care, not to mention high costs.

Herbal preparations that claim to induce hair growth (e.g. Hair Prime) are available at low cost but their effectiveness is very limited.

M. Herrmann et al. have described that a hydroalcoholic blackberry leaf extract (SymMatrix), exhibits the MMP-1, MMP-2, and MMP-9 inhibitory activity. (See, for example, US2008/0095719

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SUMMARY OF THE INVENTION

Surprisingly, we have found that a concentrated, aqueous *Rubus fruticosus* extract can effectively induce hair growth by applying a composition comprising, consisting essentially and consisting of such extract to the scalp, the skin, the eyelashes, eyebrows, mustache region or beard region of a patient a topically active composition comprising a concentration of at least 90 mg extract/ml of solution but less than 300 mg/ml of a *Rubus fruticosus* extract, which may start to increase hair coverage to the area of interest after daily application for at least five (5) to seven (7) days. We observed a potent increase in hair growth *in vivo* in all animals treated with a concentrated *Rubus fruticosus* extract. Even more surprisingly, the compositions of our invention containing *Rubus fruticosus* extract initially induced a visible telogen phase (i.e., shedding of club hairs) prior to rapid entry into the anagen phase (i.e., active growth phase of hair follicles). The compositions of our invention induced anagen in 100% of animals treated over a period of at least eight days.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As used herein, "blackberry extract" means the extract of a plant of the genus *Rubus*. Preferably, the species utilized in the compositions of this invention is *Rubus fruticosus*. Blackberry extract may be a blend of compounds isolated from the plant of the genus *Rubus*. In one embodiment, the compounds are isolated from the flowers of the plant. In another embodiment, the compounds may be isolated from dried flowers of the plant. They may also be isolated from one or more parts of the plant, including the whole plant, flower, seed, root, rhizome, stem, fruit and/or leaf of the plant. Preferably, blackberry extract useful in the compositions of this invention is isolated from the leaf of the blackberry plant.

The extraction process may include physically removing a piece of the blackberry plant and grinding it. Organic solvent extraction processes known to those of skill in the art may also be used to obtain the blackberry extracts useful in the compositions of this invention. Solvents such as lower C_1 - C_8 alcohols, C_1 - C_8 alkyl polyols, C_1 - C_8 alkyl ketones, C_1 - C_8 alkyl ethers, acetic acid C_1 - C_8 alkyl esters, and chloroform, and/or inorganic solvents such as water, inorganic acids such as hydrochloric acid, and inorganic bases such as sodium hydroxide may be used to extract active compounds from the blackberry plant.

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A blackberry leaf extract may also be prepared by an extraction produced with water, using alcohols such as ethanol or combination thereof as the extractant. However, an extract produced with an extractant
5 including both ethanol and water extractant.

Blackberry leaves are preferably dried prior to extraction. It is also preferable to use only the leaves of the blackberry plant for the extraction and not also
10 other plant parts such as the fruit (berries) of the blackberry, its branches, flowers or roots.

In one embodiment, the process of the extraction for the production of a blackberry leaf extract may have the following steps: a) addition to blackberry leaves of
15 an extractant containing an alcohol selected from the group consisting of methanol, ethanol, n-propanol, isopropanol, and b) extraction of the blackberry leaves with the extractant for up to 72 hours.

The ratio of the mass of extractant to leaf solids
20 is preferably established such that at least a 10-fold mass of extractant relative to the leaf solids and preferably no more than a 50-fold mass of extractant relative to the leaf solids is obtained, preferably a 10-to 20-fold mass. A 14-to 18-fold mass of extractant
25 relative to the leaf solids is particularly preferably used for extraction. Good results were achieved with a 16-fold mass of an ethanol-containing solvent (relative once again to the leaf solids).

The extraction time for performing step (b) is at most 72 hours but can also be shorter. With particularly short extraction times, a relatively dilute extract is obtained in step (b). It is therefore preferable to extract the blackberry leaves in step (b) for at least one (1) hour, and more preferably, for at least two (2) hours. The preferred extraction time is chosen on the basis of the quality of the blackberry leaves to be extracted, particularly their age of the leaves and of the other extraction conditions, particularly the extraction temperature.

At elevated extraction temperatures, for example, at an extraction temperature in the range from about 60 to about 100°C, preferably in the range from about 80 to about 100°C, the extraction time is preferably about one hour to about six hours and more preferably about two to about four hours.

In addition, it is most preferable to perform the extraction in step (b) by refluxing the extractant, particularly at extraction temperatures in the range from about 60°C to about 100°C, and more preferably in the range from about 80 to about 100°C. When using the refluxing process, the extraction time is preferably no more than about 24 hours.

The extraction temperature is established on the basis of the extractant that is used. If an ethanol-containing solvent is used, an extraction temperature in the range from about 60°C to about 100°C, in particular an extraction temperature in the range from about 80°C

to about 100°C, is preferred, particularly if a mixture of ethanol and water is used as the extractant.

Preferably, the extractant contains a lower alkyl alcohol solvent, more preferably ethanol, in a proportion of at least about 20 wt.%, relative to the total extractant. Preferably, the extractant should also contain water in a proportion of at least 15 wt.%, relative to the total extractant. It is more preferable for the extractant simultaneously contains both at least 20 wt.%, relative to the total extractant, of an alcohol (preferably ethanol) and water in a proportion of at least 15 wt.%, relative to the total extractant.

Blackberry leaf extracts that are particularly effective in the compositions and methods of this invention are obtained with an extract containing ethanol and water in the ratio of about 2:8 (2 parts by weight of ethanol mixed with 8 parts by weight of water) to about 8:2, more preferably in the ratio of about 3:7 to about 7:3 and most preferably in the ratio of about 3:7 to about 1:1.

Accordingly, in one preferred embodiment, the blackberry extract is a blackberry leaf extract, i.e., the extract is produced from the leaves of the blackberry plant. In a particularly preferred embodiment, the blackberry extract is produced from the leaves of *Rubus fruticosus*. In a further particularly preferred embodiment, the blackberry extract is produced by extracting the leaves of *Rubus fruticosus* with a

mixture of water and a lower alcohol such as ethanol as set forth above.

