Title: COMPOSITION AND METHOD FOR THE PREVENTION AND TREATMENT OF ACNE

Abstract: A compositions containing a suitable and effective concentration of Scutellaria baicalensis, Phellodendron amurense, Coptis chinensis Franch, Pheretima, aspergillus bisosterol, and Opuntia ficus-indica in a base of alcohol:acetone:polyethylene glycol is described to prevent and treat acne and furuncle. The method of treating acne and furuncle is described wherein the composition provides three function: antibacterial, defattening the skin and healing without forming noticeable scars.
SPECIFICATION

A. Title of the Invention: Composition and method for the prevention and treatment of acne

B. Cross-References to Related Applications: None, new application.

C. Statement Regarding Federally Sponsored Research or Development: None; not supported by Federal funds.

D. Reference to a “Microfiche Appendix”: Not Applicable.

E. Background of Invention

1. Field of the Invention:

   Acne vulgaris, also called acne, pimple, or break out, is the most common disease of the pilosebaceous unit of the skin. It generally appears in the second decade of life. It affects nearly 80 percent of persons at some time between the ages of 11 and 30 years. It is estimated that about 30 percent of teenagers suffer from acne of sufficient severity to require medical treatment. Acne is most commonly distributed on the face and lesser degree on the back and chest. It can persist for years and result in disfigurement and permanent scarring of the skin. About 20% of adults also suffer from low-grade persistent acne. There is a huge market demand in the search for a potent anti-acne agent. In the last couple of decades in research, there is still a deficit in the potent efficacy and low toxicity of medicines to treat acne, particularly those that do not leave a scar mark.

   Acne is believed to be caused typically when the sebaceous glands become clogged due to skin cell debris and an excess of a specific type of skin bacteria.
Sebaceous glands are located within the dermis layer of the skin along the hair shaft. Keratin and other chemicals associated with the skin can clog the hair shaft and the sebaceous gland. The bacteria, Propionibacterium acnes (P. acnes), which is always present, multiplies to a much greater degree when the sebaceous glands are clogged because the bacteria prefer an anaerobic environment, which is present when the glands become clogged. P. acnes produces a lipase enzyme that hydrolyzes triglycerides of the sebaceous gland into free fatty acids. The fatty acids along with bacterial proteins and keratin can irritate the skin tissues. This may lead to an inflammatory response and the formation of an acne lesion.

The basic pathology of acne includes two majority factors, inflammation (bacterial) and hypercornification of sebaceous follicles. The process of treatment leaves an inevitable scar and thus a good modality should provide a third function as well. This applies to both treatment and prevention. A good therapeutic should at least have the ability to solve these three situations. The conventional methods of the acne treatment, which may be classified into clinical, cosmetic and self-treatment, these have not provided a total acne control and prevention and thus an objective of providing a relatively safe and effective medicine is still in command.

Acne is the result of the hypercornification of sebaceous follicles that are found over most of the body surface, but are largest and most numerous on the face, chest, and upper back. In normal conditions, the cornified layer of the follicle remains thin. When the persistent cohesion between cells retards desquamation, it causes the thickening of the ductal epithelium to narrow the ductal lumen. The process of ductal hypercornification
causes the formation of a micromedo that may evolve into either a comedo or an inflammatory lesion.

Androgen is one of most important factors to cause an increased production of sebum. From the age of pubertal period and up, the adrenal glands mature and secrete an increased amount of androgen to increase the activity of sebaceous glands and produce more sebum. Males produce 10 times as much androgen as females, so it is not surprising that more males develop severe cases of acne A resident anaerobic organism, Propionibacterium acnes, proliferates in the environment created by the mixture of the excessive sebum and follicular cells and produces chemotatic factors and inflammatory mediators that may lead to inflammation.

Acne may also be exacerbated by several chemicals (drugs), such as iodides, bromides, glucocorticoids, and lithium, as well as the application of oil-containing compounds.

In occupational cases, acne prone workers placed in environments in which there is contact with oils frequently have poral occlusion problems. Hot humid environments may also cause sufficient hydration and swelling of the skin to predispose to acne.

Furuncle is also a very common skin disease. It is the focal suppurative inflammation of hair follicles. Furuncle may occur in the hair follicles anywhere on the body, but they are most common on the face, neck, back, armpit, buttocks, and thighs. Almost everyone has had some experience with furuncles. The painful swelling of the skin is caused by a deep bacterial infection of the skin. It can occur singly or in multiples. Furuncle can be very painful if it occurs in the areas like ear canal or nose. The condition
that furuncles develop as they close and/or expand and join together is called carbunculosis.

