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71. SOLICITANTE Diana J. Parsons

DOMICILIO USA

74. APODERADO Jaime Eduardo Delgado U.

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1

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☐ Patente de Modelo de Utilidad

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☒ Capítulo II

2

SOLICITANTE
(71)

Nombre: DIANA J PARSONS,

Dirección: 3001 TELEGRAPH, No 130 BERKELEY, CA 94805
USA

Nacionalidad o domicilio: ESTADOS UNIDOS

Lugar de Domicilio:

Teléfono:

Fax:

E-mail:

IDENTIFICACIÓN

C.C.

MIT

C.E.

Otro

Cual: _____

Número:

3

REPRESENTANTE
O APODERADO

Nombre: JAIME EDUARDO DELGADO WILLEGAS

Dirección: AV 23 No 37-31 Oficina 202

Teléfono:

244.40.86

Fax:

244.24.86

E-mail:

edw@willegas.com

IDENTIFICACIÓN

C.C.

X

MIT

C.E.

Otro

Cual

Número: 18,770,065

T.P. 40,304 C.B.J

4

INVENTOR (54)
(72)

Nombre: DIANA J PARSONS,

Dirección: 3001 TELEGRAPH, No 130 BERKELEY, CA 94805

Nacionalidad o Domicilio:

ESTADOS UNIDOS

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Título (54)

**METODO Y PROCESO PARA PRODUCIR UNA PIEL DE APARIENCIA JUVENIL DE POROS
PEQUEÑOS, Y SUAVE**

"A Retinoid"

7

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ANEXOS

☒ A

Comprobante de pago de la tasa de presentación de la solicitud.

☐

Documento que acredite la existencia y representación legal usando el solicitante sea persona jurídica.

☐

Poderes, si fuera el caso.

☐

Documento de origen del inventor al solicitante o a su causante.

☐

Declaraciones

☒ A

Copa de la solicitud internacional (Resumen, descripción, reivindicaciones, dibujos)

☒ X

Traducción de la solicitud internacional al castellano. (Resumen, descripción, reivindicaciones, dibujos)

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Traducción del examen preliminar internacional efectuado por la IPEA.

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De ser el caso, copia del nombre de negocio.

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De ser el caso, certificado de depósito del material biológico

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Arte final 12X12 cm.

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De ser el caso, información de otras solicitudes de patente o títulos obtenidos en el extranjero por el mismo titular o su causante, relacionados total o parcialmente con la invención de esta solicitud.

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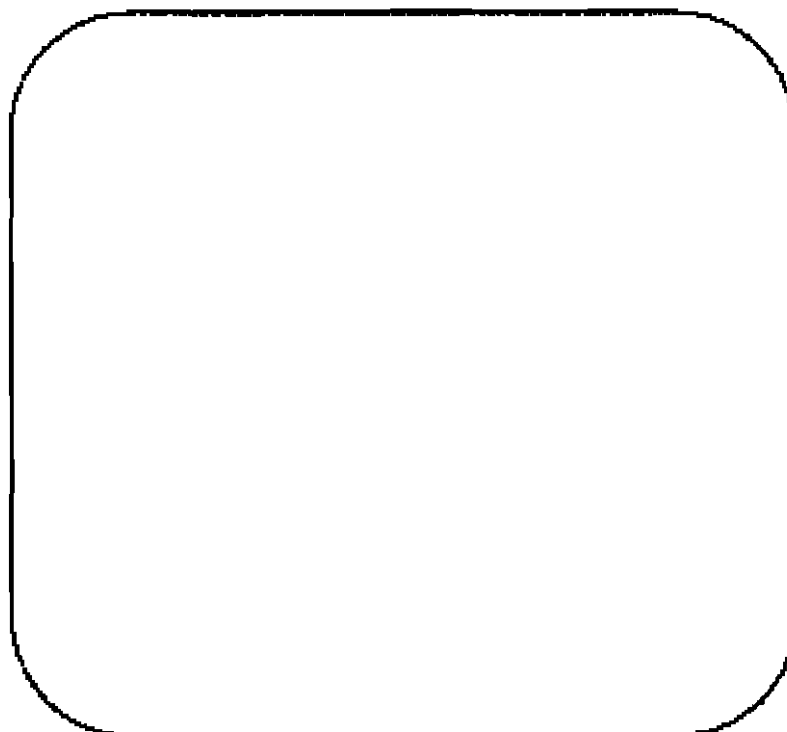
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Otros: Informe de Búsqueda de Asociaciones Internacional

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FIGURA CARACTERISTICA



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Solicito la concesión de la patente,

NOMBRE: JAIME EDUARDO DECEBALDO VILLEGAS

FIRMA:

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CONCEPTO

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For

**METHOD AND PROCESS FOR PRODUCING
YOUTHFUL-APPEARING, SMALL-PORED,
AND SMOOTH SKIN**

by

Diana J. Parsons

Express Mail Label No.: KT9271697161'S

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METHOD AND PROCESS FOR PRODUCING YOUTHFUL-APPEARING, SMALL-PORED, AND SMOOTH SKIN

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BACKGROUND OF INVENTION

1. Field of the Invention

10 The present invention relates generally to laser treatment of the skin and, more particularly, to a laser treatment inducing a chronic wound in the high dermis, leaving the epidermis intact, with topical pretreatment and post-treatment of the skin with retinoic acid.

15 2. Technical Background

 Laser light treatment of the skin is used to rejuvenate the skin, remove pigments and hair, and treat infection. In the field of dermatology and plastic surgery the use of lasers is principally based upon two types of mechanisms: a thermal effect where the
20 laser light energy is converted into heat energy, or a mechanical effect where the laser light energy is converted into shockwaves in the skin.

 Most laser treatments use thermal-based laser therapy to vaporize the superficial wrinkles and top layers of the skin so that new collagen and skin can be naturally
25 provided in a healing response. The procedure is performed under either local or general anesthetic, takes a few hours to complete, and recovery takes one to two weeks. During the first week patients may suffer a sensation of intense heat on the skin. Severe burns can occur and result in permanent scarring. Bacterial and yeast infection have been reported and can also lead to scarring. Additional potential complications include
30 changes in pigmentation and herpes infection.

 Retinoic acid (Retin-A, tretinoin) has also been used as a topical dermal treatment to improve the appearance and texture of the skin. Retinoic acid thins the stratum corneum, increases the thickness of the epidermis, and increases the production of

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collagen in the dermis. However, retinoic acid causes skin redness and sensitivity to the sun. Repeated use can cause a loss of pigment, painful irritation, dryness, swelling of the skin, and contact dermatitis.

5 In an effort to overcome these drawbacks of laser therapy and to avoid the unwanted side effects of retinoic acid, *Tanbovich et al.* (U.S. Patent No. 6,036,684) developed a laser method of photomechanical activation in the skin using a Q switched Nd:YAG laser with a wavelength of 1064nm and an exposure of 2.5 J/cm². Exposure of
10 the skin to this type of laser treatment by itself has no effect on the skin because the skin has no inherent target at the 1064nm wavelength. However, when an activating solution of graphite or carbon particles suspended in baby oil is applied to the skin, these particles become the target of this 1064nm wavelength, exploding when exposed to the laser light. Prior to application of the laser, the particles are forced into the skin, below the surface of
15 the stratum corneum using ultrasound. Thereafter, the explosion of the carbon particles by the laser light produces a localized mechanical injury in the hair follicles and pores of the skin. There is no significant injury to the skin tissue because the laser energy which is not absorbed in the carbon is harmlessly dissipated in the skin. The low fluence of 2.5 J/cm² leaves the epidermis intact and the typical adverse effects of laser treatment do not occur.

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 Although the photomechanical laser process of *Tanbovich* is considerably safer than the standard photothermal laser treatments and leaves the epidermis intact, this photomechanical laser process is relatively ineffective in treating the skin because the extent of injury in the high dermis resulting from the exploding carbon particles in the
25 epidermis is insufficient to induce adequate collagen deposition during wound healing. What is needed, therefore, is means for enhancing the collagen deposition in the high dermis during the wound healing process.

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SUMMARY OF THE INVENTION

The present invention provides a process and method for producing skin rejuvenation and therapy by pretreating the skin with retinoic acid, producing a chronic thermal injury wound in the high dermis using photomechanical laser therapy, maintaining skin rejuvenation and therapy chronically by repeating the thermal injury in the high dermis at least once per year, and by topically applying retinoic acid bi-weekly. A Q-switched Nd:YAG laser with a wave length of 1064nm is used at 2.5 J/cm² to vaporize a topical activating solution of carbon particles suspended in baby oil. A single treatment of the face can be completed in 4 minutes without anesthesia, with no need for a period of recovery, and at a relatively low cost.

15 An advantage of the present invention is the production of a chronic wound in the high dermis with no damage to the epidermis.

 Another advantage of the present invention is the enhancement of laser-induced collagen deposition in the high dermis with retinoic acid.

20 Another advantage of the present invention is the chronic life-time rejuvenation and therapy of the skin.

 Another advantage of the present invention is the removal and prevention of acne by suppression of sebaceous glands and reduction of skin pore size.

25 Another advantage of the present invention is laser therapy at a low energy level.

 Another advantage of the present invention is the use of retinoic acid without side effects.

30 Another advantage of the present invention is therapeutic removal of infections of the skin.

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Another advantage of the present invention is the chronic rejuvenation and therapy of the skin at a relatively low cost.

5 Another advantage of the present invention is that a single treatment of the skin of the face can be completed within four minutes.

BRIEF DESCRIPTION OF THE DRAWINGS

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Fig. 1 describes the method of the present invention.

Fig. 2 illustrates a cross sectional view of the skin and the role of heat and oil in the method of the present invention.

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Fig. 3 describes the process of the present invention.

Fig. 4 shows the effects of the laser method of the present invention on the restoration of the skin of a patient suffering from acne vulgaris.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

25 While the following description details the preferred embodiments of the present invention, it is to be understood that the invention is not limited in its application to the details of construction and arrangement of the parts illustrated in the accompanying drawings, since the invention is capable of other embodiments and of being practiced in various ways.

30 Wound healing in the skin occurs over a year's time after an initial wounding, regardless of the means by which the wounding is induced. In the first five days the

wound is comprised of inflammatory cells and new blood vessels. Then an immature form of collagen is laid down parallel to the skin surface. For six months the body shifts this collagen around, trying to identify the strongest repair. Around six months after the initial wounding, this immature collagen is replaced with mature collagen protein oriented perpendicular to the skin surface. Three months into this process, or months ten, eleven, and twelve from the initial wounding, these protein strands cross-link. This effect is visible on the skin's surface as an apparent shrinkage of the size of the scar to one third its original size.

10 Twelve months from the initial injury, the wound becomes quiescent. However, any additional insult to the wound site during the first six months of repair causes a signal for a stronger permanent repair. Any additional insult to the wound site during the second six months results in additional mature collagen in the wound. As long as some injury is repeated before twelve months has elapsed, the site becomes a chronic wound
15 producing more collagen, undergoing more cross-linking, and more total surface area shrinkage.

The method and process of the present invention described herein outlines a series of treatments using the *Tankovich* laser and activating solution to maximize the initial wounding signal during the first six months of application. The *Tankovich* processes disclosed in U.S. Patent No. 5,423,803 and U.S. Patent No. 6,036,684 are incorporated herein by reference. However, in the present invention the activating solution does not need to be forced into the spaces of the skin with ultrasound as required by the *Tankovich* process. Beginning at the six month from the initial wounding, a series of booster laser
20 treatments is given until the desired skin resurfacing end point is reached. At a minimum, one booster laser treatment is given before twelve months has elapsed to keep the wound active. If the wound is not kept active, it will be necessary to repeat the initial wounding series of the first six months in order to continue the resurfacing process chronically.

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The first step of the method of the present invention is shown in Fig. 1. Step 10, which is a topical pretreatment of the skin with a collagen inducing agent and an angiogenesis inducing agent, preferably, retinoic acid, and in particular its nongeneric form, such as Retin-A (tretinoin). Retinoic acid returns the architecture of the skin back to its more youthful form. As skin ages, the hill and valley nature of the dermal-epidermal junction 21 flattens (see Fig. 2). Topical retinoic acid restores the up and down pattern at the junction 21. In youth, the basal cells which originate at the dermal-epidermal junction 21 create the layers of the epidermis every three weeks. With aging, this slows to four to six weeks. Topical retinoic acid on the skin returns the process to every three weeks. The top most layer of epidermal cells, the stratum corneum, is comprised of dead cells held together by a cell glue. With age, this layer thickens making the skin less fresh-appearing and making the pores larger. Topical retinoic acid directly attacks the cell glue, thinning the stratum corneum and making the pores smaller by reducing the amount of debris in them. In my studies I have discovered that 0.05% to 1% concentration of retinoic acid in a topical formulation has the property of inducing new collagen and new blood vessel formation in the high dermis. The pre-treatment period is one to four weeks, preferably two weeks with retinoic acid being applied twice a week with at least two days in between each application. The laser therapy of the present invention will not be effective without the pre-treatment application of topical retinoic acid.

The second step 11 in the method of the present invention shown in Fig. 1 is the creation of a chronic wound in the high dermis. This is produced by a photomechanical laser treatment wherein the laser light does not interact directly with the skin but instead interacts with a contaminant in the skin. The contaminant has the properties of absorbing the laser light and exploding. The preferred contaminant is carbon or graphite particles in oil 20 which is applied to the skin (see Fig. 2). Once the contaminant or activating solution is applied to the skin, the laser treatment can begin. The energy from the laser is adjusted to be just sufficient to cause the particles to explode. As the particles explode, they cause the removal of the stratum corneum and the mineral oil 20 penetrates into the epidermis producing hydration of the epidermis by retarding the evaporation of water

(see Fig. 2) The heat from the explosion of the contaminant particles will induce a photothermal injury in the rete peg area of the high dermis 22 initiating a normal wound healing process. In order to produce a sufficient degree of injury to the wound, the laser treatment is produced several times over a six month period, preferably six times over a six month period. During this first six months the retinoic acid is applied topically twice per week as described above.

The build up of new collagen in the high dermis 22 in response to the laser treatment and retinoic acid treatment thickens the skin and increases its turgor resulting in smaller skin pores. Broken blood vessels, angiomas, and ice pick scars or suture marks are also minimized, being crowded out by the new collagen. Easy bruisability of the skin is lessened by the collagen build up. Lips become redder, fine lines are minimized, and dark circles around the eyes are minimized. As the new collagen cross-links major wrinkle lines, such as nasal labial folds and perioral and periocular lines (caused by the underlying attachment of muscles to the deep dermis), marionette lines, sunken-in corners of the mouth, and forehead, temporal, and glabellar lines, appear to melt away into the new skin. The new skin has a glowing quality resulting from the pulsating nature of the laser injury and the high content of mineral oil in the activating solution. Retinoic acid and laser treatment work together to minimize bound differential pigmentation caused by sun damage and hormones (melasma). Redness from inflammation, as in acne vulgaris, acne rosacea, or maturing scars or striae is also reduced.

Because of the closeness of the sebaceous glands to the skin surface and because of the new collagen formation which reduces the size of the skin pores, the method of process of the present invention is useful in the treatment of sebaceous gland disorders such as acne. The secretion from the sebaceous glands is reduced and the smaller skin pore size prevents bacteria from entering the skin pores. In addition, heat generated from the explosion of the contaminate particles is sufficient to kill bacteria, fungi, and viruses on the skin's surface or in the high dermis. This also allows treatment of conditions such as, for example, plantar warts, herpes cold sores, athlete's foot, psoriasis, and eczema.

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The third step 12 in the method of the present invention, depicted in Fig. 1, is the long term continued chronic maintenance of the high dermis in a wounded condition in order to produce a sustained rejuvenation of the skin and treatment of skin conditions. This is accomplished by application of the laser treatment of the present invention at least once a year and preferably twice, along with the continued application of topical retinoic acid to the skin twice per week as described above.

The process of the present invention for treating the skin is shown in Fig. 3. In the first step 40, pre-treatment is initiated with topical retinoic acid applied to the skin at least twice per week. The concentration of retinoic acid in the topical formulation is between about 0.05% to 1%, preferably about 0.1%. The pretreatment period is, preferably, two weeks. In the next step 41, an activating solution of graphite in baby oil is applied to the skin. The graphite-oil ratio may range from about 1:1 to 1:9, preferably 1:4, i.e., about 20 percent graphite suspended in about 80 percent oil by weight. In the next steps 42 and 43 a laser beam is scanned over the area treated with the activating solution so as to clean substantially all of the mixture from the skin surface by exploding or fracturing the carbon or graphite particles in the oil. This scanning process takes from about 2 to 10 minutes to complete on the face, usually about 4 minutes.