One particularly suitable blackberry extract is produced by extracting the leaves of *Rubus fruticosus* with a mixture of water and ethanol is commercially available as compounded to an activity of about 5% to about 10%, with a maltodextrin matrix, from Symrise Inc. of Teterboro, NJ, and is sold under the name, "SymMatrix."

Detailed procedures for preparing a suitable blackberry leaf extract are set forth in U.S. Patent Publication No. 2008/0095719, which is herein incorporated in its entirety.

As used herein, "topical application" means directly laying on or spreading on outer skin using, e.g., by use of the hands or an applicator such as a wipe, puff, roller, or spray.

As used herein, "cosmetically-acceptable" means that the product(s) or compound(s) which the term describes are suitable for use in contact with tissues (e.g., the skin) without undue toxicity, incompatibility, instability, irritation, allergic response, and the like. This term is not intended to limit the ingredient/product, which it describes to use solely as a cosmetic (e.g., the ingredient/product may be used as a pharmaceutical).

As used herein, "topical carrier" means one or more compatible solid or liquid filler diluents that are suitable for topical administration to a mammal.

5 Examples of topical carriers include, but are not limited to, water, waxes, oils, emollients, emulsifiers, thickening agents, gelling agents, and mixtures thereof.

10 As used herein, "hair" means scalp, head, facial and/or body hair, including but not limited to the scalp, eye lashes, brows, mustache, beard, ear, nasal, chest, pubic, auxiliary and the like.

15 As used herein, "inducing hair growth" means the earlier induction of growth of a new hair cycle, and/or prolonging the active growth phase (anagen) of the hair cycle and/or increasing the growth rate of the hair and/or increasing the width of hair shaft, including, but not limited to, the induction of the growth of hair and making it more visible to the eye.

20 As used herein, "improving hair quality" means increasing the diameter of the hair shaft and/or enhancing the visual attributes of the hair like hair volume, hair shine and hair thickness, and/or affecting the characteristics of the hair shaft and/or hair cuticles, including, but not limited to, creating a smoother look or feel, and/or increase in shine.

25 As used herein, "safe and effective amount" means an amount of a physiologically active compound or composition sufficient to induce a positive modification

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in the condition to be regulated or treated, (e.g. hair growth) but low enough to avoid serious side effects.

The safe and effective amount of the compound or composition will vary with the particular condition

being treated, the age and physical condition of the end user, the severity of the condition being

treated/prevented, the duration of the treatment, the nature of other treatments, the specific compound or product/composition employed, the particular

cosmetically-acceptable carrier utilized, and like factors.

Topical Compositions

The topical compositions useful in this invention contain formulations suitable for topical application to the hair and scalp. In one embodiment, the composition contains a blackberry extract and a cosmetically-acceptable topical carrier. In one embodiment, the cosmetically-acceptable topical carrier constitutes from about 75% to about 95%, by weight, of the composition more preferably from about 75% to about 85%, by weight, of the composition.

The compositions of this invention may be made into a wide variety of product types that include but are not limited to solid and liquid compositions such as lotions, creams, gels, sticks, sprays, ointments, cleansing liquid washes and solid bars, shampoos, pastes, powders, foams, mousses, and wipes. These

product types may contain several types of cosmetically acceptable topical carriers including, but not limited to solutions, emulsions (e.g., microemulsions and nanoemulsions), gels, solids and liposomes. Non-limiting examples of such carriers are set forth herein. Other carriers may be formulated by those of ordinary skill in the art.

The topical compositions useful in the present invention can be formulated as solutions. Solutions should preferably include an aqueous solvent (e.g., from about 75% to about 95% or from about 75% to about 85% of a cosmetically acceptable aqueous solvent). More preferably, such compositions should contain about 30% solvent, although this may vary dependent upon the formulation. Such solvents may include ethanol, propylene glycol, polyethylene glycol, mixtures thereof and the like which are good carriers for successful delivery to the hair follicles.

Topical compositions useful in the subject invention may be formulated as a solution containing an emollient. Such compositions preferably contain from about 2% to about 50% of an emollient(s). As used herein, "emollients" refer to materials used for the prevention or relief of dryness, as well as for the protection of the skin. A wide variety of suitable emollients are known and may be used herein. The International Cosmetic Ingredient Dictionary and Handbook, Fourteenth Edition, 1012 Volume 3, eds.

Gottschlack and Breslawec, pp. 3868-80, published by Personal Care Products Council (hereinafter, "INCI Handbook"), which is hereby incorporated herein by reference.

5 A lotion may be made from a solution. Lotions typically contain from about 1% to about 20% (more preferably, from about 5% to about 10%) of an emollient(s) and from about 50% to about 90% (more preferably, from about 60% to about 80%) of water.

10 Another type of product may be a solution that is a cream. A cream typically comprises from about 5% to about 50% (more preferably, from about 10% to about 20%) of an emollient(s) and from about 45% to about 85% (more preferably, from about 50% to about 75%) of water.

15 Yet another type of product that may be formulated from a solution is an ointment. An ointment may be constituted of a simple base of animal or vegetable oils or semi-solid hydrocarbons. An ointment may contain from about 2% to about 100% of an emollient(s), and from
20 about 0.1% to about 2% of a thickening agent(s). The INCI Handbook contains a list of acceptable thickening agents or viscosity increasing agents useful in the compositions and methods of this invention at pages 1693 through 1697.

25 The topical compositions useful in the present invention may also be preferably formulated as emulsions. If the carrier is an emulsion, from about 1%

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to about 10% (preferably from about 2% to about 5%) of the carrier should be made up one or more emulsifiers. Emulsifiers may be nonionic, anionic or cationic. Suitable emulsifiers may be found in, for example, the INCI Handbook, pp. 3816-191 and 3954-67.

Lotions and creams may also be formulated as emulsions. Typically such lotions preferably contain from 0.5% to about 5% of an emulsifier(s). Such creams would typically comprise from about 1% to about 20% (preferably from about 5% to about 10%) of an emollient(s); from about 20% to about 80% (preferably, from 30% to about 70%) of water; and from about 1% to about 10% (preferably, from about 2% to about 5%) of an emulsifier(s).