With a couple dozen of acne medications out on the market, it is difficult for consumers to find a good product that really works for them because there are only a few that can actually treat acne. Most products contain basically the same ingredients: retinoide and its derivatives, benzyl peroxide, salicylic acid, sulfur, antibiotics, etc. Most are only effective for a short period of time and possesses many side reactions, which include scarring of tissue.

Although the exact cause of acne is unknown, hormones, genetics, and environmental factors all seem to play a role. Androgens, such as testosterone, play an important role in the development of acne lesions. This is evidenced by the correlation between the onset of puberty and the development of acne, and the fact that acne is generally more severe in males than in females.

2. Description of the Related Art:

The type of acne treatments currently recommended depend on the type and the severity of the acne. A few over-the-counter medications (e.g., benzoyl peroxide and salicylic acid) can be used for mild forms of acne, but are ineffective for the moderate and severe cases of acne.

Tretinoin (Retin-A) is often used in combination with or as a replacement for treatment with benzoyl peroxide. Tretinoin is a derivative of vitamin A and is available for topical use. It acts to prevent comedone formation through its anti-keratinization effect. The side effects of tretinoin include heightened sensitivity to exposure to sunlight and local
irritation. Isotretinoin (Accutane ®) has been used in the treatment of severe nodulocystic acne. Accutane ® therapy can lead to improvement in acne and can, in some cases exhibit the potential to prevent most permanent scarring from inflammatory acne. The severe side effects of Accutane®, however, are often prohibitive. Dry skin, dry eyes, headache, hair thinning, musculoskeletal pain, and other complications may result from treatment with Accutane ®. Due to its teratogenicity, Accutane ® should not be used by women who are pregnant or might become pregnant.

The use of antibiotics (benzamycin, erythromycin), may be able to treat a part of the acne problem, but the side reactions which they cause to make the benefits behind the problems. They strip off layers of skin, dry and irritate skin, and make skin more susceptibility to sun burns. Topical antibiotics are mostly used for treatment of patients with mild to moderate inflammatory acne, but are ineffective against more severe inflammatory acne. To the extent antibiotics have effects against more severe (i.e. inflammatory) forms of acne, the antibiotics must be systemically administered, usually at high doses (e.g., 500 to 2,000 mg/day) initially followed by maintenance doses (e.g., 250-500 mg/day). The most commonly prescribed antibiotic is tetracycline, but erythromycin and minocycline are also used. Such antibiotics, particularly at high doses can lead to side effects including gastrointestinal symptoms such as nausea, vomiting, abdominal pain, diarrhea, rashes, and other allergic reactions. Tetracyclines also can cause fetal harm if used during pregnancy.

Hormone therapy is another approach to treatment of acne based on the involvement of androgens in the development of acne. Estrogen therapy can be effective,
but its usefulness is particularly limited in males by side effects such as gynecomastia, suppression of the testes, and uncertain effects on skeletal growth.

Most of the over counter medications contain salicylic acid, sulfur, benzyl peroxide, amino acids, etc. Most can only treat a minor aspect of acne. These topical creams, lotions, ointments and cleansers can only attack the end results of acne, but not the causes. They cannot prevent future outbreaks.

The other current treatment is systemic treatment, such as antibiotics. It is about two thirds acne reacting under these treatments. This is a long-term treatment. Other than their many side reactions, antibiotics also destroy the balance of the body bacterial system, which will create additional problems.

Currently, the common treatment of furuncle includes warm, wet compresses of the furuncle several times a day. Antibiotic soaps, topical antibiotics (applied to a localized area of the skin) are of little benefit once the furuncle has formed. Systemic antibiotics may also help to control the infection.

Based on the factor of the acne medication market, side reactions are the most common problems encountered with the current acne medications. Some medications possess potent treatment, but the patients have to stop using the drug due to the adverse effects that made their skin worse than before.

Thus, to date, there is typically a trade-off between efficacy and side effects, particularly in the treatment of more severe forms of acne. Accordingly, an effective treatment of acne, particularly its more severe forms, with clinically insignificant side effects is desired.
F. Brief Summary of the Invention:

The present invention relates a novel potent therapeutics for acne and furuncle. In the present invention, the composition has demonstrated to manage the different grade of acne, from mild, moderate to severe. It includes the treatment of the symptoms of severe acne, like comedo, papules, pustules and nodules. It does not show any kind of side reactions.

Many herbs have a long history of being used in the treatment of bacteria, virus and fungus. Several patents have been issued using herbal mixtures to treat acne.