It is preferred to use a Q-switched neodymium:yttrium-aluminum-garnet (Nd:YAG) laser for the process of the present invention. The wave length of the radiation may range from about 800nm to 2000nm, preferably about 1064nm. The frequency of the pulses from the laser range from about 1 to 20 per second, preferably, about 10 per second. The duration of each pulse ranges from about .001 to 1 microsecond, preferably about .01 microsecond. The fluence or exposure of the skin treated with the activating solution ranges from about 1 to 3 J/cm², preferably, about 2.5 J/cm².

In the next step 44 the laser process is repeated several times to create a chronic wound in the high dermis 22 (see Fig. 2). The process may be repeated 2 to 12 times within a six month period, preferably six times. During this time retinoic acid is applied

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in the skin 1 to 4 times per week, preferably 2 times per week, with 2 to 3 days between applications. The application of retinoic acid may be varied in an equivalent manner on a monthly basis, i.e., 4 to 16 applications per month, preferably 8 applications per month, where the applications may all be applied within one or two weeks of a given month, but, preferably, applied each week of a month.

In the next step 45 the laser process is repeated at least once in the next six months and thereafter at least once per year, but, preferably twice per year. The yearly treatments will maintain a chronic wound in the high dermis. At the same time, topical retinoic acid is applied weekly to the skin as described above. The continued combination of intermittent laser therapy and topical retinoic acid will maintain the rejuvenation and therapeutic results in the skin indefinitely.

Fig. 4 shows, by way of example, the effects of the laser method of the present invention on the skin of a patient suffering from acne vulgaris. The before picture presents the patient's skin prior to treatment and the after picture shows the patient's skin after the first six months of treatment of the skin with the method and process of the present invention. The lesions and scars are substantially reduced in severity and the process of acne formation has been completely prevented. Furthermore, this has been accomplished leaving the epidermis intact and normal. Continued chronic treatment with the method of the present invention is expected to provide further improvement in the appearance of the skin.

The foregoing description has been limited to specific embodiments of this invention. It will be apparent, however, that variations and modifications may be made by those skilled in the art to the disclosed embodiments of the invention, with the attainment of some or all of its advantages and without departing from the spirit and scope of the present invention. For example, agents other than retinoic acid which induce collagen and blood vessel growth may be used in place of retinoic acid. Any laser system capable of exploding or rupturing a contaminant in the skin without injuring the skin

directly can be used in the present invention. The activating solution can be made with any suitable oil with any suitable contaminant.

5 It will be understood that various changes in the details, materials, and arrangements of the parts which have been described and illustrated above in order to explain the nature of this invention may be made by those skilled in the art without departing from the principle and scope of the invention as recited in the following claims.

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CLAIMS

I claim:

- 5 1. A method for treating the skin, comprising the steps of:
 - a) pretreating the skin with a topical collagen-promoting agent;
 - b) producing a wound in the high dermis of the skin;
 - 10 c) treating the skin chronically with said topical collagen-promoting agent after producing said wound in the high dermis; and
 - d) maintaining the high dermis in a chronically wounded condition.
- 15 2. The method of claim 1 further comprising the steps of pretreating and chronically treating the skin with a blood vessel promoting agent.
3. The method of claim 1 wherein said collagen-promoting agent is retinoic acid.
- 20 4. The method of claim 2 wherein said blood vessel promoting agent is retinoic acid.
5. The method of claim 1 wherein the step of producing a wound in the high dermis is performed by exploding a container on the surface of the skin with laser light.
- 25 6. The method of claim 5 wherein said production of a chronic wound in the high dermis leaves the epidermis intact.

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7. The method of claim 5 wherein the step of producing a chronic wound in the high dermis is performed by exploding a contaminant on the skin with laser light repeatedly within a six month period of said pretreating step.
8. The method of claim 5 wherein the step of maintaining a chronic wound in the high dermis is performed by exploding a contaminant on the surface of the skin with laser light at least once every twelve months.
9. The method of claim 1 wherein the steps of producing and maintaining a chronic wound in the high dermis are performed by exploding a contaminant on the skin with a laser light having a wave length of from about 800nm to 1000nm, a pulse frequency of from about 1 to 20 per second, a pulse duration of from about .001 to 1 microsecond, and a fluence of from about 1 to 3 J/cm².
10. The method of claim 9 wherein said laser light has a wave length of about 1064nm, a pulse frequency of about 10 per second, a pulse duration of about .01 microsecond, and a fluence of about 2.5 J/cm².
11. The method of claim 3 wherein said retinoic acid is applied to the skin 4 to 16 times per month.
12. The method of claim 11 wherein said retinoic acid is applied to the skin 1 to 4 times per week.
13. The method of claim 12 wherein said retinoic acid is applied to the skin 2 times per week.
14. The method of claim 3 wherein said retinoic acid is applied topically at a concentration of from about 0.05% to 1%

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- 15 The method of claim 14 wherein said retinoic acid is applied topically at a concentration of about 0.1%
16. The method of claim 3 wherein the pretreating step is performed for two weeks.
- 5 17. The method of claim 5 wherein producing a wound in the high dermis is completed in about two to ten minutes.
18. The method of claim 17 wherein producing a wound in the high dermis is
10 completed in about four minutes.
19. The method of claim 1 wherein said method for treating the skin is used to rejuvenate the skin and to remove broken blood vessels, angiomas, scars, lines, wrinkles, pigmentation, and redness in the skin.
- 15 20. The method of claim 1 wherein said method for treating the skin is used to treat acne, warts, cold sores, excema, psoriasis, and infections of the skin.
- 21 A process for treating the skin, comprising the steps of:
20 a) pretreating the skin with topical retinoic acid;
- b) producing a chronic wound in the high dermis of the skin by exploding a
contaminant on the surface of the skin with laser light, leaving the
25 epidermis intact;
- c) treating the skin chronically with said retinoic acid after producing said chronic wound; and

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d) maintaining the high dermis in a chronically wounded condition by exploding a contaminant on the surface of the skin with laser light at least once every twelve months, leaving the epidermis intact.

5 22. The process of claim 21 wherein the step of pretreating the skin with retinoic acid comprises two weeks.

23. The process of claim 21 wherein exploding a contaminant on the surface of the skin with laser light is completed within about two to ten minutes.

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24. The process of claim 23 wherein exploding a contaminant on the surface of the skin with laser light is completed within about four minutes.

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25. The process of claim 21 wherein the step of producing a chronic wound in the high dermis comprises exploding a contaminant on the surface of the skin with laser light two to twelve times within a six month period after pretreating the skin with retinoic acid.

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26. The process of claim 25 wherein the step of producing a chronic wound in the high dermis comprises exploding a contaminant on the surface of the skin with laser light six times within a six month period after pretreating the skin with retinoic acid.

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27. The process of claim 21 wherein said laser light has a wave length of from about 800nm to 1000nm, a pulse frequency of from about 1 to 20 per second, a pulse duration of from about .001 to 1 microsecond, and a fluence of from about 1 to 3 J/cm².

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28. The process of claim 27 wherein said laser light has a wave length of about 1064nm, a pulse frequency of about 10 per second, a pulse duration of about .01 microsecond, and a fluence of about 2.5 J/cm².

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- 29. The process of claim 21 wherein said retinoic acid is applied to the skin 4 to 16 times per month.
- 30. The process of claim 29 wherein said retinoic acid is applied to the skin 1 to 4 times per week.
- 31. The process of claim 30 wherein said retinoic acid is applied to the skin 2 times per week.
- 32. The process of claim 21 wherein said retinoic acid is applied topically at a concentration of from about 0.05% to 1%.
- 33. The process of claim 32 wherein said retinoic acid is applied topically at a concentration of about 0.1%.
- 34. The process of claim 21 wherein said method is used to rejuvenate the skin and to remove broken blood vessels, angiomas, scars, lines, wrinkles, pigmentation, and redness in the skin.
- 35. The process of claim 21 wherein said method is used to treat acne, warts, cold sores, eczema, psoriasis, and infections of the skin.
- 36. The process of claim 28 wherein said laser light is produced by a Q-switched Nd:YAG laser.

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ABSTRACT OF THE DISCLOSURE

The method and process for producing youthful appearing, small-pored, and smooth skin comprises pretreating the skin topically with retinoic acid, applying a contaminate in oil to the skin, and removing the contaminate by exploding or rupturing it with laser light. When treating the face, removing the contaminate requires only about 4 minutes. The laser light itself does not injure the skin but the rupture of the contaminant produces thermal injury in the high dermis leaving the epidermis intact. Repeated intermittent laser treatments and applications of topical retinoic acid produces the desired results in the skin indefinitely as long as the treatments and applications are continued.

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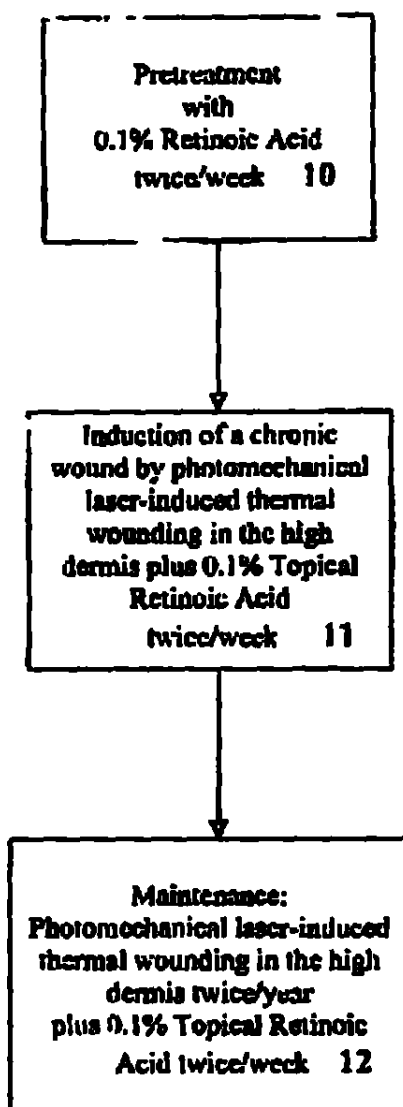


Fig. 1

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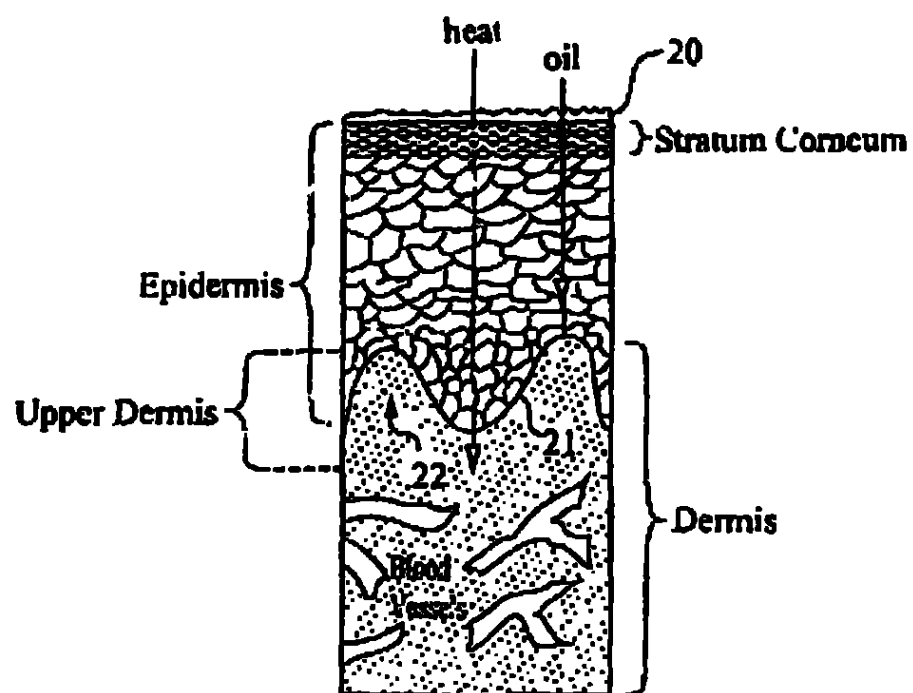


Fig. 2

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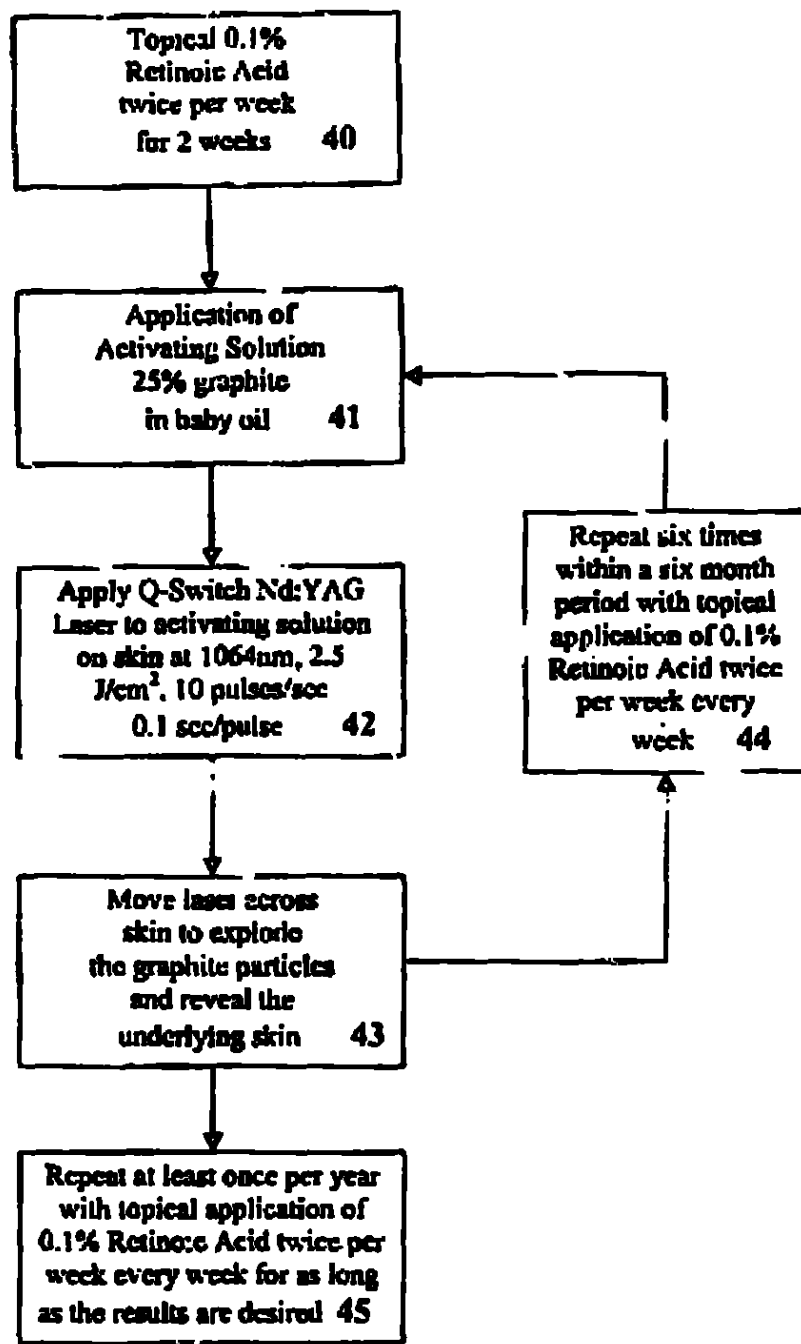


Fig. 3

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4/4

**Before****After****Fig. 4**

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METODO Y PROCESO PARA PRODUCIR UNA PIEL DE APARIENCIA JUVENIL, DE POROS PEQUEÑOS, Y SUAVE

ANTECEDENTES DE LA INVENCION

1. Campo de la invención

La invención actual trata generalmente acerca del tratamiento láser de la piel y, más particularmente, del tratamiento láser que induce una herida crónica en la dermis superior dejando la epidermis intacta, con pretratamiento local y post - tratamiento de la piel con ácido retinóico.

2. Antecedentes técnicos

El tratamiento de la piel con luz de láser se usa para rejuvenecer la piel, remover los pigmentos y pelo, y tratar la infección. En el campo de dermatología y cirugía plástica el uso de láseres se basa principalmente sobre dos tipos de mecanismos: un efecto térmico donde la energía de la luz del láser se convierte en energía de calor, o un efecto mecánico donde la energía de la luz del láser se convierte en ondas de choque en la piel.