Single emulsion skin care preparations, such as lotions and creams, of the oil-in-water type and water-in-oil type are well-known in the cosmetic art and are useful in the subject invention. Multiphase emulsion compositions, such as the water-in-oil-in-water type are also useful in the subject invention. In general, such single or multiphase emulsions contain water, emollients, and emulsifiers as essential ingredients.

Compositions of this invention may also be in the form of shampoo, hair conditioning products, leave-on hair masks, mousse, sprays, in combination with dyes and other hair care products for cleaning, treating, conditioning and coloring the hair simultaneous with

topical application of the novel compositions of this invention.

5 The topical compositions of this invention may be formulated as a gel (e.g., an aqueous gel using a suitable gelling agent(s)). Suitable gelling agents for aqueous gels include, but are not limited to, natural gums, acrylic acid and acrylate polymers and copolymers, and cellulose derivatives (e.g., hydroxymethyl cellulose and hydroxypropyl cellulose). Suitable gelling agents
10 for oils (such as mineral oil) include, but are not limited to, hydrogenated butylene/ethylene/styrene copolymer and hydrogenated ethylene/propylene/styrene copolymer. Such gels typically comprises between about 0.1% and 5%, by weight, of such gelling agents.
15 Microgels may be used to enhance follicular delivery of the formulations.

 The topical compositions of this invention may also be formulated into a solid formulation (e.g., a wax-based stick, mascara, soap bar composition, powder, or a
20 wipe containing powder.

 The topical compositions useful in this invention may contain, in addition to the aforementioned components, a wide variety of additional oil-soluble, organic solvent-soluble, and/or water-soluble materials
25 conventionally used in compositions for use on skin and hair, at their art-established levels. For example, a formulation of 70% ethanol and 30% propylene glycol or

variable amounts of these two agents may be used for enhanced delivery of the actives.

Surfactants

5 In one embodiment, the composition of this invention contains one or more surfactants. In one embodiment, the composition contains a lathering surfactant. What is meant by a "lathering surfactant" is a surfactant that generates lather when combined with water and mechanically agitated. In one embodiment, the lathering surfactant has an initial foam height reading of at least 20 mm, such as at least 50 mm, in the Standard Test Method for Foaming Properties of Surface-Active Agents D1173-53 Set forth in the ASTM Annual Book of ASTM Standards 1001 Section 15 Volume 15.04 (using a concentration of 5 grams per liter, temperature of 49° C., and water hardness of 8 grains per gallon). Examples of lathering surfactants include, but are not limited to, anionic, nonionic, cationic, and amphoteric lathering surfactants.

20 Non-limiting examples of anionic lathering surfactants include those selected from the group consisting of sarcosinates, sulfates, isethionates, taurates, phosphates, lactylates, and glutamates. Specific examples include, but are not limited to, those selected from the group consisting of sodium lauryl sulfate, ammonium lauryl sulfate, ammonium laureth sulfate, sodium laureth sulfate, sodium trideceth

sulfate, ammonium cetyl sulfate, sodium cetyl sulfate, ammonium cocoyl isethionate, sodium lauroyl isethionate, sodium lauroyl lactylate, triethanolamine lauroyl lactylate, sodium caproyl lactylate, sodium lauroyl

5 sarcosinate, sodium myristoyl sarcosinate, sodium cocoyl sarcosinate, sodium lauroyl methyl taurate, sodium cocoyl methyl taurate, sodium lauroyl glutamate, sodium myristoyl glutamate, and sodium cocoyl glutamate and mixtures thereof.

10 Non-limiting examples of nonionic lathering surfactants include those selected from the group consisting of alkyl glucosides, alkyl polyglucosides, polyhydroxy fatty acid amides, alkoxylated fatty acid esters, lathering sucrose esters, amine oxides, and

15 mixtures thereof. Specific examples include, but are not limited to, nonionic surfactants to those selected from the group consisting of C8-C14 glucose amides, C8-C14 alkyl polyglucosides, sucrose cocoate, sucrose laurate, lauramine oxide, cocoamine oxide, and mixtures thereof.

20 Non-limiting examples of amphoteric lathering surfactants (which also includes zwitterionic lathering surfactants are those selected from the group consisting of betaines, sultaines, hydroxysultaines, alkyliminoacetates, iminodialkanoates, aminoalkanoates,

25 and mixtures thereof.

Non-limiting examples of amphoteric surfactants of the present invention include disodium

lauroamphodiacetate, sodium lauroamphoacetate, cetyl dimethyl betaine, cocoamidopropyl betaine, cocoamidopropyl hydroxy sultaine, and mixtures thereof.

Additional Cosmetically Active Agents

5 In one embodiment, the compositions according to this invention may further contain one or more additional cosmetically active agent(s) as well as the above-mentioned components. What is meant by a "cosmetically active agent" is a compound, which may be
10 a synthetic compound or a compound isolated, purified or concentrated from a natural source, or a natural extract containing a mixture of compounds, that has a cosmetic or therapeutic effect on the tissue, including, but not limited to: anti-microbial agents such as anti-yeast
15 agents, anti-fungal, and anti-bacterial agents, anti-inflammatory agents, anti-aging agents, anti-parasite agents, external analgesics, sunscreens, photoprotectors, antioxidants, keratolytic agents, detergents/surfactants, moisturizers, nutrients,
20 vitamins, minerals, energy enhancers, anti-perspiration agents, astringents, hair growth enhancing agents, hair coloring agents, pigments, firming agents, agents for skin conditioning, and odor-control agents such as odor masking or pH-changing agents.