The US Patent 6,183,747 is for herbal extracts that provide potent efficacy in the treatment of acne and furuncle. The formulated extracts of Momordica charantia L. are from either the whole plant or parts of the plant. The extracts have been formulated into aqueous solution, pads, and/or lotion. These formulations have been provided to treat acne and furuncle 2 to 3 times a day. It has demonstrated the ability to manage various grades of acne, from mild, moderate to severe, which includes comedos, papules, pustules and nodules.

The US Patent 5,962,517 to Murad is for an invention that relates to a pharmaceutical composition for the treatment of acne having an acne reduction component in an amount sufficient to reduce the redness and blemishes associated with acne. The invention also relates to pharmaceutical compositions having, in addition to the acne reduction component, a skin cell conditioning component in an amount sufficient to properly regulate the keratin and sebum production of the skin cells, thereby inhibiting the appearance of acne. In a preferred form, the skin cell conditioning component is a chromium component. In another preferred form, the composition further includes at
least one of a vitamin C source, burdock root, yellow dock root, horsetail extract, a catechin-based composition, a vitamin B.sub.1 source, a vitamin B.sub.2 source, a vitamin B.sub.3 source, a vitamin B.sub.5 source, and a vitamin E source. In a more preferred form, the invention also includes at least one amino acid component, a magnesium component, a selenium component, and biotin. The invention also relates to methods for treating acne by administering, alone or in conjunction with another composition, the pharmaceutical compositions in an amount therapeutically effective in reducing the incidence of acne and methods for additionally inhibiting the appearance of acne by conditioning skin cells.

The US Patent 5,869540 to Smith is for an invention that provides herbal treatments for aged skin employing valerian extracts and other active herbal agents that are effective as relaxants. Surprisingly, mere ingestion of valerian tea on a daily basis is effective to reduce deep wrinkles. The treatments are particularly effective on persons afflicted by stress and are shown by clinical tests to reduce wrinkles and acne lesions and to improve skin texture and skin color without an increase in puffiness such as might be expected from mere hydration of the skin. The herbal agents can be administered either in a tea or a topical composition, and a combination of the two treatments is particularly effective. A preferred herbal agent is an aqueous valerian root extract. Other herbal agents include extracts of passionflower and mullein.

In this invention, we have used six natural components: five derived from herbs and one from animal source in an alcoholic-acetone-polyethylene solution. These include β-sitosterol, Opuntia ficus-indica, Pheretima aspergillum, Scutellaria baicalensis, Phellodendron amurense, and Coptis chinesis Franch. Following is a description of the
patents that are relevant to use of herbs, including but limited to the ones used in the invention, in treatment of various skin conditions: Several patents have been granted for compositions claiming to prevent or treat human tissue scar formation, use of cactus and phellodendri. The following is a summary of some patents relevant to the invention described here.

The European Patent Application EP 0 051 354 describes a polymeric substrate coated with the polysaccharide chitosan, to which is appended the antithrombotic agent heparin.

The U.S. Pat. No. 5,116,824 describes a composite material comprising an N-acylchitosan and collagen, which is suitable for, wound dressings. Heparin may be incorporated as an antithrombotic agent.

The U.S. Patent 6,159,494 to Widgerow, et al., describes a method whereby ative scars are treated by a method of applying a microporous paper tape to the ning along the length of the scar. A contact medium is applied to the exposed surface of the tape and penetrates to the skin. The contact medium comprises an expressed gel from the plant Bulbine frutescens and may contain asiaticoside and panthenol.

The U.S. Patent 6,120,520 to Saadat, et al., is for an apparatus and methods for stimulating revascularization and tissue growth having a directable end region carrying a tissue piercing end effector. The apparatus optionally includes electrodes for depositing RF energy to form a controlled degree of scar tissue formation, means for delivering a controlled amount of a bioactive agent at the treatment site, or both.
The U. S. Patent 6,127,348 to Roufa, et al., comprises the discovery that biocompatible anionic polymers can effectively inhibit fibrosis, scar formation, and surgical adhesions.

The U. S. Patent 6,110,459 to Mickle, et al., is for a method is provided for forming a graft in heart tissue which comprises the transplantation of cells chosen from cardiomyocytes, fibroblasts, smooth muscle cells, endothelial cells and skeletal myoblasts.

The U. S. Patent 6,093,388 to Fergusons is for treating fibrotic disorders using mannose-6-phosphate composition.

The U. S. Patent to Sawyer, et al., is for the inhibitors, obtainable from tissue or secretions of leeches typically of the order Rhynchobdellida to include the treatment of Crohn's disease, tumor implantation, atherosclerosis, thrombotic microangiopathy, fibrous growths of the skin, acne, scar formation, membranous glomerulonephritis, cataracts, or infection with microfilarial nematodes.