La mayoría de los tratamientos de láser usan terapia de láser de base térmica para vaporizar las arrugas superficiales y las capas superiores de la piel para que nuevo colágeno y piel puedan ser naturalmente proveídos en una respuesta de sanación. El procedimiento es realizado bajo anestesia local o general, toma unas horas para completarse, y la recuperación toma una a dos semanas. Durante la primera semana los pacientes pueden sufrir una sensación de calor intenso sobre la piel. Pueden ocurrir quemaduras severas y resultar en cicatrices permanentes. Se han informado infecciones bacterianas y por levadura y pueden también resultar cicatrices. Las complicaciones potenciales adicionales incluyen cambios en la pigmentación e infección por herpes.

El ácido retinóico (Retín - A, tretinoina) también se ha usado como un tratamiento tópico dermatológico para mejorar el aspecto y textura de la piel. El ácido retinóico adelgaza el estrato córneo, aumenta el espesor de la epidermis, y aumenta la producción de

de colágeno en la dermis. Sin embargo, el ácido retinoico ocasiona enrojecimiento de la piel y sensibilidad al sol. El uso repetido puede ocasionar una pérdida del pigmento, irritación dolorosa, sequedad, hinchazón de la piel, y dermatitis por contacto.

En un esfuerzo para superar esas desventajas de la terapia de láser y para evitar los efectos indeseables del ácido retinoico, Tankovich et al (EE.UU. Patente No. 6, 036,684) desarrolló un método de láser de activación fotomecánica en la piel usando un láser Q empujante Nd:YAG con una longitud de onda de 1064nm y una exposición de 2.5 J/cm². La exposición de la piel a este tipo de tratamiento de láser por sí mismo no tiene ningún efecto sobre la piel porque la piel no tiene ningún blanco inherente a la longitud de onda de 1064nm. Sin embargo, cuando una solución activante de las partículas de carbón o grafito suspendidas en aceite de bebé se aplica a la piel, estas partículas llegan a ser el blanco de esta longitud de onda de 1064nm, estallando al ser expuestas a la luz del láser. Anterior a la aplicación del láser, las partículas son forzadas dentro en la piel, más debajo de la superficie del estrato córneo usando ultrasonido. De ahí en adelante, la explosión de las partículas de carbón por la luz del láser produce un daño mecánico localizado en los poros y folículos de pelo de la piel. No hay daño importante al tejido de la piel porque la energía del láser que no es absorbida en las partículas de carbón es inofensivamente disipada en la piel. La fluencia baja de 2.5 J/cm² deja la epidermis intacta y los efectos adversos típicos del tratamiento de láser no ocurren.

Aunque el proceso fotomecánico de láser de Tankovich es considerablemente más seguro que los tratamientos de láser foto térmicos estándar y deja la epidermis intacta, este proceso fotomecánico de láser es relativamente ineficaz en el tratamiento de la piel por la extensión de los daños en la dermis superior resultantes de la explosión de las partículas de carbón en la epidermis es insuficiente para inducir una adecuada deposición de colágeno durante la sanación de la herida. Que es necesario, por lo tanto, para el mejoramiento de la deposición de colágeno en la dermis superior durante el proceso de recuperación de la herida.

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RESUMEN DE LA INVENCION

La invención actual provee un proceso y método para producir rejuvenecimiento de la piel y una terapia por pre-tratamiento de la piel con ácido retinoico, produciendo una herida por daño térmico crónico en la dermis superior usando la terapia fotomecánica de láser, manteniendo el rejuvenecimiento de la piel y terapia crónicamente repitiendo el daño térmico en la dermis superior por lo menos una vez al año, y aplicando típicamente ácido retinoico dos veces por semana. Un láser Q. conectado Nd:YAG con una longitud de onda de 1064nm es usado a 2.5 J/cm² para vaporizar una solución tópica activadora de las partículas de carbón suspendidas en el aceite de bebé. Un simple tratamiento de la cara puede completarse en 4 minutos sin anestesia, sin necesidad de un período de recuperación, y a un costo relativamente bajo.

Una ventaja de la invención actual es la producción de una herida crónica en la dermis superior sin daño a la epidermis.

Otra ventaja de la invención actual es el aumento de la inducción de la deposición de colágeno por láser en la dermis superior con ácido retinoico.

Otra ventaja de la invención actual es el tiempo de vida crónico del rejuvenecimiento y la terapia de la piel.

Otra ventaja de la invención actual es la remoción y prevención de acné por la supresión de glándulas sebáceas y reducción del tamaño de poro de la piel.

Otra ventaja de la invención actual es la terapia de láser a un bajo nivel de energía.

Otra ventaja de la invención actual es el uso de ácido retinoico sin efectos indeseados.

Otra ventaja de la invención actual es la remoción terapéutica de infecciones de la piel.

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Otra ventaja de la invención actual es el rejuvenecimiento crónico y la terapia de la piel a un costo relativamente bajo.

Otra ventaja de la invención actual es que un simple tratamiento de la piel de la cara puede completarse dentro de cuatro minutos.

BREVE DESCRIPCION DE LOS DIBUJOS

Fig. 1 describe el método de la invención actual.

Fig. 2 ilustra una vista entrecruzada de la piel y el papel de calor y el aceite en el método de la invención actual.

Fig. 3 describe el proceso de la invención actual.

Fig. 4 muestra los efectos del método de láser de la invención actual en la reafirmación de la piel de un paciente que sufre del urticario vulgaris.

DESCRIPCION DETALLADA DE LOS COMPUESTOS PREFERIDOS

Mientras la descripción siguiente detalla los compuestos preferidos de la presente invención, se entiende que la invención no está limitada en su aplicación al los detalles de construcción y el arreglo de las partes ilustrados en los dibujos acompañantes, ya que la invención es apta para otros compuestos y para ser practicada en diversas maneras.

La sanación de la herida en la piel ocurre en el tiempo de un año después de la herida inicial, sin considerar los medios por los que la herida es inducida. En los primeros cinco días la

herida es comprendida de células inflamatorias y nuevos vasos sanguíneos. Entonces una forma inmadura de colágeno es colocada debajo paralelo a la superficie de la piel. Por seis meses el cuerpo transporta este colágeno alrededor, tratando de identificar la reparación más fuerte. Alrededor de seis meses después de la herida inicial, este colágeno inmaduro se reemplaza con proteína de colágeno madura orientada perpendicular a la superficie de la piel. Tres meses en este proceso, o meses diez, once, y doce desde la herida inicial, estas hebras de proteína se distribuyen. Este efecto es visible sobre la superficie de la piel como una disminución evidente del tamaño de la cicatriz a un tercio de su tamaño original.

Once meses desde la herida inicial, la herida se vuelve inactiva. Sin embargo, cualquier agresión adicional al sitio de la herida durante los primeros seis meses de reparación ocasiona una señal para una reparación permanente más fuerte. Cualquier agresión adicional al sitio de la herida durante los segundos seis meses resulta en adicional colágeno maduro en la herida. Mientras algún daño se repita antes de que hayan transcurrido doce meses, el sitio se vuelve una herida crónica produciendo más colágeno, experimentando más distribución, y mayor área total de superficie disminuida.

El método y el proceso de la invención actual descrita incluso plantean una serie de tratamientos usando el láser de *Tankovich* y la solución activante para maximizar la señal de la herida inicial durante los primeros seis meses de aplicación. Los procesos de *Tankovich* revelados en EE.UU. Patente No. 5, 423,803 y EE.UU. Patente No. 6, 036,684 son incorporados incluso por referencia. Sin embargo, en la invención actual la solución activadora no necesita ser forzada en los espacios de la piel con ultrasonido como requiere el proceso de *Tankovich*. Comenzando en el sexto mes desde la herida inicial, se da una serie de tratamientos de impulso láser hasta que se haya alcanzado el punto de la resuperficie de la que piel descada. Como mínimo, un tratamiento de impulso láser se da antes de que hayan transcurrido doce meses para mantener la herida activa. Si la herida no es mantenida activa, será necesario repetir las series iniciales de la herida de los primeros seis meses a fin de continuar crónicamente el proceso de resuperficie.

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El primer paso del método de la invención actual se muestra en la Fig. 1, Paso 10, que es un pretratamiento tópico de la piel con un agente inductor de colágeno y un agente inductor de angiogénesis, preferentemente, ácido retínoico, y en particular su forma no genérica, tal como Retin - A (tretinoin). El ácido retínoico retorna la arquitectura del dorso de piel a su forma más juvenil. Mientras la piel envejece, la naturaleza de la colina y el valle de la unión 21 dermatoepidermal se aplanan (ver Fig. 2). El ácido retínoico tópico restaura el patrón de subida y bajada de la unión 21. En la juventud, las células basales que se originan en la unión 21 dermatoepidermal crean las capas de la epidermis cada tres semanas. Con el envejecimiento, esto se demora de cuatro a seis semanas. El ácido retínoico tópico sobre la piel devuelve el proceso a cada tres semanas. La capa más superficial de células, el estrato córneo, está comprendido por células muertas retenidas juntas por un pegamento celular. Con la edad, esta capa se engruesa y hace que la piel luzca menos fresca y hace los poros más grandes. El ácido retínoico tópico directamente ataca el pegamento celular, adelgazando el estrato córneo y haciendo los poros más pequeños reduciendo la cantidad de desechos en ellos. En mis estudios he descubierto que 0.05% a 1% concentración de ácido retínoico en una fórmula tópica tiene la propiedad de inducir nuevo colágeno y nueva formación de vasos sanguíneos en la dermis superior. El periodo de pre - tratamiento es de una a cuatro semanas, preferentemente dos semanas con ácido retínoico siendo aplicado dos veces por semana con por lo menos dos días entre cada aplicación. La terapia de láser de la invención actual no será efectiva sin la aplicación pre-tratamiento de ácido retínoico tópico.

El segundo paso 11 en el método de la invención actual mostrado en la Fig. 1 es la creación de una herida crónica en la dermis superior. Esta es producida por un tratamiento fotomecánico de láser en donde la luz del láser no interactúa directamente con la piel pero en lugar de esto interactúa con un contaminante en la piel. El contaminante tiene las propiedades de absorber la luz de láser y estallar. El contaminante preferido son las partículas de grafito o carbón en el petróleo 20 que se aplican a la piel (vistas la Fig. 2). Una vez el contaminante o la solución activadora se aplica a la piel, el tratamiento de láser puede comenzar. La energía desde el láser se ajusta para que sea simplemente suficiente para causar el estallido de las partículas. Mientras las partículas estallan, ocasionan la remoción del estrato córneo y el aceite mineral 20 penetra en la epidermis que produciendo hidratación de la epidermis por retardo de la evaporación de agua.

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(ver Fig. 2). El calor desde la explosión de las partículas contaminantes inducirá un daño intotermal en el área plexo de clavija de la dermis superior 22 iniciando un proceso de recuperación normal de la herida. A fin de producir un grado suficiente de daño a la herida, el tratamiento de láser se produce varias veces sobre un período de seis meses, preferentemente seis veces en un período de seis meses. Durante estos primeros seis meses el ácido retinoico se aplica típicamente dos veces por semana como fue descrito arriba.

La construcción de nuevo colágeno en la dermis superior 22 en respuesta al tratamiento de láser y al tratamiento con ácido retinoico aumenta el grosor de la piel y aumenta su turgor resultando en poros cutáneos pequeños. Los vasos sanguíneos rotos, angiomata y las cicatrices pico de hielo o marcas de sutura se minimizan también, siendo apiladas fuera por el nuevo colágeno. La fácil magullación de la piel es disminuida por el colágeno construido. Los labios se vuelven más, las líneas finas se minimizan, y los círculos oscuros alrededor los ojos se minimizan. A medida que el nuevo colágeno se distribuye líneas de expresión importantes, tales como dobleces labiales nasales y líneas perioral y periocular (ocasionadas por el apego subyacente de músculos a la dermis profunda), las líneas de marioneta, sumergidas en los ángulos de la boca, y frente, temporal, y las líneas glabellares, parecen derretirse en la nueva piel. La nueva piel tiene una calidad reluciente que resulta desde la naturaleza pulsante del daño del láser y el alto contenido de aceite mineral en la solución activante. El tratamiento de láser y ácido retinoico trabajan juntos para minimizar la pigmentación diferencial causada por el daño solar y las hormonas (melasma). El enrugamiento por la inflamación, como en el acné vulgaris, el acné rosácea, o cicatrices en maduración o las estrías también se reducen.

A causa de la cercanía de las glándulas sebáceas a la superficie de la piel y a causa de la nueva formación de colágeno que reduce el tamaño de los poros cutáneos, el método del proceso de la invención actual es útil en el tratamiento del desorden de la glándula sebacea tal como acné. La secreción de las glándulas sebáceas se reduce y el menor tamaño del poro cutáneo impide la entrada de bacterias en los poros cutáneos. Además, el calor generado desde la explosión de las partículas contaminantes es suficiente para matar las bacterias, los hongos, y virus sobre la superficie de la piel o en la dermis superior. Esto también permite tratamiento de condiciones tales como, por ejemplo, verrugas plantares, úlceras frías de herpes, pie de atleta, psoriasis, y excema.

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El tercer paso 12 en el método de la invención actual, representado en la Fig. 1, es el mantenimiento crónico continuado a largo plazo de la dermis superior en una condición de la herida a fin de producir un rejuvenecimiento sostenido de la piel y tratamiento de las condiciones de la piel. Esto es realizado por la aplicación del tratamiento de láser de la invención actual por lo menos una vez al año y preferentemente dos veces, conjuntamente con la aplicación continuada de ácido retinoico tópico a la piel dos veces por semana como se describió arriba.

El proceso de la invención actual para el tratamiento de la piel se muestra en la Fig. 3. En el primer paso 40, el pre - tratamiento se inicia con ácido retinoico tópico aplicado a la piel por lo menos dos veces por semana. La concentración de ácido retinoico en la fórmula tópica está entre 0.05% a 1%, preferentemente sobre 0.1%. El período de pretratamiento es, preferentemente, dos semanas. En el próximo paso 41, una solución activadora de grafito en el aceite de hacha se aplica a la piel. La relación grafito - aceite puede oscilar desde 1:1 a 1:9, preferentemente 1:4, es decir, sobre 20 por ciento de grafito suspendido en aproximadamente 80 por ciento de aceite por peso. En los próximos pasos 42 y 43 un haz de láser es escaneado sobre el área tratada con la solución activadora para limpiar considerablemente toda la mezcla desde la superficie de la piel por estallido o fractura de las partículas de grafito o carbón en el aceite. Este proceso de exploración toma de 2 a 10 minutos para completarse sobre la cara, comúnmente 4 minutos.

Se prefiere usar un láser Q-conectado neodimio: yttrium - aluminio - garnet (Nd:YAG) para el proceso de la invención actual. La longitud de onda de la radiación puede oscilar desde 800nm a 2000nm, preferentemente sobre 1064nm. La frecuencia de los pulsos desde el láser oscila desde 1 a 20 por segundo, preferentemente, sobre 10 por segundo. La duración de cada pulso oscila desde .001 a 1 microsegundo, preferentemente sobre .01 microsegundo. La fluencia o la exposición de la piel tratada con la solución activante oscila desde 1 a 3 J/cm², preferentemente, sobre 2.5 J/cm².

En el próximo paso 44 el proceso de láser se repite varias veces para crear una herida crónica en la dermis superior 22 (ver Fig. 2). El proceso puede repetirse 2 a 12 veces dentro de un período de seis meses, preferentemente seis veces. Durante este tiempo el ácido retinoico se aplica

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a la piel 1 a 4 veces por semana, preferentemente 2 veces por semana, con 2 a 3 días entre las aplicaciones. La aplicación del ácido retinico puede variarse en una manera equivalente mensualmente, es decir, 4 a 16 aplicaciones por mes, preferentemente 8 aplicaciones por mes, donde las aplicaciones pueden todas ser aplicadas dentro de una o dos de semanas de un mes determinado, pero, preferentemente, aplicado cada semana de un mes.

En el próximo paso 43 el proceso de láser se repite por lo menos una vez en los próximos seis meses y de ahí en adelante por lo menos una vez al año, pero, preferentemente dos veces al año. Los tratamientos anuales mantendrán una herida crónica en la dermis superior. A la vez, el ácido retinico tópico se aplica semanal a la piel como se describió arriba. La combinación continuada de la terapia intermitente de láser y el ácido retinico tópico mantendrá el rejuvenecimiento y los resultados terapéuticos en la piel indefinidamente.