25 In one embodiment, the cosmetically active agent may be selected from, but not limited to, the group consisting of hydroxy acids, benzoyl peroxide, D-

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panthenol, octyl methoxycinnamate, titanium dioxide, octyl salicylate, homosalate, avobenzene, carotenoids, free radical scavengers, spin traps, retinoids such as retinoic acid (tretinoin) and retinoid precursors such as retinol and retinyl palmitate, vitamins such as vitamin E (alpha, beta or delta tocopherols and/or their mixtures) ceramides, polyunsaturated fatty acids, essential fatty acids, enzymes, enzyme inhibitors, minerals, hormones such as progesterones, steroids such as hydrocortisone, 2-dimethylaminoethanol, metal (including but not limited to iron or zinc) salts such as copper chloride, peptides containing copper such as Cu:Gly-His-Lys, coenzyme Q10, amino acids, vitamins, acetyl-coenzyme A, niacin, riboflavin, thiamin, ribose, electron transporters such as NADH and FADH2, botanical extracts such as aloe vera, feverfew, and soy, and derivatives and mixtures thereof. The cosmetically active agent will preferably be present in the composition of the invention in an amount of from about 0.001% to about 20% by weight of the composition, more preferably, from about 0.005% to about 10% and most preferably, from about 0.01% to about 5%.

Also expected to be particularly effective in the compositions and methods of this invention are the presence of synthetic or natural 5-alpha reductase inhibitors, or other anti-sebum ingredients including, but not limited to, Sepicontrol (Capryloyl Glycine, Sarcosine and Cinamomum Zeylanicum Bark Extract), licorice powder or extract, and the like. MC5 receptor

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antagonists may also be utilized in the compositions of this invention. Examples of MC5-R antagonists may be found in U.S. Pat. No.7,049,331.

5 The compositions of this invention may also be utilized in combination with compounds known to promote hair growth that are available as drugs, such as finasteride (Propecia), a type 2 5-alpha-reductase inhibitor, and dutasteride, a type 1- and 2-5-alpha-reductase inhibitor, as well as flutamide, bicalutamide, 10 pregnane derivatives, progesterone derivatives, experimental agents such as FCE 28260 and the like. Spironolactone and other diuretics may also be utilized as it is indicated for women in some cases (also known as Aldactone: an aldosterone receptor antagonist). 15 Potassium channel openers, such as Minoxidil (Rogaine), which are known to promote hair growth, are also believed to be especially promising combinations.

Herbal remedies that may have 5-alpha reductase inhibitory action may include: Saw Palmetto and Pygeum 20 africanum. Other agents that may have such activity are Beta-sisterol, Sepicontrol and Licorice, gamma-linolenic acid and other unsaturated fatty acids (Tehming LIANG and Shutsung LIAO) Biochem. J. (1992) 285, 557-562, Inhibition of steroid 5-alpha-reductase by specific 25 aliphatic unsaturated fatty acids), Zinc and Zinc salts, green tea catechin (-)-epigallocatechin gallate (EGCG) and other polyphenols, and the like. Grape seed, apple seed, apple juice and barley extracts may also be

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potential agents that may induce hair growth, although they are not thought to be very common(s) or satisfactory in achieving satisfactory results (Takahashi et al., Procyanidin Oligomers Selectively and Intensively Promote Proliferation of Mouse Hair Epithelial Cells In Vitro and Activate Hair Follicle Growth In Vivo, J Invest Dermatol 112:310-316).

Additional combinations may include other known stimulators of hair growth, such as, zinc, calcineurin inhibitors such as FK506 (Tacrolimus, Fujimycin), a macrolide antibiotic produced by *Streptomyces tsukubaensis*, and its derivatives, or Cyclosporin A, a cyclic endecapeptide and a T cell-specific immunosuppressant, and the like.

Active ingredients in Provillus, a product suggested to block DHT (Vitamin B6, Biotin, Magnesium, Zinc, Saw Palmetto, Nettle, Gotu Kola, Pumpkin, Eleuthero Root, Uva-Ursi, Muria Puama) may also be included in the compositions of this invention.

Examples of vitamins that may be constituents of the compositions of this invention include, but are not limited to, vitamin A, vitamin Bs such as vitamin B3, vitamin B5, and vitamin B12, vitamin C, vitamin K, vitamin E such as alpha, gamma or delta-tocopherol, and derivatives (such as salts and esters) and mixtures thereof.

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Examples of hydroxy acids include, but are not limited, to glycolic acid, lactic acid, malic acid, salicylic acid, citric acid, and tartaric acid. Such hydroxy acids, it is believed, serve to support the regeneration of the corneous layer of the scalp. We also believe that such hydroxy acids assist in normalizing the pH of the compositions of this invention and may, as with lactic acid, add a conditioning effect to the hair.

Examples of antioxidants which may be utilized in the compositions and methods of this invention include, but are not limited to, water-soluble antioxidants such as sulfhydryl compounds and their derivatives (e.g., sodium metabisulfite and N-acetyl-cysteine), lipoic acid and dihydrolipoic acid, resveratrol, lactoferrin, and ascorbic acid and ascorbic acid derivatives (e.g., ascorbyl palmitate and ascorbyl polypeptide). Oil-soluble antioxidants suitable for use in the compositions of this invention include, but are not limited to, butylated hydroxytoluene, retinoids (e.g., retinol and retinyl palmitate), different types of tocopherols (e.g., alpha-, gamma-, and delta-tocopherols and their esters such as acetate) and their mixtures, tocotrienols, and ubiquinone. Natural extracts containing antioxidants suitable for use in the compositions of this invention, include, but not limited to, extracts containing flavonoids, isoflavonoids, and their derivatives such as genistein and daidzein (e.g., such as soy and clover extracts, extracts containing resveratrol and the like. Examples of such natural

extracts include grape seed, green tea, pine bark, and propolis.

Progesterones, and naturally-derived ingredients with progesterone-like activity, on the other hand, may be useful, as well as astringents such as witch hazel, triclosan, cerulenin, alpha-methylene-gamma-butylalactone, glycine derivatives such as capryloylglycine and methylglycine, salicylic acid, or benzoyl peroxide.

Fabao 101, which has the following active ingredients, may also be included in the compositions of this invention: *Aralia Quinquetolia*, *Astragalus Glycyphyllos*, *Angelica Arhangolica* Root, *Salvia Officinalis*, *Capsicum*, *Carya Alba*, *Corthamis Tinctorius*, Cortex dictamni radicis, Flos Chrysanthemum, Heshouwu, Iron-Fist Ginseng, Miltiorrhizae, Notoginseng, Paorulca Glandulosa, Peach Kernel Oil, Rhizome of Szechuan Lovage, Radix astragali, Radix Ginseng, Radix Polygoni Multiflori, Red-rooted Salvia, Rhizoma gastroidia ginseng, Seu radix notopterygii, *Sophera flavescens*.