The U. S. Patent 5,994,325 to Roufa, et al., relates to the discovery that biocompatible anionic polymers can effectively inhibit fibrosis, scar formation, and surgical adhesions. The invention is predicated on the discovery that anionic polymers effectively inhibit invasion of cells associated with detrimental healing processes, and in particular, that the effectiveness of an anionic polymer at inhibiting cell invasion correlates with the anionic charge density of the polymer.

The U. S. Patent 5,981,606 to Martin pertains to invention of therapeutic TGF-beta-wound healing compositions for reducing the formation of scar tissue and increasing
the proliferation and resuscitation rate of mammalian cells using pyruvate, an antioxidant and a mixture of saturated and unsaturated fatty acids and TGF-beta (GF) to form TGF-beta-wound healing compositions (II.A-D+GF). This invention also pertains to methods for preparing and using the TGF-beta-wound healing compositions.

The U. S. Patent 5,919,476 to Fischer, et al., is for a bandage in the form of a reinforced silicone gel sheet for the treatment of scar tissue.

The U. S. Patent 5,902,609 to Lee is for an invention that pertains to a composition for controlling wound scar production containing a calcium antagonist and a protein synthesis inhibitor.

The U. S. Patent to Fabo 5,891,076 is for a hypertrophic scar dressing that includes silicone-gel on that side of the dressing, which lies against the user's skin when worn.

The U. S. Patent 5,885,982 to Dolynchuk, et al., is for a method of treating or preventing hypertrophic scar tissue in human skin comprising applying topically an effective amount of a non-toxic amine compound that is a transglutaminase inhibitor having a free amino group is disclosed. The amine compound that is a transglutaminase inhibitor is also selective for inhibiting Type III collagen peptide cross-linking.

The U. S. Patent 5,885,581 to Massand is for a dermatological composition for use in improving the appearance of scars comprising 20-30 parts by weight of polyethylene glycol 200, 0.005-0.03 parts by weight of preservative, 0.05-0.2 parts by weight of sorbic acid, 0.5-2 parts by weight of allantoin, 1-3 parts by weight of xanthan
gum, 5-15 parts by weight of fluid onion extract (Extract Allium Cepa), dermatologically acceptable aqueous carrier 55-65 parts by weight.

The U. S. Patent 5,789,445 to Schweiger is for a topical application of benzoyl peroxide to regions of tissue scarring of a composition comprising several ingredients commonly used in cosmetic products for reduction and a softening of scar tissue.

The U. S. Patent 5,736,508 to McMichael is for methods to eliminate or reduce the appearance of scar tissue by administration of streptolysin O.

The U. S. Patent 5,731,298 to Reinmuller is for a pharmaceutical composition for non-topical wound, scar and keloid treatment is described which contains cross-linked glycosaminoglycans and conventional pharmaceutical auxiliary and/or carrier substances. The pharmaceutical composition is preferably administered intralesionally e.g. by injection in the form of a gel containing water. The cross-linked glycosaminoglycans are also suitable for use as cosmetics and skin care products.

The U. S. Patent 5,686,425 to Lee is for a composition and method that are effective in revitalizing scar tissue by introducing a bioactive substance having angiogenic activity into the scar tissue. The bioactive substance can be introduced by itself, or it can be introduced into the scar tissue in a timed-release form. The present invention is effective in treating stress urinary incontinence or localized muscular dysfunction.

The U. S. Patent 5,662,904 to Ferguson et al., is for a composition for use in the treatment of wounds to inhibit scar tissue formation during healing, comprising an effective amount of an activity-inhibiting growth factor neutralizing agent or agents.
specific against all TGF-β, except for TGF-β.sub.3, and PDGF, together with a pharmaceutically acceptable carrier.

The U. S. Patent 5,569,678 to Lee pertains to a method for controlling wound scar production by administering a calcium antagonist, alone or in a combination with or followed by a steroid, to the wound site.

The U. S. Patent 5,555,162 to Lee is for a method for improving the size and appearance of a scar associated with a fibromatosis, a keloid, or a hypertrophic wound healing disorder comprises stimulating collagenase activity in the scar. Preferably, stimulating collagenase activity is accomplished by covering said scar with a thermal insulating material that elevates the surface temperature of the scar.

The U. S. Patent 5,532,275 to Grumet is for treating wounds that is based on the system and/or topically administration of an effective amount, of para-amoio benzoic acid or its derivatives.