La Fig. 4 muestra, a manera de ejemplo, los efectos del método de láser de la presente invención sobre la piel de un paciente que sufre del acné vulgaris. La fotografía del antes presenta la piel del paciente con anterioridad al tratamiento y la fotografía del después muestra la piel del paciente después de los primeros seis meses de tratamiento de la piel con el método y proceso de la invención actual. Las lesiones y las cicatrices se reducen considerablemente en severidad y el proceso de formación de acné se ha prevenido completamente. Además, esto ha sido realizado dejando la epidermis intacta y normal. El tratamiento crónico continuado con el método de la invención actual está de esperar proveer un mejoramiento adicional en la apariencia de la piel.

La descripción anterior se ha limitado a compuestos específicos de esta invención. Será evidente, sin embargo, que pueden hacerse variaciones y modificaciones por aquellos diestros en el arte de los compuestos revelados en la invención, con la obtención de algunas o todas sus ventajas y sin alejarse del espíritu y esencia de la invención actual. Por ejemplo, otros agentes además del ácido retinico que induzcan colágeno y el crecimiento de vasos sanguíneos pueden usarse en lugar del ácido retinico. Cualquier sistema de láser capaz de estallar o romper un contaminante en la piel

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sin lastimar la piel directamente puede usarse en la invención actual. La solución activante puede hacerse con cualquier aceite apropiado con cualquier contaminante apropiado.

Se entenderá que diversos cambios en los detalles, materiales, y arreglos de las partes que se han descrito e ilustrados arriba a fin de explicar la naturaleza de esta invención puede ser hecha por aquellos expertos en el arte sin alejarse de el principio y la esencia de la invención como se apunta en las reivindicaciones siguientes.

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REIVINDICACIONES

1 reivindicación:

1. Un método para el tratamiento de la piel, comprendiendo los pasos de:
 - a) pretratamiento de la piel con un agente tópico promotor de colágeno;
 - b) produciendo una herida en la dermis superior de la piel;
 - c) tratando la piel crónicamente con el mencionado agente tópico promotor de colágeno después de producir dicha herida en la dermis superior; y
 - d) manteniendo la dermis superior en una condición crónicamente herida.
2. El método de reivindicación 1 además comprende los pasos de pretratamiento y el tratamiento crónico de la piel con un agente promotor de vasos sanguíneos.
3. El método de reivindicación 1 en donde el dicho agente promotor de colágeno es el ácido retinoico.
4. El método de reivindicación 2 en donde el dicho agente promotor de vasos sanguíneos es el ácido retinoico.
5. El método de reivindicación 1 en donde el paso de producir una herida en la dermis superior es desempeñado estallando un contaminante sobre la superficie de la piel con la luz del láser.
6. El método de reivindicación 5 producción en donde dicha producción de una herida crónica en la dermis superior deja la epidermis intacta.

7. El método de reivindicación 5 en donde el paso de producir una herida crónica en la dermis superior es desempeñado estallando un contaminante sobre la piel con la luz del láser repetidamente dentro de un período de seis meses de dicho paso de pretratamiento.
8. El método de reivindicación 5 en donde el paso de mantener una herida crónica en la dermis superior es desempeñado estallando un contaminante sobre la superficie de la piel con la luz del láser por lo menos una vez cada doce meses.
9. El método de reivindicación 1 en donde los pasos de producir y mantener una herida crónica en la dermis superior son desempeñados estallando un contaminante sobre la piel con una luz de láser con una longitud de onda de sobre 800nm a 1000nm, una frecuencia de pulso de sobre 1 a 20 por segundo, una duración de pulso de sobre .001 a 1 microsegundos, y una fluencia de sobre 1 a 3 J/cm².
10. El método de reivindicación 9 en donde dicha luz de láser tiene una longitud de onda de sobre 1064nm, una frecuencia de pulso de sobre 10 por segundo, una duración de pulso de sobre .01 microsegundos, y una fluencia de sobre 2.5 J/cm².
11. El método de reivindicación 3 en donde dicho ácido retinoico se aplica a la piel 4 a 16 veces por mes.
12. El método de reivindicación 11 en donde dicho ácido retinoico se aplica a la piel 1 a 4 veces por semana.
13. El método de reivindicación 12 en donde dicho ácido retinoico se aplica a la piel 2 veces por semana.
14. El método de reivindicación 3 en donde dicho ácido retinoico se aplica tópicamente a una concentración de desde 0.05% a 1%.

15. El método de reivindicación 14 en donde dicho ácido retinoico se aplica tópicamente a una concentración de sobre 0.1%
16. El método de reivindicación 3 en donde el paso de pretratamiento se desempeña por dos semanas.
17. El método de reivindicación 5 en donde la producción de una herida en la dermis superior se completa en dos a diez minutos.
18. El método de reivindicación 17 en donde la producción de una herida en la dermis superior se completa en cuatro minutos.
19. El método de reivindicación 1 en donde dicho método para tratar la piel se usa para rejuvenecer la piel y para remover vasos sanguíneos rocos, angiomata, cicatrices, líneas, arrugas, pigmentación, y enrojecimiento de la piel.
20. El método de reivindicación 1 en donde dicho método para tratar la piel se usa para tratar acné, verrugas, úlceras frías, eccema, psoriasis, e infecciones de la piel.
21. Un proceso para el tratamiento de la piel, comprendiendo los pasos de:
 - a) pretratamiento de la piel con ácido retinoico tópico;
 - b) producción de una herida crónica en la dermis superior de la piel por estallido de un contaminante sobre la superficie de la piel con luz de láser, dejando la epidermis intacta;
 - c) tratamiento crónico de la piel con dicho ácido retinoico después de producir dicha herida crónica; y

d) manteniendo la dermis superior en una condición de herida crónica por estallido de un contaminante sobre la superficie de la piel con la luz de láser por lo menos una vez cada doce meses, dejando la epidermis intacta.

22. El proceso de reivindicación 21 en donde el paso de pretratamiento de la piel con ácido retinoico comprende dos semanas.
23. El proceso de reivindicación 21 en donde el estallido de un contaminante sobre la superficie de la piel con la luz de láser se completa dentro de dos a diez minutos.
24. El proceso de reivindicación 23 en donde el estallido de un contaminante sobre la superficie de la piel con la luz de láser se completa dentro de cuatro minutos.
25. El proceso de reivindicación 21 en donde el paso de producir una herida crónica en la dermis superior comprende estallar un contaminante sobre la superficie de la piel con la luz de láser dos a doce veces dentro de un periodo de seis meses después del pretratamiento de la piel con ácido retinoico.
26. El proceso de reivindicación 25 en donde el paso de producir una herida crónica en la dermis superior comprende estallar un contaminante sobre la superficie de la piel con la luz de láser seis veces dentro de un periodo de seis meses después del pretratamiento de la piel con ácido retinoico.
27. El proceso de reivindicación 21 en donde dicha luz de láser tiene una longitud de onda de desde 800nm a 1000nm, una frecuencia de pulso de desde 1 a 20 por segundo, una duración de pulso de desde .001 a 1 microsegundos, y una fluencia de desde 1 a 3 J/cm².
28. El proceso de reivindicación 27 en donde dicha luz de láser tiene una longitud de onda de sobre 1064nm, una frecuencia de pulso de sobre 10 por segundo, una duración de pulso de sobre .01 microsegundos, y una fluencia de sobre 2.5 J/cm².

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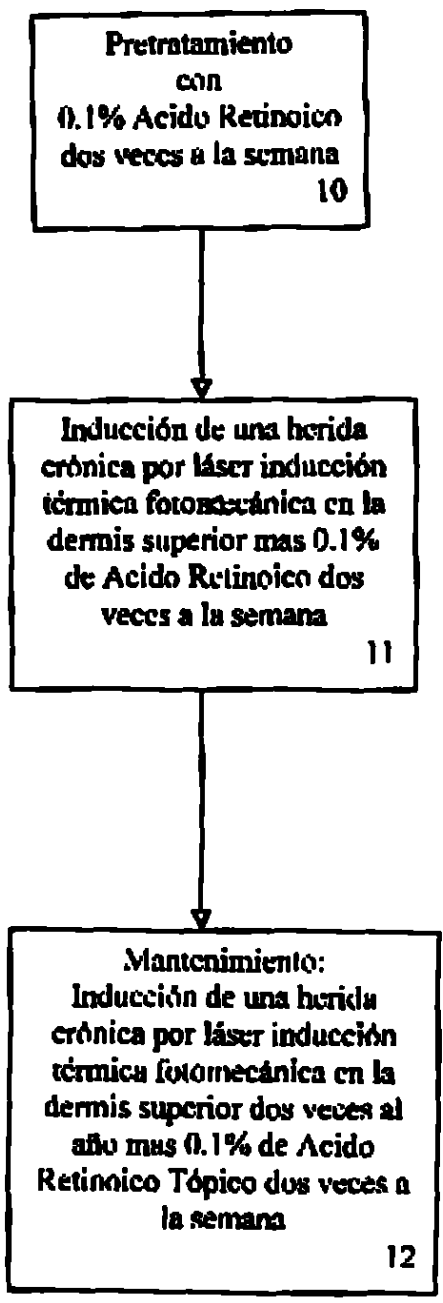
29. El proceso de reivindicación 21 en donde dicho ácido retinoico se aplica a la piel 4 a 16 veces por mes.
30. El proceso de reivindicación 29 en donde dicho ácido retinoico se aplica a la piel 1 a 4 veces por semana.
31. El proceso de reivindicación 30 en donde dicho ácido retinoico se aplica a la piel 2 veces por semana.
32. El proceso de reivindicación 21 en donde dicho ácido retinoico se aplica típicamente a una concentración de desde 0.05% a 1%.
33. El proceso de reivindicación 32 en donde dicho ácido retinoico se aplica típicamente a una concentración de sobre 0.1%.
34. El proceso de reivindicación 21 en donde dicho método se usa para rejuvenecer la piel y para remover los vasos sanguíneos rotos, angiomata, cicatrices, líneas, arrugas, pigmentación, y envejecimiento de la piel.
35. El proceso de reivindicación 21 en donde dicho método se usa para tratar acné, verrugas, úlceras frías, eccema, psoriasis, e infecciones de la piel.
36. El proceso de reivindicación 28 en donde dicha luz de láser es producida por un láser Q-conectado Nd:YAG.

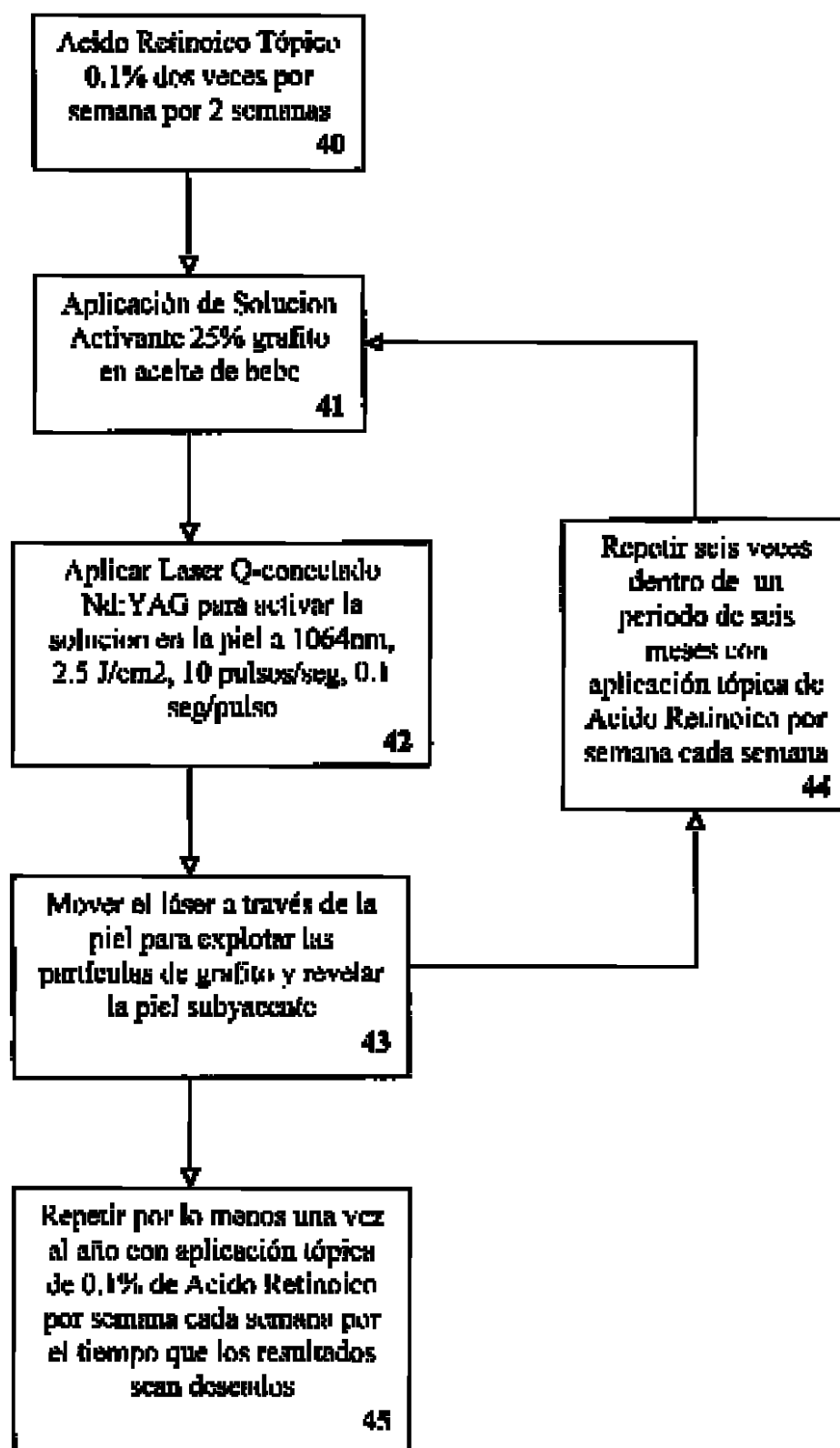
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RESUMEN DE LA DECLARACION

El método y proceso para producir rejuvenecimiento aparente, poros pequeños, y piel suave comprende el pretratamiento de la piel tópicamente con ácido retinoico, aplicando un contaminante en aceite a la piel, y removiendo el contaminante por catálisis o ruptura del mismo con la luz de láser. Cuando se está tratando la cara, remover el contaminante requiere solo aproximadamente 4 minutos. La luz de láser por sí misma no lastima la piel pero la ruptura del contaminante produce daño térmico en la dermis superior dejando la epidermis intacta. Los tratamientos intermitentes repetidos de láser y las aplicaciones tópicas de ácido retinoico producen los resultados deseados en la piel indefinidamente siempre y cuando los tratamientos y las aplicaciones sean continuos.

1/4 Fig. 1





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REOL'EST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

Form 10-75 L 10-75

1. International Application No. _____

2. Date of Filing _____

3. Name of Applicant (Name and "FIC" International Application) _____

4. Applicant's address (include telephone number) (12 of 12) _____

01-2047.02

Fig. 4. TITLE OF INVENTION
Method and Process for Producing Textured-Apperting, Non-Pared, and Smooth Sides

Form No. 11	APPLICANT	☒ This person is an inventor
Name and address. Fully name followed by given name, for a legal name, full official designation (or address) name number, postal code and name of country. The names of the address indicated in the box's of the applicant's State (that is, country) of residence of 40 State of residence is indicated below:		Telephone No. (501) 474-2614
PARSONS, Diana J. 3031 Telegraph, #130 Berkeley, CA 94805 119		Telex No.
		Applicant's registration No. of the Office
State (that is, country) of nationality.		State (that is, country) of residence.
US		US

Is this an inventor's application for the grant of a patent?	☐ All designated States	☒ All designated States except the United States of America	☐ The United States of America only	☐ The States indicated in the application itself
Part No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)				
Is there a name and address of the applicant(s) given in this form for a legal entity full official designation. The address must be a postal code and name of country. The country of the address indicated in this form is the applicant's State (that is, country) of residence if an individual, or country of residence of the legal entity.			This person is ☐ applicant only ☐ applicant and inventor ☐ inventor only (if it is established in practice, the said person is inventor) Applicant's registration No. with the office	
State (that is, country) of residence of:			State (that is, country) of residence of:	

☐ the person is applying for the purposes of ☐ a foreign and ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States of America in the appropriate box
☐ For full applicants (multiple) questions are indicated on a consecutive sheet

Part No. IV AGENT OR COMMON REPRESENTATIVE OR ADDRESS WITH CORRESPONDENCE	
The person identified below is hereby ~~has~~ been appointed to act on behalf of the applicant before the corporate International Authorities on	
☒ Agent	☐ Corporate Representative
Name and address (Usually name followed by given name for a legal entity. All official designations. The address must include postal code and name of country.) WALSH, Gerald M., Ph.D. Lanier Ford Shaver & Payne P C 200 West Side Square, Suite 5000 P.O. Box 2087 Montville, AL 35804 U.S.	Telephone No. (256) 533-1100 Facsimile No. (256) 511-9322 Teletype No. Applicant's registration No. with the Office. 34,946

Address for correspondence: Mark the check box where an agent or someone representative of him has been appointed and the space above is used to add or indicate a special address to which correspondence should be sent.