Other Materials

Various other materials may also be present in the compositions useful in the subject invention. These include humectants, proteins and polypeptides, preservatives and an alkaline agent. Examples of such agents are disclosed in the INCI Handbook, pp. 1650-1667. The compositions of the present invention may also

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comprise chelating agents (e.g., EDTA) and preservatives (e.g., parabens). Examples of suitable preservatives and chelating agents are listed in pp. 1626 and 1654-55 of the INCI Handbook. In addition, the topical compositions
5 useful herein can contain conventional cosmetic adjuvants, such as dyes, opacifiers (e.g., titanium dioxide), pigments, and fragrances.

Darkening Agents

In one embodiment, the compositions of the present
10 invention further contain darkening agents such as melanin or synthetic melanin derivatives, or melanin-like molecules, vanillin polymers, natural extracts such as, but not limited to *Coleus Forskoli* extract, *Bugrane-P* extract, extracts from natural sources containing
15 pigments (e.g., brown pigments from plants from the *Hedychium* genus or *Bearberry* genus or yellow, orange and red pigments, from plants containing carotenoids or canthaxanthins); or synthetic chemicals such as compounds containing copper (e.g., copper salts such as
20 CuCl_2) or synthetic carotenoids or canthaxantins.

Examples of synthetic melanin derivatives are set forth in U.S. Pat. Nos. 5,618,519, 5,384,116, and 5,227,459. Examples of soluble melanin derivatives are set forth in 5,744,125, 5,225,435, 5,218,079, and 5,216,116. Examples
25 of commercially available soluble melanin derivatives include Melasyn-100™ from San-mar laboratories, Inc. (Elmsford, N.Y.) and MelanZe™ from Zylepsis (Ashford, Kent, United Kingdom).

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These agents will preferably be present in the composition in an amount from about 0.001% to about 10% by weight, in particular in an amount from about 0.01% to about 5% by weight.

5 In another embodiment, the composition may include a peptide. Examples of darkening peptides are set forth in U.S. Pat. No. 7,025,951. The peptide of the invention set forth therein may be provided in the form of
10 cosmetically acceptable salts. Examples of preferred salts are those with therapeutically acceptable organic acids, e.g., acetic, palmitic, oleic, stearic, lactic, maleic, citric, malic, ascorbic, succinic, benzoic, salicylic, methanesulfonic, or Palmoic acid, as well as
15 polymeric acids such as tannic acid or carboxymethyl cellulose, and salts with inorganic acids such as the hydrohalic acids (e.g., hydrochloric acid), sulfuric acid or phosphoric acid.

20 The amount of peptide present in the composition depends on the peptide used. The peptide should be present in the composition in an amount from about 0.001% to about 10% by weight, in particular in an amount from about 0.005% to about 5% by weight.

Mineral Water

25 The compositions of the present invention may be prepared using a mineral water, for example mineral water that has been naturally mineralized such as Evian® Mineral Water (Evian, France). In one embodiment, the

5 mineral water has a mineralization of at least about 200 mg/L (e.g., from about 300 mg/L to about 1000 mg/L). In one embodiment, the mineral water comprises at least about 10 mg/L of calcium and/or at least about 5 mg/L of magnesium.

Methods of Use

10 The compositions of this invention may be utilized to induce hair growth by topical application of said compositions to the area of the body on which hair growth is desired. Preferably, the compositions of this invention are applied topically to the desired area of the body at least once per day for at least five (5) days and more preferably on a daily basis for at least six weeks and most preferably, indefinitely. For
15 improvement to hair quality, said compositions should be applied at least once per day for at least twelve weeks. After about two weeks, the user may begin to observe increased hair growth and may be able to observe increased hair shaft diameter and/or enhanced visual
20 attributes of the hair, such as hair volume, hair shine and hair thickness.

Examples

Example 1

25 A gel base formula **A1** was prepared according to Table 1 below:

The following ingredients were combined in a mixing vessel: DI water, Disodium EDTA, Glycerin, Dimethicone and Butylated Hydroxytoluene (BHT) and heated to 40-45°C while using prop mixing at medium to high speed (sweep blade) and mixed until uniform. Once a temperature below 40°C was achieved the following ingredients were added one at a time with prop mixing (sweep blade, medium speed): Sepigel 305, Phenonip XB. The pH was adjusted to 5.0 with Sodium Hydroxide.

Table 1

<u>INCI Name</u>	<u>gms</u>
Water	364.5
Disodium EDTA	10.00
Glycerin	30.00
Dimethicone	20.00
Butylated Hydroxytoluene	0.50
Polyacrylamide & Laureth 7 & C13 - 14	65.00
Isoparaffin	
Phenoxyethanol & Methylparaben & Propylparaben & Ethylparaben	10.00
NaOH, 20% w/w in water	Qs

Example 2

A composition containing blackberry extract (A2) and a composition containing only butylene glycol and water (A3) were prepared in accordance with the procedure set forth in Example 1 with the following formulas set forth in Table 2.

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Table 2

INCI Name	A2 %w/w	A3 %w/w
Rubus fruticosus	50.00	0.00
Butylene Glycol	25.00	25.00
Water	25.00	75.00
Total	100	100.00

5

Example 3

Compositions E1 and C were prepared according to the following formula in Table 3. Inventive example E1 was prepared by combining the gel base A1 of Example 1 and the Blackberry extract composition A2 of Example 2 to yield a concentration of 25% blackberry extract (a 1:1 ratio of A1 and A2) by mixing until uniformity was achieved. Additionally, comparative example C1 was prepared by combining gel base A1 and A3 of Example 2.

10

15

Table 3

	E1 %w/w	C1 %w/w
A1	50.00	50.00
A2	50.00	0
A3	0.00	50.00
Total	100 .00	100.00

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Example 4

Hair growth induction in C3H mice with Blackberry (*Rubus fruticosus*) extract

Hair growth induction in C3H mice was measured as a percentage of mice entering the anagen phase as a function of time (days of study).