The U. S. Patent 5,520,926 to Ferguson is where mannose-6- and 1-phosphates and their pharmaceutically acceptable salts and bioprecursors thereof are useful in the treatment of fibrotic disorders.

The U. S. Patent 5,194,248 to Holick is for providing vitamin D analogs to an individual with topical compositions comprising tachysterol and lumisterol analogs are disclosed. Optionally, the compositions may comprise one or more sunscreen agents. Also disclosed are methods for treating decubitus or diabetic foot ulcers; ulcerative keratitis; psoriasis; wounds; and inhibiting scar formation by administering the pharmaceutical compositions comprising tachysterol or lumisterol analogs.
The U. S. Patent 5,128,375 to Tanaka, et al., is a keloid treating agent comprising as an active ingredient ethanolamine or a pharmaceutically acceptable salt thereof which is useful for the treatment of keloid such as true keloid, cicatrical keloid, hypertrophic scar, etc.

The U. S. Patent 4,865,031 to O'Keefe is for a mesh like fabric for implantation beneath or within the dermis to control formation of scar tissue.

The U. S. Patent 4,839,159 to Winter, et al., provides a composition comprising L-carnitine in a suitable vehicle for topical application in improving or healing skin conditions including wrinkling, dry or peeling skin, and burns (particularly sunburn), and in healing and prevention of scar formation, particularly that caused by infection by a pathogen.

The U. S. Patent 4,772,591 to Meisner is for a method comprising administration of ascorbic acid, a source of biologically available calcium, a precursor or stimulant of epinephrine or nor-epinephrine selected from tyrosine and phenylalanine, and an anti-inflammatory substance selected from anti-inflammatory sugars, amino sugars and biocompatible acid addition salts thereof; and anti-inflammatory amino acids to treat or reduce or tissue degenerative effects of the inflammation associated with the natural wound healing process and promotes connective tissue (scar tissue) growth in the wound.

The U. S. Patent 4,694,021 to Schweiger is for topical application to regions of tissue scarring of a composition comprised of several ingredients commonly used in cosmetic products, such as urea, which leads to a reduction and a softening of scar tissue.
The U.S. Patent 6,174,855 to Hansson provides the use of a thrombin inhibitor in
the manufacture of a product for use in the control of wound healing processes within the
body, in particular, the inhibition or prevention of fibrin-related adhesion and/or scar
tissue formation, as well as products for use in the control of wound healing processes
within the body comprising polysaccharides (e.g., chitosans) and low molecular weight
peptide-based thrombin inhibitors.

The U.S. Patent 5,736,584 to Kunkel is for an insect repelling composition
comprising mineral oil cactus extract made from the leaves and stem of the Prickly Pear
cactus.

The U.S. Patent 5,747,462 to Feunteu relates to the area of pharmacology; its
objective is to solve the technical problem of inflammation, pain, pruritus and local
hyperthermia in human beings and animal species. The composition and the
subcompositions thereof are obtained from plants of the family Cactaceae the main
methodological steps being a set of processes: production, purification, physicochemical
quantification, biotherapeutic evaluation, biopharmaceutical formulation and molecular
identification. From the molecular identification a set of molecules is recognized,
comprising carbohydrates and an aromatic amine.

The U.S. Patent 6,039,954 to Yu, et al., is for herbal compositions containing for
the treatment of gastrointestinal disorders, in particular Irritable Bowel Syndrome (IBS).
The compositions are formulated preferably with powdered herbs including phellodendri.

The U.S. Patent 5,916,555 to Lee, et al., is for a pharmaceutical composition
containing a combination of natural drugs for treatment of diabetes. More specifically,
the present invention relates to a composition containing 17 kinds of main natural drugs,
i.e., Cordyceps, Bezoar bovis, Carthami flos, Astragali radix, Hirudo, Polygoni cuspidati radix, Polygonati falcati rhizoma, Euonymi lignum suberalatum, Corni fructus, Moutan cortex, Lycii cortex radicis, Lycii fructus, Atractylodis rhizoma alba, Atractylodis rhizoma, Coptidis rhizoma, Puerariae radix and Rehmaniae radix crudae. In addition to 17 kinds of main natural drugs, if desired, the composition of the present invention can contain one or more supplementary natural drugs selected from the group consisting of Liriopis tuber, Cistanchis herba, Adenophorae radix, Salviae radix, Ginseng radix rubra, Anemarrhenae rhizoma, Pachymae fungus, Phellodendri cortex, Mori radixis cortex, Schizandrae fructus, Galli stomachichum corium, Trichosanthis radix, Rhei rhizoma, Dioscoreae rhizoma, Alisma rhizoma, Polygoni multiflori radix, Galla rhois, Formica fusca L., Sanchi ginseng, Margaritum and Gecko.