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Provisionary Designation Statements: In addition to the designations above, the applicant also states under Rule 4.3 of the Patent Office Regulations which would be permitted under the PCT except any designation(s) indicated in the Supplement(s) filed as being excluded from the scope of this statement. The applicant declares that these additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *Confirmation deadline filed on/with the receiving office within the 15-month time limit from P. 156(1)(11) (second class) (4th of 20th March 2003) (see office for the reasons) (see*

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If the Supplemental of Five is not used, this sheet should not be included in the return.

Frank M. Caprio, Attorney; Stephen H. Hall, Attorney; Gerald M. Walsh, Ph.D., Attorney; and Anita S. Damian, Attorney
Lanier Ford Shaver & Payne, P.C.
200 West Side Square, Suite 5000
P.O. Box 2087
Huntsville, AL 35704
U.S.
Phone: 256-535-1100
Fax: 256-533-9322

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Box No. VI PRIORITY CLAIM

The priority of the following earlier application(s) is hereby claimed:

Filing Date of earlier application (Month/Year)	Number of earlier application	Where earlier application is:		
		national application: country	regional application: regional office	international application: receiving office
Item (1) 21 January 02 (1+ 01/02)	100047336	USA		
Item (2)				
Item (3)				
Item (4)				

☐ Further priority claims are claimed in the Supplemental Box.

The receiving Office is requested to prepare and to send to the International Bureau a certified copy of the earlier application(s) for which the earlier application was filed with the Office where for the purpose of the international application is the receiving Office(s) identified above.

☐ Item (1) ☒ Item (1) ☐ Item (2) ☐ Item (3) ☐ Item (4) ☐ Item (5) ☐ other, see Supplement Box

* Where all earlier applications is or are AUPC application, indicate at least one authority party to the Paris Convention for the Protection of Industrial Property or one Member of the World Trade Organization for which that earlier application was filed (Rule 4.1(c)(iv)).

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA)/ISA's or more International Searching Authorities are competent to carry out the international search. Indicate the authority chosen, the two-letter code may be used.

ISA / USA (703) 705-3757

Request to give results of earlier search reference to that search if an earlier search has been carried out by or requested from the International Searching Authority (IS):

Date (day/month/year) Number Country (or regional Office)

Box No. VIII DECLARATIONS

The following declarations are essential in Boxes Nos. VII (i) to (v) (mark the appropriate check-boxes below and indicate in the right column the number of each type of declaration):

		Number of declarations
☐ Box No. VII (i)	Declaration as to the identity of the inventor	.
☐ Box No. VII (ii)	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	.
☐ Box No. VII (iii)	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	.
☐ Box No. VII (iv)	Declaration as to the inventorship (only for the purposes of the designation of the United States of America)	.
☐ Box No. VII (v)	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	.

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Unit No. 02 CHECK LIST: LANGUAGE OF FILING																																																																								
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Box No. 3 SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE Use a seal/signature in accordance with the power of attorney and the signature is valid in the power of attorney if each copy is in the same form as the original <u>Gerald M. Walsh</u> Gerald M. Walsh, Ph.D., Attorney Practitioner																																																																								

For receiving Office use only	
1 Date of receipt of the international application	2 Drawings
3 Corrected drawing(s) except due to letter box change, received from the applicant (for purposes of international application)	☐ received
4 Date of receipt of the required documents under PCT Article 17.2	☐ not received
5 International Searching Authority of the or more the application(s): ISA/	6 ☐ Despatch of search copy delayed until search fee is paid

For International Bureau use only
Date of receipt of the second copy by the International Bureau

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**SOLICITUD
PCT**

El abajo firmante solicita que la presente solicitud internacional sea procesada de acuerdo al Tratado de Cooperación de Patente.

Referencia del depósito del solicitante o agente: 01-2047.02

TÍTULO DE LA INVENCIÓN:

Método y Proceso para Producir una Piel de apariencia Juvenil, de Poros Pequeños y Suaves.

SOLICITANTE: Esta Persona también es el inventor ☒

Nombre y Dirección: PARSONS, Diana J.
3031 Telegraph #130
Berkeley, CA 94805
USA

Teléfono: (501) 664-2614

Estado de Nacionalidad: US

Estado de Residencia: US

Esta Persona es solicitante para el efecto de: todos los Estados designados excepto Los Estados Unidos de América.

AGENTE O REPRESENTANTE COMÚN; O DIRECCIÓN PARA CORRESPONDENCIA.

La persona identificada debajo por este medio es nombrada para actuar en nombre del solicitante ante las autoridades internacionales competentes como: Agente.

Nombre y Dirección: WALSH, Gerald M., Ph.D.
Lanier Ford Shaver & Payne P.C.
200 West Side Square, Suite 5000
P.O. Box 2087
Huntsville, AL 35804
U.S.

Número de Teléfono: (256) 535-1100

Número de Fax: (256) 533-9322

Número de registro del solicitante con la oficina: 34,946

Frank M. Caprin, Abogado; Stephen H. Hall, Abogado; Gerald M. Walsh, Ph.D., Abogado; y Anita S. Damian, Abogada;
Lanier Ford Shaver & Payne, P.C.
200 West Side Square, Suite 5000
P.O. Box 2087
Huntsville, AL 35704 U.S.
Teléfono: 256-535-1100
Fax: 256-533-9322

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DESIGNACION DE ESTADOS

Las siguientes designaciones son hechas por este medio bajo la regla 4.9(a)

Patente regional

EA Patente Eursiánica: AM Armenia, AZ Azerbaiyán, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD República de Moldavia, RU Federación Rusa, TJ Tajikistán, TM Turkmenistán, y cualquier otro estado el cual sea un Contratante de Estado de la Convención de Patente Eursiánica y de la PCT.

EP Patente Europea: AT Austria, BE Bélgica, CH & LI Suiza y Liechtenstein, CY Chipre, DE Alemania, DK Dinamarca, ES España, FI Finlandia, FR Francia, GB Reino Unido, GR Grecia, IR Irlanda, IT Italia, LU Luxemburgo, MC Mónaco, NL Holanda, PT Portugal, SE Suecia, TR Turquía y cualquier otro estado el cual sea un Contratante de Estado de la Convención de Patente Europea y de la PCT.

Patente Nacional (si desea otro tipo de protección o tratamiento, especifique en la línea de puntos):

- AE Emiratos de Arabia unida.....GD Grenada
- AG antigua y Barbuda.....GE Georgia
- AL Albania.....GH Ghana
- AM Armenia.....GM Gambia
- AT Austria.....HR Croacia
- AU Australia.....HU Hungría
- AZ Azerbaiyán.....ID Indonesia
- BA Bosnia y Herzegovina.....IL Israel
- BB Barbados.....IN India
- BG Bulgaria.....IS Islandia
- BR Brasil.....JP Japón
- BY Belarus.....KE Kenia
- BZ Belice.....KG Kyrgyzstan
- CA Canadá.....KP Gente Democrática de
- CH & LI.....KR República de Corea
- CN China.....KZ Kazakstan
- CO Colombia.....LC Santa Lucia
- CR Costa Rica.....LK Lanka del Sri
- CU Cuba.....LR Liberia
- CZ República Checa.....LS Lesotho
- DE Alemania.....LT Lituania
- DK Dinamarca.....LU Luxemburgo
- DM Dominica.....LV Latvia
- DZ Argelia.....MA Marruecos
- EC Ecuador.....MD Republica de Moldova
- EE Estonia.....MG Madagascar
- ES España.....MK Macedonia
- FI Finlandia.....MN Mongolia
- GB Reino Unido.....MW Malawi
- MX México
- MZ Mozambique

NO Noruega
NZ Nueva Zelanda
OM Omán
PH Filipinas
PL Polonia
PT Portugal
RO Rumanía
RU Federación Rusa
SD Sudan
SE Suecia
SG Singapur
SL Eslovenia
SK Eslovaquia
SL Sierra León
TJ Tayikistán
TM Turkmenistán
TN Túnez
TR Turquía
TT Trinidad y Tobago
TZ República Unida de Tanzania
UA Ucrania
UG Uganda
US Estados Unidos de América
UZ Uzbekistán
VN Vietnam
YU Yugoslavia
ZA Sur de África
ZM Zambia
ZW Zimbabwe

REIVINDICACIONES DE LA PRIORIDAD

La Prioridad de la siguiente solicitud anterior se reivindica por esta medio:

Fecha de depósito de la solicitud anterior: Enero 14, 2002

Número de la solicitud anterior: 10/047,335

País de la Solicitud Nacional: Estados Unidos de América.

La oficina de recepción es solicitada a preparar y transmitir copia de la solicitud anterior a la Oficina Internacional (solo si la solicitud anterior fue depositada en la Oficina para propósitos de esta solicitud internacional será recibida en la Oficina) identificada debajo como:

Item 1

BUSQUEDA DE LA AUTORIDAD INTERNACIONAL

Elección de la Búsqueda de la Autoridad Internacional (ISA) (si dos o más Búsquedas de la Autoridad Internacional son competentes para llevar fuera de la búsqueda internacional, indicando la elección de la Autoridad; los dos códigos de letras pueden ser usados).

ISA / USA (703) 305-3257

LISTA DE REVISIÓN: LENGUAJE DEL DEPÓSITO

Esta solicitud internacional contiene:

a) Las siguientes números de hojas en forma de papel:

Solicitud (incluyendo las hojas de declaración): 5

Descripción (excluyendo la parte del listado de secuencia): 11

Reivindicaciones: 5

Abstractos: 1

Dibujos: 4

Sub-Total de número de hojas: 26

Esta solicitud internacional está acompañada por los siguientes items (indique el número de items).

1. Hoja de cálculo de honorarios.
2. Poder de abogado original.
3. Documento de prioridad arriba identificado. 1
4. Otro (especificar) Recibo de tarjeta postal.

Figura de los dibujos los cuales deberán acompañar el abstracto: Pág. 1

Lenguaje del depósito de la solicitud internacional: inglés.

FIRMA DEL SOLICITANTE, AGENTE O REPRESENTANTE COMUN

Firma ilegible

Gerald M. Walsh, Ph.D.,

Abogado Patrocinador.

PATENT COOPERATION TREATY

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
GERALD M. WALSH, Ph.D.
IN/III INTELLECTUAL PROPERTY LAW GROUP LLC
P.O. BOX 3811-0
BIRMINGHAM, AL 35208

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of Mailing (day/month/year) 28 August 2004	
Application's or agent's file reference PARSONS 2	
REPLY DUE: within 2 months/days from the above date of mailing	
International application No. PCT/US03/27530	International filing date (day/month/year) 28 August 2002 (28.08.2002)
Priority date (day/month/year) 14 January 2002 (14.01.2002)	
International Patent Classification (IPC) or both national classification and IPC (IPC): A61B 17/00, 17/50; A61B 31/74, 7/42 and US CL: 606/1, 2, 9, 131; 607/89; 324/400, 318, 718/92	
Applicant PARSONS, DIANA J.	

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 46.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Cause document cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2 (d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.5 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 14 May 2004 (14.05.2004).

Name and mailing address of the IPEA/US Mail Stop PCT, Ann IPEA/US Department of Patent P.O. Box 3450 Alexandria Virginia 22313-1450 Facsimile No. (703) 305-3232	Authorized Officer <i>Cherise Ball - Harris</i> S. Commissioner Telephone No. (703) 318-0194
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Form PCT/PEA/406 (new) dated July 1998

Dated 4/25/04
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WRITTEN OPINION

International application No. _____

PCT/US03/27270

1. Basis of the opinion

1. With regard to the elements of the international application:

- ☒ the international application as originally filed
- ☒ the description:
 pages 1-11 as originally filed
 pages NONE filed with the demand
 pages NONE filed with the letter of _____
- ☒ the claims:
 pages 12-16 as originally filed
 pages NONE as amended (together with any statement) under Article 19
 pages NONE filed with the demand
 pages NONE filed with the letter of _____
- ☒ the drawings:
 pages 1-4 as originally filed
 pages NONE filed with the demand
 pages NONE filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages NONE as originally filed
 pages NONE filed with the demand
 pages NONE filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheet(s) NONE

5. ☐ This opinion has been drawn as if none of the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacements sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

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WRITTEN OPINION

International Application No.
PCT/US2002/000001

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>8-10, 13, 15, 17, 18, 23-25, 31, 32 and 36</u>	YES
	Claims <u>1-7, 11, 12, 14, 16, 19-22, 29, 30, 33, 34 and 35</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-36</u>	NO
Industrial Applicability (IA)	Claims <u>1-36</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Please See attached examination sheet for explanations.

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Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.104(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

V. 2. Claims and Explanation:

Claims 1-7, 11-12, 14, 16, 19-22, 29-30, 32, 34, and 35 lack novelty under PCT Article 33(2) as being anticipated by Kye YC (Dermatologic Surgery, 1997 October, 23(10): 680-683).

Kye YC discloses a method of resurfacing pitted facial scars with a pulsed Er:YAG laser. The patients were treated with 0.05% tretinoin and hydroquinone for two to four weeks before and after the laser procedure. The laser setting was at 50J/cm². See abstract.

Claims 1, 5-7, and 17-20 lack novelty under PCT Article 33(2) as being anticipated by Obagi (4,874,361).

Obagi discloses a method of treating chronic skin problems (acne, wrinkles, pigmentation disorders). Patients are treated with a composition that stimulates skin regeneration. After the composition is applied, the area is treated with light. The parameters chosen are dependent on the skin type and severity of the skin condition. See column 5. However, usually the time range is 2-15 minutes with repeated treatments. See examples.

Claims 1-7, 11-12, 14, 16, 19-22, 29-30, 32, 34-35 lack novelty under PCT Article 33(2) as being anticipated by Ho et al (Dermatologic Surgery, 1995 December, 21(12): 1033-7).

Ho et al teach laser resurfacing in pigmented skin and skin with acne scars. Ho utilizes a CO₂ laser. The patients were treated with 0.05% tretinoin cream 2-4 weeks before and after the procedure. See abstract.

Claims 1-8, 11-26, lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Obagi (4,874,361).

Ho et al teach laser resurfacing in pigmented skin and skin with acne scars. Ho utilizes a CO₂ laser. The patients were treated with 0.05% tretinoin cream 2-4 weeks before and after the procedure. See abstract.

Ho et al do not specify the length of the treatment.

Obagi discloses a method of treating chronic skin problems (acne, wrinkles, pigmentation disorders). Patients are treated with a composition that stimulates skin regeneration. After the composition is applied, the area is treated with light. The parameters chosen are dependent on the skin type (dark versus light), the type of peel (light versus deep), and severity of the skin condition. See column 5. However, usually the time range is 2-15 minutes with repeated treatments. See examples.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Ho et al and Obagi, and utilize the instant parameters. One would be motivated to do so since Obagi discloses that the length of treatment depends on several factors; however the time can only be in the order of minutes regardless of race. Therefore, one would be motivated to manipulate the parameters depending on the patient treated and Obagi discloses that it is within the skill of the art to do so (column 5).

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

In regards to the amount of the use of 0.1% versus 0.05% tretinoin, it is within the skill of the art to utilize the dose size in best suited for the patient absent unexpected data.

Claims 9-10, 27-28, 29-36 looks an inventive step under PCT Article 33(3) as being obvious over Ho et al (Dermatologic Surgery, 1995 December, 21(12), 1433-7 in view of Tanovich et al (5,423,803).

Ho et al teach laser resurfacing in pigmented skin and skin with acne scars. Ho utilizes a CO2 laser. The patients were treated with 0.05% tretinoin cream 2-4 weeks before and after the procedure. See abstract.

Ho et al do not teach the specific laser parameters.