C3H female mice age 6-7 weeks was purchased from Taconic Farms (Germantown, NY). Mice were housed in appropriately sized cages in an environmentally controlled room with a 12-hour light-12-hour dark photoperiod and supplied with food and water *ad libitum*. Animal care was based on the "Guide for the Care and Use of Laboratory Animals", NIH Publication No. 85-23. Animals were acclimated for a week before study starts. Once all mice have entered their prolonged telogen/resting phase (about 50-60 days long) of the hair cycle, they were clipped over the dorsal area about 1.5 x 5cm (Wahl Clippers 8900 Series, Blade # 1086). Four female mice per group were clipped while sedated with 2% induction and maintenance isoflurane and 0.5L Oxygen. In addition to E1 (250mg/ml *Rubus fruticosus* formulation), the treatment groups included a placebo (C1) and an untreated group (n=4) to serve as control for natural hair growth initiation and to observe placebo effects and 200µl of test materials were applied topically to the area daily, five days a week (Monday through Friday). Images were taken at the first signs of anagen/active growth phase and when needed based on

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visual observation. A study log documenting day-to-day observations of mice entering anagen (grey skin) was recorded. Treatments continued for up to about 8 weeks.

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Table 4

HAIR GROWTH INDUCTION IN C3H MICE REPRESENTING %
OF MICE ENTERING ANAGEN AS A FUNCTION OF TIME (DAYS OF
STUDY)

Groups/Day % mice entering anagen	7	8	9	10	14	20	22	23	24	29	31	35	42	43	44	45	46	50
Untreated (n=4 animals)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
25% Symmatrix (n=4 animals) (E1)	50	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
Symmatrix Placebo (n=4 animals) (C1)	0	0	0	0	0	0	0	0	0	0	0	0	0	25	50	50	75	100
Most effective of 5% Minoxidil (N=4 studies)	0	0	20	40	80	80	80	80	75	100	100	100	100	100	100	NA	NA	NA
Average 5% Minoxidil (N=4 studies)	0	0	7	18	31	32	41	38	36	36	45	48	63	87	93	NA	NA	NA

10

Number of animals per group for Minoxidil reference: Day 7-22 (N=7), Day 23-26 (N=6), Day 27-44 (N=5)
NA=Not Assessed

15

Surprisingly the *Rubus fruticosus* topical treatment (E1) induced hair growth in all the C3H mice by day 8. When evaluations are compared against a commercially available hair growth product (5% Generic Minoxidil Solution for Men purchased from Eckerd Pharmacy) using the same test model, the induction with E1 topical application occurred faster and at a higher incidence/responder rate. On average about 63% of mice treated with 5% marketed Minoxidil entered anagen by week 6 (N=4 studies) with 100% by week 4 (Day 29) where Minoxidil performed the best as a positive control.

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Hence, we conclude that the hair growth induction occurred faster and at a higher incidence when treated with E1 resulting in a 100% responder rate at eight (8) days compared with 5% marketed Minoxidil where on average about 63% of mice (n=4 studies) entered anagen by week 6 and with 100% by week 4 (Day 29) where Minoxidil performed the best as a positive control.

Example 5

Medium consisting of Williams E medium (minus glutamine), L-glutamine, Fungizone, penicillin and streptomycin (supplied by Gibco) was prepared. A stock solution of Blackberry extract and medium was prepared. 1:10 serial dilutions of the stock solution were prepared until the appropriate concentration was achieved.

Human terminal hair follicles are isolated from fresh facial cosmetic surgery samples. Individual follicles are placed into 12 well Falcon insert cell culture plates in a 0.4um insert filled with 0.5ml of medium. Treatments are added to the medium using a w/v calculation. Medium is changed every other day. Images are taken on Day 0, 1, 3, 5, 7 & 9. Image analysis is done by measuring the length of the hair shaft. Means of each group and percent increases are calculated.

Table 5

Treatment	N	% change over untreated
Untreated	9	0
Blackberry Ext. 0.01%	10	-4.278326281
Blackberry Ext. 0.001%	7	63.6577339

Blackberry extract (*Rubus fruticosus*) at 0.001% (w/v) was able to increase hair shaft elongation by 63.65% compared to follicles grown medium without the blackberry extract.

Example 6

Human hair follicles were isolated from fresh facial cosmetic surgery samples. Individual follicles were placed into 6 well Falcon insert cell culture plates onto 0.4 μ m inserts filled with 2.0 mL of medium. The medium and a stock solution as in Example 5 were prepared. Treatments were added to the medium using a w/v calculation. Medium was changed every other day. Images were taken on Day 0, 1, 3, 5, 7, and 9. Image analysis was done by measuring the length of the hair shaft. Means of each group and percent increases were calculated.

Table 6

Treatment	N	% Change over untreated
Untreated	12	0
Blackberry Ext. 0.001%	5	51.936
Blackberry Ext. 0.001%	4	44.412
Blackberry Ext. 0.0001%	4	15.466
Blackberry Ext. 0.05%	5	-27.4437

Blackberry extract (*Rubus fruticosus*) at
concentration ranges between 0.0001% to 0.001% (w/v) was
able to increase hair shaft elongation by more than 15%
compared to follicles grown medium without the
blackberry extract. It should be noted that,
unexpectedly, blackberry extract at the higher
concentration range of 0.05% did not increase hair shaft
elongation.

Example 7

The following embodiments were made using the
formulations set forth in Table 7:

INCI Name	C2	C3	C4	C5	C6	C7	C8	C9	E2	E3	E4	E5
Water DI	88.97	88.97	64.97	64.67	63.47	75.97	74.97	73.97	79.47	79.17	60.3	69.8
Carbomer-Acrylic Acid, Cyclohexane			0.5	0.8					1	1.5	2	2.5
Sodium Polyacrylate (and) Hydrogenated Polydecene					2							
Methylcellulose and Hydroxypropyl Methylcellulose						5						
Lithium Magnesium Sodium Silicate						2	3	4				
Dehydroxanthan Gum	0.5					0.5	0.5	0.5				
Butylene Glycol						2	2	2				
Sodium Hydroxide 20% Soln.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Glycerin	1											
Glyceryl Polymethacrylate			24	24	24	10	10	10	10	10	20	10
Maltodextrin (40%) Rubus Fruticosus (Blackberry) Leaf Extract (60%)	8.33	8.33	8.33	8.33	8.33	8.33	8.33	8.33	8.33	8.33	16.7	16.7
Phenoxyethanol	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7			
Sodium Benzoate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5			
Phenoxyethanol (and) Caprylyl Glycol (and) Sorbic Acid										1	1	1
Polyacrylamide (and)			1	1	1							