The U.S. Patent 5,908,628 to Hou provides compositions comprising talc, silkworm excrement, and ingredients of plants of species of the genera Stephania, Coix, Pinellia, Prunus, Phellodendron, Sophora, Tetrapanax, Stemona, Glycyrrhiza, Tripterygium, Forsythia and Siegesbeckia, wherein such compositions have analgesic, antipyretic, and antiinflammatory properties. The present invention also provides methods of using such compositions for treating various diseases, including osteoarthritis and rheumatoid arthritis.

The U.S. Patent 5,405,608 to Xu relates to a pharmaceutical composition mainly used for treating thermal injuries of warm blooded mammals and human. It is composed of 3 to 15% by weight of beeswax and 85 to 97% by weight of sesame oil extract of Huangqin, Huanglian, Huangbai, earthworm and poppy capsule. In the sesame oil extract,
each of Huangqin, Huanglian, Huangbai, earthworm and poppy capsule is in an amount of 2 to 10 weight percent based upon the total weight of sesame oil.

The U. S. Patent 5,344,648 to Haga, et al., is for a central nervous system activator comprising a body or a dried product of a plant belonging to Rutaceae, or an extraction product selected from the group consisting of a lower alkane insoluble portion thereof, a lower fatty acid ester extract of the lower alkane insoluble portion, a lower fatty acid ester-halogenated lower alkane soluble portion of the lower fatty acid ester extract, a limonin fraction of the lower fatty acid ester-halogenated lower alkane soluble portion, and an obacunone fraction of the lower fatty acid ester-halogenated lower alkane soluble portion and a central nervous system activator comprising a limonoid.

The U.S. Patent 6,133,440 to Qiu, et al., provides a rapid and efficient method for the preparation and isolation of biologically active polysaccharides from Aloe, "Immuno-10" and the use of the polysaccharides as immunostimulating, immunomodulating and wound healing agents.

The U.S. Patent 6,027,728 to Yuen comprises a selection of herbal materials with curative effects combined in a powdered form for application to human skin to accomplish skin regeneration, particularly for application to human skin affected with eczema, psoriasis, allergic reactions, inflammatory rash and the like. The process of application is critical to effectiveness of the present invention. The application of the herbal powder to the skin is intended to cause a temporary inflammation, which removes at least an upper skin layer, with some mild to noticeable discomfort, and causes accelerated skin regeneration so that soft, unaffected skin replaces the scaling and/or lesioned skin.
The U.S. Patent 5,693,327 to Shah relates to the preparation and use of compositions for the treatment of skin disorders such as psoriasis, eczema and lichen planus, as well as for the promotion of good health and the alleviation of stress. The compositions are based on extracts from the plants Melia azadirachta and/or Centrtherum anthelminticum. A variety of other herbal extracts may be included, and the compositions may take the form of a cream or ointment based on ghee, or they may be in a powdered form of suitable for preparing decoctions in hot water.

The U.S. Patent 5,766,614 to Yong is a new Burn Treatment Composition which provides healing to the skin of people who have received burns or are afflicted with other skin complications that require healing. The inventive device includes effective amounts of Chinese rhubarb; calcium hydroxide; sanguisorba officinalis rhizome; common camphor; coptis chinensis rhizome; phellodendron amurense bark and oldenlandia diffusa roxd.

The U.S. Patent 6,126,950 to Bindra, et al., relates to a formulation of herbal cream for cracked heels and palms. It is comprised of a natural wax as an emulsifier, extract of curcuma and the gum of Acacia or Colophonium or Shorea. The gum gives a synergistic effect in binding and healing the skin with natural wound healing herbal extract selected from the aqueous extracts of curcuma, neem and allantoin. This is combined with a wound healing fragrant oil. The natural wound healing herbal extract acts as a humectant and the gum gives a synergistic effect in binding the skin thereby reducing water loss from the skin. The cream spreads evenly and smoothly when applied on the affected parts, and quickens healing, restores natural suppleness and softness and also serves as an antiseptic.
The U.S. Patent 5,405,608 to Xu for an invention that relates to a pharmaceutical preparation mainly used for treating thermal injuries of warm-blooded mammals and human. It is composed of 3 to 15% by weight of beeswax and 85 to 97% by weight of sesame oil extract of Huangqin, Huanglian, Huangbai, earthworm and poppy capsule. Scorched in the sesame oil extract, each of Huangqin, Huanglian, Huangbai, earthworm and poppy capsule is in an amount of 2 to 10 weight percent based upon the total weight of sesame oil. This invention also relates to a process for preparing the pharmaceutical preparation and includes as its essential component, beeswax. Our invention does not make use of poppy capsule, nor does it require use of sesame oil or beeswax; the present invention contains Opuntia not included in Xu's patent and utilizes a different method for the extraction of active ingredients, viz., in alcohol or water ersus high-heat cooking in sesame oil. It is further noteworthy that a significant population is allergic to sesame oil, which is often used as a positive control for measure allergenicity. Also, direct application of poppy capsule extract can lead to many systemic complications because of the narcotic nature of the ingredients of this herb. The base used in our invention is alcohol:acetone:polyethylene glycol whereas in Xu's patent it is anhydrous wax and oil matrix.