Tanovich et al teach a process of skin surface peeling using laser, preferably Nd:YAG. See abstract. The method includes applying a compound to the skin to increase penetration of the light, followed by irradiating the skin with laser pulses of about 3 J/cm² and a wavelength of 1.06 micrometers. See column 3, lines 16-29. The skin is also treated by a CO2 laser having a wavelength of 1.06 micrometers and 2.5 J/cm² at pulse duration of 50ms. See column 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings the teachings of Ho et al and Tanovich et al and utilize the instant laser parameters. One would be motivated to do so since Tanovich also teaches laser resurfacing using different types of lasers, each having their own parameters. Tanovich teaches the use of both CO2 laser, with instant parameters and Nd:YAG laser with its own parameters. Therefore, one would be motivated to manipulate the laser settings and parameters, depending on the laser used.

Claims 1-6 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

-----NEW CITATION-----

US 4,374,562 A (OBAGI) 17 October 1980, see abstract and column 5.

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TRATADO DE COOPERACION DE LA PATENTE

De:
LA AUTORIDAD DE EXAMINACION PRELIMINAR INTERNACIONAL

A:
GERALD M. WALSH, PII.D.
BUSH INTELLECTUAL, PROPERTY LAW GROUP, LLC.
P.O. BOX 381146
BIRMINGHAM, AL 35238

PCT OPINION ESCRITA (PCT Regla 66)

Fecha de entrega: Febrero 25, 2004
Referencia del depósito del agente o el solicitante: PARSONS 2
Dehida Respuesta: dentro de 2 meses/días de la fecha de entrega de arriba
Número de la solicitud internacional: PCT/US02/27570
Fecha del depósito internacional: Agosto 28, 2002
Fecha de la Prioridad: Enero 14, 2002
Clasificación de Patente Internacional (IPC) o ambas, clasificación nacional y Clasificación internacional (IPC): IPC: A61B 17/00, 17/50; A61K 31/74, 7/42 y
US Cl.: 606/1, 2, 9, 131; 607/89; 424/400, 59, 78.02
Solicitante: PARSONS, DIANA J.

1. Esta opinión escrita es la primera (primera, etc.) dibujada por esta Autoridad de Examinación Preliminar Internacional.
2. Esta opinión escrita contiene indicaciones relacionadas a los siguientes ítems:
 - Base de la opinión.
 - Declaración razonada bajo la Regla 66.2 con respecto a la novedad, paso inventivo o aplicabilidad industrial: citaciones y exposiciones que apoyen tal declaración.

3. El solicitante por este medio invita a responder a esta opinión.

¿Cuándo? Mirar el tiempo límite indicado debajo.

¿Cómo? Por el sometimiento de una respuesta escrita, acompañada, cuando sea apropiado, por acuerdos, de acuerdo a la Regla 66.3. Para la forma y el lenguaje de los acuerdos, mirar Regla 66.8. y 66.9.

Además Para una oportunidad adicional a los acuerdos sometidos, mirar Regla 66.4.
Para la obligación de los examinadores para considerar acuerdos y/o argumentos, mirar regla 66.4 bis
Para una comunicación informal con el examinador, mirar regla 66.6.

Si la respuesta no es depositado, el reporte de la examinación preliminar internacional la establecerá en las bases de esta opinión.

4. La fecha final para la cual se deberá establecer el reporte de examinación preliminar internacional de acuerdo a la Regla 69.2 es: Mayo 14, 2004

Oficial Autorizado
(Firma ilegible)

Teléfono: (703) 308-0196

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4. La fecha final para la cual se deberá establecer el reporte de examinación preliminar internacional de acuerdo a la Regla 69.2 es: Mayo 14, 2004

Oficial Autorizado
(Firma ilegible)

Teléfono: (703) 308-0196

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OPINIÓN ESCRITA

Solicitud Internacional No.
PCT/US02/27570

BASE DE LA OPINION

- Con respecto a los elementos de la solicitud internacional:
 - ☒ La solicitud internacional según depositada originalmente.
 - ☒ La Descripción:
Páginas 1-11, según depositada originalmente.
 - ☒ Las Reivindicaciones:
Páginas 12-16, según depositada originalmente.
 - ☒ Los Dibujos:
Páginas 1-4, según depositada originalmente.

Razonamientos declarados bajo la Regla 66.2 con relación a la novedad, paso inventivo o aplicabilidad industrial; citaciones y exposiciones que apoyen tales declaraciones.

• DECLARACION

Novedad (N)	Reivindicación 8-10, 13, 15, 17, 18, 23-28, 31, 33 y 36	SI
	Reivindicación 1-7, 11, 12, 14, 16, 19-22, 29, 30, 32, 34 y 35	NO
Paso Inventivo (IS)	Reivindicación NINGUNA	SI
	Reivindicación 1-36	NO
Aplicabilidad Industrial (IA)	Reivindicación 1-36	SI
	Reivindicación NINGUNA	NO

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Citaciones y Exposiciones.

Reivindicaciones 1-7, 11-12, 14, 16, 19-22, 29-30, 32, 34 y 35 falta novedad bajo Artículo PCT 33(2) según ha sido anticipado por Kye YC (Cirugía Dermatológica, Octubre 23, 1997: 880-883).

Kye YC descubre un método de volver a allanar las cicatrices faciales marcadas con hoyos con un pulsado de láser Er: YAG. Los pacientes eran tratados con 0.05% tretinoín e hidrocortisona por dos a cuatro horas a la semana antes y después del proceso del láser. El láser era ajustado a 500mj/ mirar abstracto.

Reivindicaciones 1, 5-7, y 17-20 falta de novedad bajo Artículo PCT 33(2) según ha sido anticipado por Ohagi (4,874,361). Ohagi descubre un método para tratar problemas crónicos de la piel (acné, arrugas, desórdenes de pigmentación). Los pacientes son tratados con una composición que estimula la regeneración de la piel. Después que la composición es aplicada, el área es tratada con luz. Los parámetros elegidos son dependientes del tipo de piel y la severidad de la condición de la piel. Mirar columna 5. Sin embargo, usualmente la escala de tiempo es de 2-15 minutos con tratamientos repetidos. Mirar ejemplos.

Reivindicaciones 1-7, 11-12, 14, 16, 19-22, 29-30, 32, 34-35 falta de novedad bajo Artículo PCT 33(2) según ha sido anticipado por Ho et al (Cirugía Dermatológica Diciembre 21, 1995 1035-7).

Ho et al enseña un láser para volver a allanar una piel pigmentada y una piel con cicatrices de acné. Ho utilizó un láser de CO2. Los pacientes fueron tratados con 0.05% de crema tretinoín de 2-4 semanas antes y después del proceso. Mirar abstracto.

Reivindicaciones 1-8, 11-26, falta un paso inventivo bajo Artículo PCT 33(2) como siendo obvio sobre el anterior arte según se aplicó en el párrafo precedente inmediatamente y además en vista de Ohagi (4,874,361).

Ho et al enseña un láser para volver a allanar una piel pigmentada y una piel con cicatrices de acné. Ho utilizó un láser de CO2. Los pacientes fueron tratados con 0.05% de crema tretinoín de 2-4 semanas antes y después del proceso. Mirar abstracto.

Ho et al no especifica la longitud del tratamiento.

Ohagi descubre un método para tratar problemas crónicos de la piel (acné, arrugas, desórdenes de pigmentación). Los pacientes son tratados con una composición que estimula la regeneración de la piel. Después que la composición es aplicada, el área es tratada con luz. Los parámetros elegidos son dependientes del tipo de piel (oscura versus luz), el tipo de corteza (luz versus profunda), y la severidad de la condición de la piel. Mirar columna 5. Sin embargo, usualmente la escala de tiempo es de 2-15 minutos con tratamientos repetidos. Mirar ejemplos.

Esto habría sido obvio para una de habilidad ordinaria en el arte en el tiempo que la invención fue hecha para combinar las enseñanzas de Ho et al y Ohagi y utilizar los parámetros instantáneos. Uno podría estar motivado a hacer desde entonces los descubrimientos de Ohagi que la longitud del tratamiento depende de varios factores; sin embargo, el tiempo solo podrá ser en la orden de minutos sin importar la raza. Por lo tanto, uno puede estar motivado a manipular los parámetros dependientes en el tratamiento del paciente y Ohagi descubre que esto es dentro de habilidad del arte para hacer tanto. (Columna 5).

En respecto a la cantidad de uso de tretinoín 0.1% versus 0.05%, esto es dentro de la habilidad del arte a utilizar la dosis que satisfaga mejor el dato inesperado en ausencia del paciente.

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Reivindicación 9-10, 27-28, 29-36 falta un paso inventivo bajo el Artículo PCT 33(3) según ha sido obvio bajo Ho et al (Cirugía Dermatológica, Diciembre 21, 1995, 1035-7 en vista de Tanovich et al (5,423,803).

Ho et al enseña un láser de reallanamiento en una piel pigmentada y piel con cicatrices de acné. Ho utiliza un láser de CO2. El paciente fueron tratados con 0.05% de crema de tretinoin de 2-4 semanas antes y después del procedimiento. Mirar abstracto.

Ho et al no enseña los parámetros específicos del láser.

Tanovich et al enseña un proceso de un láser para uso de depilación de superficie de piel, preferiblemente Nd: YAG. Mirar abstracto. El método incluye la aplicación de un contaminante a la piel para incrementar la penetración de la luz, seguido por la irradiación de la piel con pulsos de láser de aproximadamente 3J/cm² y una longitud de onda de 1.06 micrómetro. Mirar la columna 3. Líneas 10-29. La piel también es tratada por un láser CO2 teniendo una longitud de onda de 1.06 micrómetro y 2.5J/cm² a una duración de pulsos de 50ns. Mirar columna 4.

Podría haber sido obvio que una de la habilidad ordinaria en el arte del tiempo de la invención fue hecha para combinar la enseñanzas de Ho et al y Tanovich et al y utilizar los parámetros de láser instantáneos. Uno podría estar motivado a hacer esto desde que Tanovich también enseña el láser de reallanamiento usando diferentes tipos de láser, cada uno teniendo sus propios parámetros. Tanovich enseña el uso de ambos láser CO2 con parámetros instantáneos y láser Nd: YAG con sus propios parámetros. Por lo tanto, uno puede estar motivado para manipular el ajuste y parámetros del láser, dependiendo el láser usado.

Reivindicación 1-36 cumple los criterios reservados en el Artículo PCT 33(4), y así cumple la aplicabilidad industrial porque la reivindicación del problema de referencia puede ser hecha o usada en la industria.

Nueva Citación

US 4,874,361 A (OBAGI) Octubre 17 1989, mirar abstracto y columna 5

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United States Patent [11]

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Obey

[13] Date of Patent: Oct. 17, 1989

[54] METHOD FOR HEALING DAMAGED SKIN

[76] Invention: Zeta Z. Obey, 200 Sunny Dr., Donita, Calif. 92002

[21] Appl. No.: 847,885

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[31] Int. Cl. AGIN 1/30

[32] U.S. Cl. 404/20; 128/395

[33] Field of Search 404/20, 21; 128/L1, 128/L2, 395 424/L1

[56] References Cited

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4,592,700	12/1983	Mauldin	128/395

Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—BROWN, MARIN, HALL & McClain

[57] ABSTRACT

A composition and method of using the same for treating human skin of all types for a wide variety of skin ailments, including acne, blemishes, aging, sun damage and cancerous lesions, and other problems associated with skin disorders. The method comprises applying to a region of damaged skin a composition of retinoid-acetic acid, a surfactant having cell growth stimulatory properties, and an emulsifier. The ratio of the various ingredients can be varied to affect optimal treatment for a particular type of skin. For treatment of certain disorders, the effects of the composition is enhanced if the skin is irradiated with a suitable light source. The latter stimulates even skin regeneration.

Several days after treatment, the damaged area peels off, and a new layer of vibrant, evenly colored, healthy skin is apparent. The procedure can be repeated without adverse effects, although generally a single application is sufficient.

16 Claims, No Drawings

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METHOD FOR HEALING DAMAGED SKIN

BACKGROUND OF THE INVENTION

Over the years, a variety of medical treatments have been developed to treat chronic skin problems, such as acne, sun damage, precancerous lesions, scars, pigmentation disorders, wrinkles, and the like. These can be classified as procedures and methods that either supplement or prevent the loss of nutrients needed for healthy skin, or that remove regions of damaged skin. The former category encompasses a truly bewildering variety of skin creams, lotions and ointments that are generally available over-the-counter. These creams either act to prevent water loss from the skin, or to deliver nutrients into the dermal layers. Suitable examples of such creams can be found in U.S. Pat. Nos. 4,424,114 and 4,211,889. Also, medical creams and antibiotics are used to treat acne vulgaris, or other skin conditions, are known to those skilled in the art.

For the most part, only three methods are now in routine medical use for removing damaged skin. They all involve the application of particular chemicals. The first can be termed the trichloroacetic acid peel; the second, retinoic acid or retic acid peel; and third, the chemical peel. All three are of limited use, because as they are generally restricted to fair skinned people, and can often cause severe complications.

The trichloroacetic acid peel involves the application of trichloroacetic acid to the damaged area, followed by a short reaction time to allow it to interact with the damaged skin. Several days later, the damaged area peels off. The limitation of this method is that it is generally not suitable for deep peel dark skinned people with significant pigmentation because it peels the skin unevenly, and then leaves uneven pigmented skin. For that reason, only fair skinned people are peeled with trichloroacetic acid treatment. Blacks and other dark skin race groups are excluded.

The second peel process involves the use of either retinoic acid or retic acid. The use of either of these chemicals is generally restricted to correcting superficial skin problems. They are further limited in that they often can cause skin irritation.

The third peel process, or chemical peel, also has numerous drawbacks. First, it involves the use of phenol. The latter is known to be toxic and is thought to be potentially carcinogenic. Thus, this method cannot be carried out in a hospital, or in a similar controlled setting. In addition, the method is very painful and often requires that the patient be given anesthesia during its application. Further, while the procedure does peel the skin evenly, it nevertheless often leaves uneven pigmentation of varying skin shades, or total loss of color, and, moreover, does not lend itself to repeat application because of its severe nature.

In addition to the above-described three types of skin peels, there exist a myriad number of less useful materials and procedures. For example, short exposure to ultraviolet light, with UVA or UVB, is known to be beneficial for psoriasis, vitiligo and sunburns, freckles, and simultaneously causes tanning of the skin. None of these methods uses full spectrum sun lamps.

It should be apparent from the above description that there is a need for additional methods of treating chronic skin disorders, particularly a method that would be universally applicable to all races, that is easy

to perform, and, if need be, can be repeated one or more times

SUMMARY OF THE INVENTION

A novel composition and method is described that has hitherto not been recognized as being useful for treating a wide variety of chronic skin problems, particularly, pigmentation disorders, acne, wrinkles, aging spots, and superficial precancerous skin spots, as well as other disorders. The composition can be used alone, or with brief exposure to a suitable light source.

Presently, virtually all these disorders are either untreatable or treatable with limited success. The procedure consists of applying to the skin a composition comprising trichloroacetic acid, a surfactant having cell growth stimulatory properties, and an emulsifier that enhances even application of the composition to the skin so as to ensure subsequent uniform exposure of the skin to the composition, as well as to facilitate light treatment if the latter is used. In addition, anti-oxidant agents or chemicals that prevent oxidation can be added to the composition.

Depending on the type of skin disorder, as well as the race of the patient, the concentrations of the three main ingredients, that is, trichloroacetic acid, surfactant and emulsifier, will vary. For high-skinned patients or for superficial skin problems, low concentrations of trichloroacetic acid will be utilized in the range of about 10%, while for dark-skinned patients, or if more severe treatment is required, concentrations up to approximately 30% will be employed.

For treatment of deep skin disorders the effect of the composition is enhanced if a short time after application of the composition, the skin is irradiated with a light source that generates ultraviolet, infrared, and full spectrum visible light. The light causes with the composition thereby causing skin regeneration without burning. Depending upon the severity of the skin disorder, exposure to the light source will be for either short or long durations of time. The latter generally will not exceed 15 minutes.

About three days following application of the composition and irradiation, the skin begins to peel, and the peeling process is essentially complete by the end of the tenth day. During this time, the cell growth stimulating agent effectively provides a vibrant new layer of skin to replace the damaged skin. The procedure can be used to treat virtually all parts of body skin and is not restricted, as are most other methods, to treatment of the face. Moreover, unlike other methods, the process described herein can be repeated as often as is needed as it does not irreversibly kill skin cells needed for future skin growth.