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C13-14 Isoparaffin (and) Laureth- 7												
	100	100	100	100	100	100	100	100	100	100	100	100
Result	Too thin	too thin	did not thicken	insufficiently thick o form gel	pancake mix with clumps	thin	paste	thick grit	GEL	Stable Gel	Thin Gel	Gel

5

Each of the embodiment compositions set forth in Table 7 was independently prepared as follows:

E2- E5:

10

Water was measured into a main vessel and stirring with vortex initiated. Carbomer- Acrylic Acid, Cyclohexane was slowly added by screen sifting. The mixture was heated until the temperature reached 55-60°C. A 20% Sodium Hydroxide solution was made. The pH was adjusted with a 20% Solution Sodium Hydroxide to pH 5.5-6 to neutralize the Carbomer. The heat was turned off and the mixture was cooled down to 45°C. The Maltodextrin (40%) Rubus Fruticosus (Blackberry) Leaf Extract (60%) was pre-mixed in Glyceryl Polymethacrylate. The Maltodextrin (40%) Rubus Fruticosus (Blackberry) Leaf Extract (60%), Glyceryl Polymethacrylate paste was added to the vessel with stirring. The viscosity continued to decrease as it was added. The pH was adjusted with a 20% solution of Sodium Hydroxide to pH 5.5-6.0. The Phenoxyethanol (and) Caprylyl Glycol (and) Sorbic Acid were added to

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the beaker (Formulation C12 had Phenoxyethanol and Sodium Benzoate) with stirring. The pH was adjusted with a 20% Solution of Sodium Hydroxide to pH 5.5-6. QS with Water was performed. A gel was formed.

5 E-2 - A stable gel was formed and the formula passed 13 weeks stability. Stability was tested using a T spindle at 20 RPM for two weeks and four weeks. The samples were kept at room temperature, 4°C, 40°C and 50°C. The sample kept at 50°C was taken out of the test
10 at six weeks and the other samples (room temperature, 4°C and 40°C) were read at eight weeks and 13 weeks. A freeze/thaw test was performed on three cycles. As more (40%) Rubus Fruticosus (Blackberry) Leaf Extract (60%) is added, more Carbomer must be added.

15 C2 - For C2, the same procedure was followed with the exception that Dehydroxanthan Gum was pre-wet with glycerin and slowly added to the vessel with stirring. The Maltodextrin (40%) Rubus Fruticosus (Blackberry) Leaf Extract (60%) was not pre-wet with Glyceryl
20 Polymethacrylate. The preservative added was Phenoxyethanol and Sodium Benzoate.

C3 - For C3 the same procedure was followed with the exception of after the water was added to the vessel, it was heated until the temperature reached 55-60°C.
25 Methylcellulose and Hydroxy Propyl Methylcellulose were slowly added with stirring for 30 minutes. The Maltodextrin (40%) Rubus Fruticosus (Blackberry) Leaf Extract (60%) was not pre-wet with Glyceryl Polymethacrylate. It was sprinkled in directly to the vessel.

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C4 and C5- For C4 and C5, the same procedure was followed with the exception that Polyacrylamide (and) C13-14 Isoparaffin (and) Laureth-7 was post added to the composition.

5 C6 - For C6, the same procedure was followed with the exception that Sodium Polyacrylate (and) Hydrogenated Polydecene was sprinkled in the water. Polyacrylamide (and) C13-14 Isoparaffin (and) Laureth-7 was post added to the formula.

10 C7, C8 and C9 - For C7, C8 and C9, the same procedure was followed with the addition of Dehydroxanthan Gum pre-wet in Butylene Glycol. Continued mixing and slowly added Lithium Magnesium Sodium Silicate. It was noted that as more Laponite was added to the composition, the consistency became more of
15 a paste as opposed to becoming a gel).

WHAT IS CLAIMED IS:

1. A method of enhancing hair growth by applying to
the scalp, the skin, the eyelashes, eyebrows,
5 mustache region or beard region of a patient a
topically active composition comprising a
concentration of at least 90 mg extract/ml of
solution but less than 300 mg/ml of a *Rubus*
fruticosus extract, which increase hair coverage to
10 the scalp after daily application for at least seven
days.
2. A method according to claim 1 wherein said
composition comprises a concentration of at least
120 mg/ml but less than 300 mg/ml of a *Rubus*
15 *fruticosus* extract.
3. A method according to claim 1 wherein said
composition comprises a concentration of at least
250 mg/ml but less than 300 mg/ml of a *Rubus*
fruticosus extract.
- 20 4. A topical composition for enhancing hair growth
comprising at least 90 mg/ml less than 300 mg/ml of
a *Rubus fruticosus* extract.
5. A topical composition for enhancing hair growth
comprising at least 120 mg/ml less than 300 mg/ml
25 of a *Rubus fruticosus* extract.
6. A topical composition for enhancing hair growth
comprising at least 250 mg/ml less than 300 mg/ml
of a *Rubus fruticosus* extract.
7. A topical composition according to claim 4 wherein
30 said composition further comprises skin care agents

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consisting of vitamins, minerals, proteins, peptides, fatty acids, antioxidants, anti-inflammatory agents, darkening agents, botanical extracts and mixtures thereof.

- 5 8. A composition for enhancing hair growth on the scalp, the skin, the eyelashes, eyebrows, mustache region or beard region of a patient comprising a concentration of at least 90 mg extract/ml of solution but less than 300 mg/ml of a *Rubus*
- 10 *fruticosus* extract and at least 1 weight percent of carbomer by weight of the composition.

45

ABSTRACT

5 Compositions and methods for inducing hair growth
and improving hair quality utilizing extracts of
blackberry in an amount effective to induce hair growth
when applied topically to an area of the skin on which
hair growth is desired.