The U.S. Pat. No. 4,837,024 describes compositions which enhance and promote the wound healing process and which comprise suspensions of the fibrous protein, collagen, and of a polysaccharide, namely a glycosaminoglycan. The glycosaminoglycan is one which exhibits chemotaxis for fibroblasts or endothelial cells; the preferred glycosaminoglycans are said to be heparin, heparan sulfate and alginate, although it should be noted that alginate is not in fact a glycosaminoglycan.
G. Brief Description of the Several Views of the Drawing(s): Not Applicable

H. Detailed Description of the Invention:

The primary objectives of the present invention is to provide a new method for the treatment of acne wherein the formulation composition serves three functions: to provide an anti-infective remedy, to remove sebaceous fluids and reduce formation of the same and finally, to clear the skin without leaving any significant scar marks.

The objectives described above are accomplished as follows: a mixture of herbal extracts that are known to have strong antibacterial activity, particularly against the microbial organisms that form the majority of the infected tissue reservoir. These herbs include: Scutellaria baicalensis, Phellodendron amurense, and Coptis chinensis Franch. The debridement function is provided by Pheretima aspergillum and the fast healing of skin without causing any scars is provided by β-sitosterol, Opuntia ficus-indica, and Phellodendron amurense. The defattening of the skin layer is provided by the medium used to formulate the composition: acetone:alcohol:polyethylene glycol. In addition, the herbs included in the composition also provide defattening of the tissue function. It is thus a complete modality of action that treats and when applied frequently to acne-prone surfaces, acts as a prophylactic.

This invention relates to a method for treating acne by administering to an afflicted patient a therapeutically effective amount of a mixture of herbal extract in an alcoholic-acetone solution. A typical composition of the preparation is described below:

A typical composition to manufacture one liter of the product includes as given below. The quantity of extracts used is approximate and is corrected according to the assay value. The quantity of alcohol is adjusted based on the quantity of extracts used.
[Typical Composition for 1 L of product]

<table>
<thead>
<tr>
<th>Composition</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>β-sitosterol (0.5%),</td>
<td></td>
</tr>
<tr>
<td>use Soybean oil extract containing not less than 40% β-sitosterol</td>
<td>12.50 g</td>
</tr>
<tr>
<td>Opuntia ficus-indica (1:10 extract)</td>
<td>5 mL*</td>
</tr>
<tr>
<td>Pheretima aspergillum (1:10 extract)</td>
<td>5 mL*</td>
</tr>
<tr>
<td>Phellodendron amurnese (1:10 extract)</td>
<td>5 mL*</td>
</tr>
<tr>
<td>Coptis chinesis Franch (1:10 extract)</td>
<td>5 mL*</td>
</tr>
<tr>
<td>Polyethylene glycol NF Low Color</td>
<td>100.00 g</td>
</tr>
<tr>
<td>Acetone NF</td>
<td>65.00 g</td>
</tr>
<tr>
<td>Ethanol (Use Alcohol SD 23 A, 92.6%)</td>
<td>815.00 mL</td>
</tr>
</tbody>
</table>

Nitrogen NF is used to flush the container before sealing.

Prickly Opuntia ficus-indica (Mission Cactus, Yellow Tuna, Prickly Pear, Indian Fig, Nopal) comprises mainly the whole plant of Opuntia ficus indica (Cactaceae family) as the main constituents. It is indigenous to the Americas as well as South Asia, Southeast Asia and the Middle East. Other species and varieties of Opuntia genus of the Cactaceae family are included here by reference. The reported pharmacologic properties of Opuntia include: analgesia, antiinflammatory, antiulcerogenic, antioxidative, affecting activity of aromatase and reductase, free radical scavenger, antiviral, lowering LDL cholesterol levels, glucose-6-phosphatase and fructose-1, 6-diphosphatase activity, antidiabetic, a rich source of biologically active alkaloids and other nutritional elements.
often considered essential for tissue growth. It is also an excellent source of beta-
sitosterol. It contains mescaline, tyramine, N-methyltyramine.