DETAILED DESCRIPTION OF THE INVENTION

A preferred embodiment of the instant invention consists of applying a composition to damaged areas of skin, followed by irradiating the area to effect a peeling and removal of the skin. Exposure to light acts to stimulate a total regeneration of the treated area and aids in correcting the damage. It should be noted that while the peeling process is enhanced by the application of light, that for superficial peels, the composition alone performs satisfactorily.

The composition contains essentially of three ingredients. The first is an acidic substance, such as for example, trichloroacetic acid. The second is a surfactant

having cell growth stimulatory activity, and the third is an emulsifier. By mixing trichloroacetic acid with the other two components, a special emulsion known composition is formed which can be used to remove either deep or superficial or damaged skin. Auxiliary materials and methods can be employed prior to, or after, treatment, with the composition alone, or the composition coupled with light exposure. These are not directly involved in affecting the skin peeling process. For example, regions of skin that are not the subject of treatment are protected from irradiation, such as the patient's eyes, lips, etc. The methods for protecting these areas are well known to those skilled in the art which consist of sunglasses, or cloth coverings, bandages, emulsions, etc. In addition, prior to the application of the composition, the area to which it is applied can be cleaned with a suitable bacteriostatic agent.

While it is anticipated that a variety of acidic substances, in addition to trichloroacetic acid, may be used in the subject invention, such as for example phenol, resorcinol, etc., trichloroacetic acid is preferred as it has been extensively tested in prior art peeling processes and found to be relatively safe for such treatments. Generally, the composition will contain from 10 to about 50% trichloroacetic acid. Determinative of the concentration is whether a patient needs a superficial or deep peel as well as the patient's skin color. For superficial treatments, a concentration in the range of 10% will generally be adequate, while for more severe cases, higher concentrations of trichloroacetic acid are desirable. It will be apparent to those skilled in the art what the preferred concentration of trichloroacetic acid is for a particular application. For those treatments where the concentration of trichloroacetic acid is in doubt, however, patch testing a very small area of the patient's skin will indicate the concentration of trichloroacetic acid that should be employed. While the use of trichloroacetic acid in the peel process is not hazardous, if used alone, it may cause uneven peeling and thus yield uneven pigmented skin. Therefore, after extensive research novel surfactants and emulsifiers have been discovered that combine with the trichloroacetic acid to overcome these problems.

The second ingredient of the composition is a surfactant having cell growth stimulatory activity. The term surfactant is meant to encompass either a molecularly identified substance, or a mixture of particularly chemically characterized molecules having the described properties. A variety of suitable surfactants, either of plant or animal origin are now known to those skilled in the art. For example, epidermal growth factor, and fibroblast growth factor are two such molecules. We have found, however, that steroid saponins are preferred in the subject invention, particularly squalene saponins approved for use by the FDA having registry #121,113. Generally, they will be used at a concentration of about 0.1%; however this concentration can vary depending on the need for a light or deep peel. The deeper the peel, the higher the concentration of the cell growth stimulatory molecules that will be utilized.

The third ingredient in the invention composition is an emulsifier. Emulsifiers are defined as those compounds which are pharmacologically and physiologically inert by the dermal skin surface and which impart a favorable cosurfactancy to the compositions for their topical application to the skin, and moreover, which facilitate the taking up of the composition by absorption and/or reabsorption and/or permeation. A

variety of emulsifiers can be used, particularly salts of aliphatic monocarboxylic acids with 10 to 22 carbon atoms, such as calcium stearate, magnesium stearate, aluminum stearate or zinc stearate. Also, emulsifier mixtures of mono- and/or diglycerides of aliphatic monocarboxylic acids with 10 to 22 carbon atoms can be used, but these tend to reduce the activity of the trichloroacetic acid. However, we have determined that chlorbutadiene gluconate works satisfactorily when it is in a solution containing isopropyl alcohol. A concentration in the range of about 0.4% chlorbutadiene gluconate is most effective. The emulsifier is required to effect even spreading and absorption of the composition across and into the areas of damaged skin, and in this way ensures that upon subsequent irradiation, that the peeling of the damaged layer occurs uniformly. This in turn ensures that the new skin layer resulting after peeling does not exhibit light or dark patchy areas, rather the entire layer of skin is of uniform shading.

The composition of the instant invention can also contain small amounts of antioxidants to prevent oxidative destruction of those components of the composition susceptible thereto. Suitable antioxidants as well as their uses are described in "Antioxidants" in Volume 8 of *Ullmann's Encyclopedia of Technical Chemistry*, Fourth Edition. In addition, the composition may also contain small amounts of chemical preservatives to prevent or retard microbial degradation. Examples of useful preservatives are described on pages 440 to 441 in Volume 11, 1960, of *Ullmann's Encyclopedia of Technical Chemistry*, Third Edition. In general, the addition of about 0.01 to 0.2% by weight of preservative, relative to the weight of the total composition, suffices to prevent growth of molds, yeasts and bacteria.

Several properties of the cell growth stimulatory ingredients merit discussion. In addition to stimulating dermal cell growth, a further desirable property is its capacity to penetrate into the skin, thereby stimulating cell growth in the layers beneath those that are being removed during the peel process. While steroid saponins have been determined to have this skin penetrating property, and therefore is the preferred emulsifier in the instant invention, it is to be anticipated that a variety of other cell growth stimulatory molecules can be combined with suitable skin penetrating agents, for example such as dimethyl sulfoxide, and hence be similarly employed. In addition, it is to be further anticipated that similar results can be realized by associating, via chemical coupling, nesting in lipid vesicles or other means, a surface active substance and a cell growth stimulatory compound. In this instance, the surface active property of the ingredient will not be intrinsic to the cell growth stimulatory property, but still be deliverable to the dermal layers.

An additional property associated with the use of steroid saponins is that they ameliorate skin irritation arising from ultraviolet light treatment. While this aspect of the surfactant ingredient is appealing, it is not requisite for satisfactory results.

From a wide variety of surfactants tested, we have found that the preferred surfactant is a steroid saponin, (Caryophyll 272) produced and owned by Milbosc Company, Inc.

For certain treatments, after application of the composition to the damaged area of skin, it is treated with light that has both ultraviolet and infrared components. It is important to be aware that the purpose of light treatment is not to tan the skin, rather the light has a

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skin regenerating effect. Depending on the care of the individual, the duration of light treatment will vary. Any method for determining the sensitivity of a patient's skin to ultraviolet radiation may be used to first determine its sensitivity to a particular dose. These methods are well known to those skilled in the art, and consist of basically performing minimal erythema dose test for different time periods of exposure to determine the proper dose to be administered to a particular patient. By performing many such tests it is possible to construct a graph establishing the optimal time of exposure for a particular skin type. Generally, times on the order of minutes will be utilized regardless of race.

By doing various tests, we have found that for the purposes of the instant invention the major skin types are: Type A—very blonde and fair skin; Type B—blonde with fair skin; Type C—light skin, able to tan, easily sunburned; Type D—dark skin, able to tan, rarely sunburned; and Type E—black skin, rarely sunburned. For these classes we have further found that the amount of radiation is approximately two minutes for Type A skin, three minutes for Type B skin, three and a half minutes for Type C skin, four minutes for Type D skin, and about five minutes for Type E skin. It will of course be obvious to those skilled in the art that these times are only approximate and can be varied.

In addition to skin coloration, other factors will also be determinative of the duration of radiation. If there is a need to perform a deep peel, then radiation treatment can be expected to be carried out for longer periods of time. This is necessary as the skin has on the order of 20 to 30 layers, and if the damaged area is many layers deep, then in order to effectively peel these layers, it is desirable to prolong the period of exposure to ultraviolet light.

A variety of lamps can be utilized as a source of ultraviolet radiation with which to irradiate the skin, provided that they generate ultraviolet radiation in the range of about 290-400 nanometers. In addition it is also preferred that these lamps generate infra-red (heat) radiation typical of the spectrum of such radiation produced naturally by the sun. A variety of suitable lamps can be disposed between the lamp and the patient's skin to control either the extent or intensity of exposure.

It is important to note that the lamps utilized in the instant invention are not tanning lamps. The lamps most effectively employed are those that burn or peel the skin but do not tan it. There are a wide variety of commercial lamps from which one can choose to practice the present invention. However, we have found that the Alpine Lamp, produced by Haeovia Corporation, is particularly useful. Additionally, examples of other useful lamps are the Blake-Ray Lamp produced by Ultraviolet Products, Inc. or the Burtin Lamp produced by Burtin Company. Other can also be employed. It is further desirable that the lamp be readily portable. This facilitates practicing the invention in a doctor's office.

As described above, the dose of ultraviolet radiation is a function of the race of the patient being treated, as well as the severity of skin damage. It is anticipated that for most applications, the Alpine Lamp (Haeovia) will be located about 12 to 24 inches from the patient's skin and the skin irradiated for a time in the range of about 2-15 minutes. Generally, a dark skinned patient will require longer irradiation time than a fair skinned patient. It is worth noting that if suitable empirical tests are performed to precisely determine the dose of ultra-

violet light needed, that irradiation need be performed only once. However, it will be appreciated that the nature of the invention lends itself to multiple applications if this should be desired.

A key feature of the instant invention alluded to above is that it is applicable for treating skin of different races. It is particularly advantageously suited to peel dark skin which has a tendency to produce uneven, uncomfortable skin shading. The invention can also be used with great success to treat Oriental skin.

After application of the composition, with or without subsequent irradiation, a variety of washing and cleansing procedures can be employed to remove the composition. Subsequent care of the skin is minimal and generally consists of merely washing with any number of commercially available soap formulations. After about three days post-irradiation, noticeable peeling will occur, and this should be complete at about 15 days post-irradiation. During this time, the patient can employ standard facial hygiene washing procedures, and in some instances, it may be desirable to apply a topical cream containing a suitable antibiotic should it appear that there is a risk of dermal infection. Further auxiliary methods to aid the peeling process, but which are not necessary for its realization, is the application of a suitable skin benzoyl peroxide cream, or retinoic acid, which enhance cell regeneration to the treated area. The latter enhances the peeling process and contributes to the overall appearance of the new skin layer. At later times during the peeling process, a variety of skin whitening agents can be favorably applied to the patient's skin to reduce any redness, or discoloration that may appear.

It will be understood by those skilled in the art that the following examples are mere representations of several readily conceivable formulations of the methods utilized to realize the instant invention. Thus, they are provided by way of illustration and not limitation.

EXAMPLE I

Preparation of Saccharum Cell Growth Stimulatory Ingredient

An organic extract of the yucca plant was prepared using standard synthetic organic chemistry techniques, which yielded a steroidal saponin fraction. The fraction is slightly hygroscopic, and yields a clear solution at a 10% concentration in water. Moreover, a 20% solution has a pH of approximately 4.5, and a density of about 373 gms/per liter. The steroidal saponin fraction is slightly hygroscopic, water soluble, and insoluble in benzene and ether. The material is approved for use by the United States government under Federal Registration number paragraph 121.1163.

EXAMPLE II

The face of a 20 year old female suffering from acne vulgaris was washed with suitable antibacterial cleansing agents, and then a composition consisting of 10% trichloroacetic acid, 0.1% cell growth stimulatory agent as described in Example I, and 0.4% chlorhexidine gluconate, was applied to the damaged areas. Areas of the skin were covered with suitably fastened cloth to protect it from unnecessary ultraviolet light damage, and then the patient placed a distance of 12 inches from the light source. A Burtin K lamp (Haeovia) was utilized, and the patient's face was irradiated for a period of 5 minutes. Next, following irradiation, the patient's skin was cleansed to remove the com-

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portion, and washed with a mild soap solution. Three days after returning home, significant peeling was apparent upon a routine check-up, and by ten days, the peeling process was complete. A second treatment done one month after the first treatment was similar and the composition alone was used.

EXAMPLE III

Treatment of a Dark Skinned Patient

A composition having approximately 30% trichloroacetic acid, 0.1% compound 272 as described in Example I, and 0.4% chlorhexidine gluconate, was applied to the skin of a 45 year old negro female with severe facial acne, scars, and pigmentary problems. These areas of the skin that were not the subject of treatment were shielded from exposure to ultraviolet light, and then the face irradiated at a distance of 1 1/2 feet, for 12 minutes utilizing a Burdick K Lamp as described in Example II. Similar to the results seen in the preceding Example, after three days post treatment peeling was apparent, and was substantially complete by 10 days. Three treatments were needed, one with light and two without.

EXAMPLE IV

Treatment of Dark Skinned Patients With Severe Pigmentary Complications

A 44 year old female negro patient suffering from severe acne scarring, and congenital skin problems associated with sebaceous gland hyperplasia was treated as described in the above examples with the following modifications. Trichloroacetic acid was used at a concentration of 30%, and 3 treatments were performed, one with light and four without. Light exposure was for 12 minutes. Marked improvement in the patient's facial appearance was apparent after the first treatment, and was complete by the end of the fifth treatment.

EXAMPLE V

Peel Process Applied to Sun Damaged White Skin

A composition containing approximately 30% trichloroacetic acid, 0.1% compound 272 obtained from Milbuck Corp., and an emulsifier, chlorhexidine gluconate, was applied to the face of a 70 year old caucasian male exhibiting severely sun damaged skin. Because of the severe skin damage, a slightly higher amount of trichloroacetic acid was used when compared to the patient treated in Example II. The remaining treatment was similar to that described in Examples II and III, except that only one treatment with light was needed. Ten days post treatment the patient revealed new skin clearly lacking the sun damaged regions.

EXAMPLE VI

Removal of Wrinkles

A white 63 year old man was treated as described in the above examples excepting that the composition had 30% trichloroacetic acid, and the patient was exposed to light for 6 minutes. Two treatments were performed, one with light, the other without. Virtually all wrinkles were removed several weeks post treatment.

EXAMPLE VII

Treatment of Oriental Skin

A 60 year old Chinese female with age spots (lentigo senilis), and displays sun damage and wrinkles on the

face was treated as follows. A composition as described in Example III was applied to the face, and the patient irradiated with light generated from an Burdick K (Hamonite) for about 3 minutes. After radiation treatment the face was washed with a mild soap solution. Three days post treatment peeling was apparent, and complete by the end of ten days.

EXAMPLE VIII

Treatment of Actinic Keratosis (precancerous lesions) and Leukoplakia

A white skinned 52 year old male was treated as described in Example V with the following changes. 30% trichloroacetic acid was used, and a single exposure to light for 8 minutes was employed. Nearly complete elimination of the skin disorder was achieved.

EXAMPLE IX

Removal of Precancerous Lesions from Oriental Skin

A 44 year old Chinese female was treated to remove precancerous lesions using the materials and methods as described above. The composition consisted of 30% trichloroacetic acid, and treatment was effected 2 times, once with light and once without. Light exposure was for 10 minutes. Ten days post treatment there was a marked reduction in the severity and number of wrinkles.

EXAMPLE X

Treatment of Hispanic Skin Suffering From Improper Facial Peel

A 62 year old Hispanic female suffering from severe pigmentation problems caused by a prior facial peel was treated by the method of the instant invention using the materials and methods described in the preceding examples with the following exceptions. Approximately 30% trichloroacetic acid was utilized in the composition, and the duration of light exposure was 12 minutes. Additionally, a total of 4 treatments were formed, one with light alone, and three with the composition alone. It will be apparent to those that are skilled in the art that there are a variety of modifications that can be made to the materials and methods described above without departing from the intended purpose of this instant invention. Thus, it is intended that the instant invention is not to be construed as being limited to the presented examples, and is only limited by the scope of the appended claims.

Claims

1. A method of treating damaged areas of skin comprising the steps of:
 - applying to said damaged area a therapeutically effective amount of a composition comprising trichloroacetic acid, a surfactant having growth stimulatory activity, and an emulsifier, and
 - irradiating said area of damaged skin in contact with said composition for a time sufficient to reduce peeling of said damaged area.
2. A method as described in claim 1 wherein said composition comprises about 10-50% trichloroacetic acid, and 0.1% surfactant having growth stimulatory activity.
3. A method as described in claim 2 wherein said growth stimulatory agent is a steroid epoxide.

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4. A method as described in claim 3 wherein said steroid saponein is registered with the Federal government and has Federal registration no. 121-1161.

5. A method as described in claim 6 wherein said emulsifier is oleylalkylamine glucosate.

6. A method as described in claim 1 wherein said emulsifier is selected from the group consisting of acids and mono- and diglycerides of aliphatic monocarboxylic acids having 10-22 carbon atoms.

7. A method as described in claim 1 wherein irradiation of damaged skin comprises light of wavelengths from about 290-400 nanometers, visible light and infrared light.