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Application Number	
Filing Date	February 12, 2013
First Named Inventor	Bruning et al.
Title	Methods and Compositions for Enhancing Hair Quality Using Blackberry Extract
Art Unit	
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Attorney Docket Number	JCO5093USNP

SIGNATURE of Applicant or Patent Practitioner

Signature	/Andrea L. Colby/	Date	February 12, 2013
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NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications.

☒ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in the attached transmittal letter.

- ☒ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A or equivalent):

27777

OR

- ☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A or equivalent):

Name	Registration Number	Name	Registration Number

Please recognize or change the correspondence address for the application identified in the attached transmittal letter to:

- ☒ The address associated with the above-mentioned Customer Number.

OR

- ☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name

Address

City

State

Zip

Country

Telephone

Email

I am the Applicant:

- ☐ Inventor or Joint Inventor
- ☐ Legal Representative of a Deceased or Legally Incapacitated Inventor
- ☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign
- ☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document)

SIGNATURE of Applicant for Patent

Signature	/Andrea L. Colby/	Date	February 12, 2013
Name	Andrea L. Colby	Telephone	732-524-2792
Title and Company	Assistant Secretary		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms for more than one signature, see below *.

- ☒ *Total of 2 forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

48

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	JCO5093USNP
		Application Number	
Title of Invention	Methods and Compositions for Enhancing Hair Quality Using Blackberry Extract		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
--

Inventor Information:

Inventor 1					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Elizabeth		Bruning			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	Somerset	State/Province	NJ	Country of Residence	US	
Mailing Address of Inventor:						
Address 1		314 Classon Court				
Address 2						
City	Somerset	State/Province	NJ			
Postal Code	08873	Country	US			
Inventor 2					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Euen Thomas Graham Ekman		Gunn			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	Hopewell	State/Province	NJ	Country of Residence	US	
Mailing Address of Inventor:						
Address 1		34 2nd Street				
Address 2						
City	Hopewell	State/Province	NJ			
Postal Code	08525	Country	US			
Inventor 3					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Frank		Liebel			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		JCO5093USNP	
		Application Number			
Title of Invention		Methods and Compositions for Enhancing Hair Quality Using Blackberry Extract			
City	Point Pleasant	State/Province	NJ	Country of Residence i	US
Mailing Address of Inventor:					
Address 1		515 Hardenberg Avenue			
Address 2					
City	Point Pleasant	State/Province	NJ		
Postal Code	08742	Country i	US		
Inventor 4					Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Samantha		Tucker-Samaras		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Long Valley	State/Province	NJ	Country of Residence i	US
Mailing Address of Inventor:					
Address 1		71 West Valley Brook Road			
Address 2					
City	Long Valley	State/Province	NJ		
Postal Code	07853	Country i	US		
Inventor 5					Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Dina		VanWyck		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Toms River	State/Province	NJ	Country of Residence i	US
Mailing Address of Inventor:					
Address 1		815 Vaughn Avenue			
Address 2					
City	Toms River	State/Province	NJ		
Postal Code	08753	Country i	US		
Inventor 6					Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Delores		Santora		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Ringoes	State/Province	NJ	Country of Residence i	US

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	JCO5093USNP	
		Application Number		
Title of Invention	Methods and Compositions for Enhancing Hair Quality Using Blackberry Extract			
Mailing Address of Inventor:				
Address 1	2 Brockton Court			
Address 2				
City	Ringoes	State/Province	NJ	
Postal Code	08551	Country	US	
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.				

Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).			
☐ An Address is being provided for the correspondence information of this application.			
Customer Number	27777		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	Methods and Compositions for Enhancing Hair Quality Using Blackberry Extract		
Attorney Docket Number	JCO5093USNP	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		Sub Class (if any)	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)		Suggested Figure for Publication (if any)	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐ Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.
--

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	JCO5093USNP
		Application Number	
Title of Invention	Methods and Compositions for Enhancing Hair Quality Using Blackberry Extract		
Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	27777		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

Prior Application Status		Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. [Add](#)

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

			Remove
Application Number	Country i	Filing Date (YYYY-MM-DD)	Priority Claimed
			☒ Yes ☐ No

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. [Add](#)

Authorization to Permit Access:

☒ Authorization to Permit Access to the Instant Application by the Participating Offices
--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	JCO5093USNP
		Application Number	
Title of Invention	Methods and Compositions for Enhancing Hair Quality Using Blackberry Extract		

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1		Remove
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.		
Clear		
☒ Assignee	☐ Legal Representative under 35 U.S.C. 117	☐ Joint Inventor
☐ Person to whom the inventor is obligated to assign.	☐ Person who shows sufficient proprietary interest	
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:		

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. ☒

Organization Name Johnson and Johnson Consumer Companies, Inc.

Mailing Address Information:

Address 1	199 Grandview Road		
Address 2			
City	Skillman	State/Province	NJ
Country ⁱ	US	Postal Code	08558
Phone Number	732-524-2792	Fax Number	732-524-2808

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	JCO5093USNP
		Application Number	
Title of Invention	Methods and Compositions for Enhancing Hair Quality Using Blackberry Extract		
Email Address	jnjustpatent@corus.com		
Additional Applicant Data may be generated within this form by selecting the Add button.			Add

Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1				
Complete this section only if non-applicant assignee information is desired to be included on the patent application publication in accordance with 37 CFR 1.215(b). Do not include in this section an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest), as the patent application publication will include the name of the applicant(s).				
				Remove
If the Assignee is an Organization check here. ☐				
Prefix	Given Name	Middle Name	Family Name	Suffix
Mailing Address Information:				
Address 1				
Address 2				
City		State/Province		
Country i		Postal Code		
Phone Number		Fax Number		
Email Address				
Additional Assignee Data may be generated within this form by selecting the Add button.				Add

Signature:

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications				
Signature	/Andrea L. Colby/		Date (YYYY-MM-DD)	2013-02-12
First Name	Andrea	Last Name	Colby	Registration Number
				30194
Additional Signature may be generated within this form by selecting the Add button.				Add

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	JCO5093USNP
	Application Number	
Title of Invention	Methods and Compositions for Enhancing Hair Quality Using Blackberry Extract	

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Privacy Act Statement

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