8. A method as described in claim 1 wherein said damaged skin is selected from the group consisting of subcorneal keratosis, acne rosacea, keratosis actinica, and acne vulgaris, melasma, actinic keratosis, and seborrhea.

9. A method of treating damaged areas of skin comprising the steps of

testing the skin to determine its sensitivity to light radiation;

shielding non-damaged areas of skin from said radiation;

applying to said damaged area a therapeutically effective amount of a composition comprising trichloro-

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acetic acid, a surfactant having cell growth stimulatory activity, and an emulsifier; and radiating the damaged area of skin having said composition for a time sufficient to induce peeling of said skin based on its sensitivity to said radiation.

10. A method as described according to claim 9 wherein said composition comprises about 10-30% trichloroacetic acid.

11. A method as described in claim 10 wherein said surfactant having growth stimulatory activity is a steroid saponin.

12. A method as described in claim 11 wherein said steroid saponin has Federal Registry No. 121-1161.

13. A method as described in claim 12 wherein said composition comprises 0.1% surfactant.

14. A method as described in claim 13 wherein said light radiation comprises light in the region of about 290-400 nanometers, visible and infrared light.

15. A method for treating skin disorders comprising applying to a region of skin a therapeutically effective amount of a composition comprising between about 10-50% trichloroacetic acid, 0.1% steroid saponin, and an emulsifier for a time sufficient to induce peeling of said skin.

16. A method as described in claim 15 wherein said emulsifier is oleylalkylamine glucosate.

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PATENTE DE ESTADOS UNIDOS
Obagi

Patente Número: 4,874,361
Fecha de la Patente: Octubre 17, 1989

METODO PARA CURAR DAÑOS DE LA PIEL

Inventor: Zein E. Obagi, 200 Surry Dr., Bonita, Calif. 92002

Número de Solicitud: 947,085

Depositada: Diciembre 29, 1986

Clase Internacional: A61N 1/30

Clase Estadounidense: 604/20; 128/395

Campo de búsqueda: 604/20, 21; 128/1.1, 128/1.2, 395; 424/1.1

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4,558,700	12/1985	Mutzhos	128/395

Examinador Primario - John D. Yasko

Abogado, Agente, o Firma - Brown, Martin, Haller & McClain

ABSTRACTO

Una composición y método de uso del mismo para tratar piel humana de todas las razas para una variedad amplia de enfermedades de piel, incluyendo acné, manchas, envejecimiento, daños del sol y lesiones cancerosas, y otros problemas asociados con los desórdenes de la piel. El método consiste en aplicar a la región del daño de la piel una composición de ácido tricloroacético, un surfactante teniendo propiedades de crecimiento estimulador de células y un emulsificador. El cociente de los varios ingredientes puede ser variado al efecto del tratamiento óptimo para un particular tipo de piel. Para el tratamiento de ciertos desórdenes, el efecto de la composición es realzado con una fuente de luz conveniente si la piel está irritada. El último estimula la regeneración uniforme de la piel.

Varios días después del tratamiento, el área dañada es descascarada, y aparenta que es una piel saludable con una nueva capa de vibrante, coloreada uniformemente. El proceso puede ser repetido sin efectos adversos, aunque generalmente una sola aplicación es suficiente.

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**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

PATENT NO. : 4,874,361

DATED : October 17, 1989

INVENTOR(S) : Obagi, et al

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page item (76) should read --

Zein E. Obagi and
George H. Michel ---

Signed and Sealed this
Twenty-eighth Day of April, 1990

Attest

HARRY F. MARBLE, JR.

Acting Officer

Commissioner of Patents and Trademarks

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OFICINA DE MARCAS Y PATENTES DE ESTADOS UNIDOS

CERTIFICADO DE CORRECCIÓN

Patente no. : 4,874,361

Fecha: Octubre 17, 1989

Inventor: Obagi, et al

Esto certifica que aparece un error en la patente arriba identificada y que dicha letra de patentes es por este medio corregida como se muestra debajo:

En el ítem de la página titulada (76) deberá leerse:

Zein E. Obagi y
George H. Michel

Firmado y Sellado este día Veintiocho de Abril del 1992

Harry F. Manbeck, Jr.
Comisionado de patentes y marcas

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PCT FEE CALCULATION SHEET

Annex to the Request

Applicant's reference
to a reference 01-2047.02
Applicant

International Application No.

Date stamp of the receiving Office

CALCULATION OF PRESCRIBED FEES

1 TRANSMITTAL FEE 240.00 Y
2 SEARCH FEE 450.00 X

International Search to be carried out by US
(If two or more international Searching Offices are designated to carry out the international search, indicate the name of the Authority which is chosen to carry out the international search.)

3 INTERNATIONAL FEE

Basic Fee

Where class (b) of Box No. IX applies, enter Sub-total number of sheets 26

Where class (b) of Box No. IX does not apply, enter Total number of sheets

b1 For 30 sheets 407.00 b1

b2 0 9.00 = 0.00 b2
number of sheets for sheets of 30

b3 additional documents (only if separate listing part of document is filed in computer readable form under Section 87(1)(i), or both in that form and on paper, under Section 88(1)(ii))

b3 for per sheet b3

Add amounts entered at b1, b2 and b3 and enter total at B 407.00 B

Designation Fees

The international application contains 29 designations

S 28.00 = 440.00 D
number of designations for amount of designation fee payable (maximum 3)

Add amounts entered at B and D and enter total at C 847.00 C

(Applicants from certain States are entitled to a reduction of 35% of the international fee. Where the applicant is for all applications are so entitled, the fee is to be entered at 1 to 35% of the sum of the amounts entered at B and D.)

4 FEE FOR PRIORITY DOCUMENT (if applicable) 15.00 F

5 TOTAL FEES PAYABLE 1,552.00
AGS amount entered at T, S, I and P, and enter total in the TOTAL box TOTAL

The designation fees are not paid at this time

MODE OF PAYMENT

X authorisation to charge deposit account (see below)

postal money order

cash

cheques

X cheques

bank draft

revenue stamps

other (specify):

AUTHORISATION TO CHARGE (OR CREDIT) DEPOSIT ACCOUNT (This mode of payment may not be available at all receiving Offices)

Authorisation to charge the total fees indicated above

X (This section may be marked only if the conditions for deposit accounts of the receiving Office are provided) Authorisation to charge any deficiency or credit any overpayment in the total fees indicated above.

Authorisation to charge the fee for priority document

Receiving Office RO US

Deposit Account No 90-0656

Date Aug-28-02

Name Gerald M. Walsh, Ph.D

Signature: Gerald M. Walsh

Form PCT/PROTON (Admin) (January 2002)

See Annex to the fee calculation sheet

Express Mail Label No.: ET927169716US

7.1

7A

Esta hoja no es parte y no cuenta como una hoja de la solicitud internacional
PCT

HOJA DE CALCULO DE HONORARIOS

Referencia del Depósito del Agente o Solicitante: 01-2047.02

CALCULO DE LOS HONORARIOS PRESCRITOS.

1. TRANSMISIÓN DE HONORARIOS..... 240.00 T
2. HONORARIOS DE BUSQUEDA..... 450.00 S

Busqueda Internacional será llevada a cabo por US

3. HONORARIOS INTERNACIONALES

Honorarios básicos

Subtotal de hojas 26

Total de hojas 26

Primeras 30 hojas.....407.00

Número de hojas en exceso de 30= 0 Costo por hoja 9.00

La solicitud internacional contiene 89 designaciones

5	x	88.00	=	440.00
número de designaciones		cantidad de costo		
de honorarios pagables		de designación		

Suma de Cantidades 407 + 440= 847.00

Honorarios por documento de prioridad: 15.00

TOTAL DE HONORARIOS PAGANDEROS: 1,352.00

MODO DEL PAGO

- Autorización para cargar a una cuenta de depósitos (mirar debajo).
- Cheque

AUTORIZACIÓN PARA CARGAR EN UNA CUENTA DEPOSITO O CRÉDITO

- Autorización para cargar cualquier deficiencia o crédito, cualquier sobrepago en los honorarios totales indicados arriba.

Oficina de Recepción: RO/ US

Número de Cuenta de Depósito: 50-0686

Fecha: Agosto 28, 2002

Nombre: Gerald M. Walsh, Ph.D.

Firma: (Firma ilegible)

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SOLICITUD PREVIA PARA RESCINDIR LA SOLICITUD DE NO PUBLICACION

Número de solicitud: 10/047,335

Fecha de depósito: Enero 14, 2004

Primer inventor nombrado: Diana J. Parsons

Título: Método y proceso para producir una piel de apariencia juvenil, de poros pequeños y suave.

Número de Abogado: 01-2047.02

Grupo de arte unitario: 1616

Examinador: Williamson, Michael A.

Yo por este medio rescindo la solicitud previa que la solicitud identificada arriba no está publicada bajo 35 U.S.C. 122(b).

Fecha: Agosto 28, 2002

Firma: (Firma ilegible)

Nombre Mecnografiado o impreso: Gerald M. Walsh, Ph.D.

Esta solicitud deberá ser firmada en conformidad con 37 CFR 1.33 (b)

Nota: Depositando esta rescisión de una solicitud de no publicación previa es considerada el aviso de un depósito de requerimiento subsecuente extranjero o internacional por 35 USC 122(b)(2)(B)(iii) y 37 CFR 1.213(c) si esta rescisión es depositada a no más tardar que 45 días después de la fecha de depósito de tal solicitud extranjera o internacional. Mirar 37 CFR 1.137(f) si un aviso de depósito de requerimiento subsecuente extranjero o internacional por 35 USC 122(b)(B)(iii) y 37 CFR 1.213(c) no está depositada dentro de cuarenta y cinco (45) días después de la fecha del depósito de la solicitud extranjera o internacional.

CERTIFICADO DE ENTREGA O TRANSMISION

Yo por este medio certifico que esta correspondencia está siendo depositada con los Servicios Postales de Estados Unidos con suficiente franqueo según la primera clase entregada en una dirección sobre la: Comisionada de Patentes, P.O. Box PG Pub, Washington, DC 20231, o transmisión por fax a la Oficina de marcas y patentes de Estados Unidos.

Nombre (impreso/mecnografiado) Gerald M. Walsh, Ph.D.

Firma: (Firma ilegible)

Fecha: Agosto 28, 2002

74

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PCT

POWER OF ATTORNEY

(for an international application filed under the Patent Cooperation Treaty)

[PCT Rule 90.4]

The undersigned applicant(s) (names should be indicated as they appear in the request)

Diana J. Parsons

hereby appoints (appoints) the following person as: ☒ agent ☐ authorized representative

Name and address

(if only name follows, give name for a legal entity; full official designation. The address must include postal code and name of country)

Gerald M. Walsh, Ph.D., Attorney; Frank M. Caprio, Attorney; Stephen H. Hall, Attorney, and
Arlita S. Darnian, Attorney
Lunier Ford Shaver & Payne, P.C.
200 West Side Square, Suite 5000
P.O. Box 2087
Huntsville, Alabama 35804
U.S.

to represent the undersigned before

- ☒ all the competent International Authorities
☐ the International Searching Authority Only
☐ the International Preliminary Examining Authority Only

in connection with the international application identified below:

Title of the invention: Method and Process for Producing Youthful-Appearing, Small-Pored, and Smooth Skin

Applicant's or agent's file reference: 01-2047.02

International application number (if already available):

Deal with the following Office US as receiving Office
and to make or receive payments on behalf of the undersigned.

Signature of the applicant(s) (where there are several applicants each of them must sign; where there is one applicant, indicate the name of the person
filling out the request in which the person signs. If such signature is not sufficient, then attach the request to the power)

Diana J. Parsons

Date: August 14, 1992

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PCT

PODER DE ABOGADO

(PCT Regla 90.4)

(para una solicitud internacional depositada bajo el Tratado de Cooperación de Patente)

El solicitante firmante: Diana J. Parsons

Por este medio designa a la siguiente persona como: AGENTE

Nombre y Dirección:

Gerald M. Walsh, Ph.D., Abogado; Frank M. Caprin, Abogado; Stephen H. Hall, Abogado; y Anita S. Dunham, Abogado.

Lanier Ford Shaver & Payne, P.C.

200 West Side Square, Suite 5000

P.O. Box 2087

Huntsville, Alabama 35804

U.S.

Para representar al firmante anterior: Todas las Autoridades Internacionales Competentes.

En conexión con la solicitud internacional arriba identificada:

Título de la invención: Método y proceso para producir una piel de apariencia juvenil, de poros pequeños y suave.

Referencia de depósito del agente o solicitante: 01-2047.02

Número de solicitud internacional (si ya está disponible):

Depositada en la siguiente oficina según la oficina de recepción para hacer y recibir pagos en nombre del abajo firmante.

Firma del Solicitante:

(Firma ilegible)

Diana J. Parsons

Fecha: Agosto 19, 2002

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SUPERINDUSTRIA Y COMERCIO

Indicación : 04073355 03000000

Folios: 76

Fecha VCTD: 2024-03-04 15:10:24

Trámite : 001 PET-PRIME 379 FREE REC1 411 PRESENTAR

Características: 0000 DISEÑO DE MARCA COMERCIAL

REQUISITOS NECESARIOS PARA PRESENTACION Y AGILIZACION DEL TRAMITE

	USUARIO	RADIADOR
PATENTE DE INVENCION	()	()
MODELO DE UTILIDAD	()	()
- Indicación de que se solicita la concesión de una patente.	()	()
- Datos de identificación del solicitante o de la persona que se presenta la solicitud.	()	()
- Descripción de la invención.	()	()
- Dibujos de ser estos pertinentes.	()	()
- Comprobante de Pago de las tasas establecidas.	()	()
COMPLETA ()	INCOMPLETA ()	()
DISEÑO INDUSTRIAL ()		
- Indicación de que se solicita el registro de Diseño Industrial	()	()
- Datos de identificación del solicitante o de la persona que presenta la solicitud.	()	()
- Representación gráfica o fotográfica del Diseño Industrial o muestra del Material que incorpora el diseño.	()	()
- Comprobante de pago de las tasas establecidas	()	()
COMPLETA ()	INCOMPLETA ()	()
ESQUEMA DE TRAZADO ()		
- Indicación de que solicita el registro de un Esquema de trazado.	()	()
- Datos de identificación del solicitante o de la persona que presenta La solicitud.	()	()
- Representación gráfica del esquema de trazado	()	()
- Comprobante de pago de las tasas establecidas.	()	()
COMPLETA ()	INCOMPLETA ()	()

Firma Responsable:

Claudia M. Nova

Fecha:

79.

2020
Bogotá, D.C.,

Doctor:
JAIME EDUARDO DELGADO VILLEGAS
Apoderado
DIANA J PARSONS

Oficio N°
65425

ASUNTO:	Radicación N°	04-75585
	Solicitud internacional	PCT/US2002/27570
	Fecha inicio fase nacional	14/08/2004
	Trámite	011
	Evento	379
	Actuación	416
	Folios	001

Como resultado del examen de forma, realizado con fundamento en el artículo 38 de la Decisión 486 de la Comisión de la Comunidad Andina, artículo 27 del Tratado de Cooperación en Materia de Patentes (PCT), regla 51 bis del Reglamento y Circular Única de la Superintendencia de Industria y Comercio, se le comunica que:

- ☐ La solicitud no contiene el poder debidamente otorgado, con el lleno de los requisitos exigidos por los artículos 63 y subsiguientes del Código de Procedimiento Civil.
- ☐ La solicitud no contiene los dibujos correspondientes a las figuras 2 y 4. (Art. 26-d) Decisión 486 y numeral 5.2.5, capítulo quinto del título décimo de la Circular Única de la SIC).

En cumplimiento de lo dispuesto por el artículo 39 de la Decisión 486, se le requiere para que dentro del término de dos meses siguientes a la fecha de notificación del presente oficio, complete los requisitos anteriormente enunciados. En caso de no dar cumplimiento al presente requerimiento, la solicitud se considerará abandonada y perderá su prelación.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal), del capítulo quinto del título primero de la Circular Única N° 10 de 2001.


ALIX CARMEN CESPEDES DE VERGEL
Jefe de la División de Nuevas Creaciones.

El anterior requerimiento fue notificado por fijación en lista de fecha, 17.08.2004

202047

Sede Central Cámara LI No. 27-08 Pisos 2, 3, 7 y 10
Cecundador: 3 505220-10 Tlx: 3 505220
Sede CAH: Tlx 40A No. 34-50 2153265 al 69
Tlx: 3 505220. Línea 9881-910 168
Web: www.sic.gov.co e-mail: info@sic.gov.co
Bogotá D.C. - Colombia