Earthworm also called Dilong (earth dragon) is selected one or more from the
group of Pheretima aspergillum (E. Perrier) and Allobophora caliginosa trapezoides
(Ant. Duges). The whole worm dried or fresh is used. (A Dictionary of Chinese Materia
Medica, Shanghai Science and Technology Press, 1988, pages 2111 to 2114). It is widely
used in clinical practice in TCM. In 1974, it was found that the bioactive elements of
earthworm included glutamic and succinic acid. Dilong is effective in the treatment of
bronchial asthma. Recently, a kind of kinase was identified that had significant effect on
improving microcirculation, preventing microthrombosis and produce thrombolysis. The
urokinase is the primary component that is well known for its thrombolytic effect.

Huangqin (Scutellaria baicalensis Georgi) used in the invention is selected one or
more from the group of Scutellaria viscidula Bge, Scutellaria amoena C. H. Wright,
Scutellaria rehderiana Diels, Scutellaria ikomnikovii Juz, Scutellaria likiangensis Diels
and Scutellaria hypericifolia Levl of Labiatae Family. The root or radix is used. (A
Dictionary of Chinese Materia Medica, Shanghai Science and Technology Press, 1988,
pages 2017 to 2021). The major chemical components include: baicalin, neobicalein,
wogonin, baicalein, skullcapflavone, chrysin, oroxylin. It is known to have antilipidemic,
antiagulant, antithrombotic, antiallergy, vasodilatation and antibacterial properties.

Huangbo (Phellodendron amurense Rupr) used in the invention is selected from
one or more groups of Phellodendron chinense Schneid, Phellodendron chinense Scheid
var. glabriusculum Schneid, Phellodendron chinense Schneid var. omeiense Huang,
Phellodendron Schneid var. yunnanense Huang and Phellodendron chinense Schneid var.
falcum Huang. The bark or cortex is used. (A Dictionary of Chinese Materia Medica, Shanghai Science and Technology Press, 1988, pages 2031 to 2035). The major components include berberine, phellodendrine, β-sitosterol, candeicine, menisperine, campesterol, obukulactone, obacunone and nootkatrin. It has a very strong antibacterial activity; the effect of phellodendrine is to produce vasodilatation. It also acts as immunosuppressive, anti-inflammatory, bile secretion stimulant, gastric secretion stimulant and a strong antiacne action.

Coptis chinensis Franch used in the invention is selected but not limited to one or more from the group of Coptis deltoidea C. Y. Cheng et Hsiao, Coptis omeiensis (Chen) C. Y. Cheng, and Coptis teetoides C. Y. Cheng of Ranunculaceae Family. The root is used. (A Dictionary of Chinese Materia Medica, Shanghai Science and Technology Press, 1988, pages 2022 to 2030). The primary components include: berberine, coptisine, worenine, palantime, jatrorrhizine, epiberberine, magnoflorine, and columbamine. It has a very broad spectrum antibacterial property against gram-positive and gram-negative pathogens such as alpha and beta hemolytic streptococci, staphylococcus aureus, virbio cholerae, diplococcus intracellularis, diplococcus pneumoniae, bacillus anthracis, bacillus tetani, diptheria bacillus, tuberculosis bacillus, E coli. It also inhibits leptospira. A remarkable effect of huanglian is that it enhances the phagocytic activities of leukocytes and liver reticuloendothelial system. It also acts as vasodilator.

The major pharmacological effects of β-sitosterol are anti-inflammation, antiulcer, promotion of injured tissue and as we have demonstrated, stimulation of basal dermal stem cell cells. Soybean extract containing a minimum of 40% β-sitosterol as used in this invention (Sigma Chemicals Catalog S5753), which also contains
campesterol, dihydro-brassicacasterol prepared according to the method of N. Kozumi, et al., Chem. Pharm. Bull., 27: 38, 1979. The source of β-sitosterol however is not relevant. It could be obtained from natural sources or from synthetic sources. β-sitosterol (C_{29}H_{50}O, molecular weight 414.72) is a common sterol in plants. It is generally isolated from wheat germ, soybean or corn oil.

Sterols are important cyclized triterpenoids that perform many critical functions in cells. Phytosterols such as campesterol, stigmasterol and β-sitosterol in plants, ergosterol in fungi and cholesterol in animals are each primary components of the cellular and sub-cellular membranes in their respective cell types. The dietary source of phytosterols in humans comes from vegetables and plant oils. The estimated daily phytosterol content in the conventional western-type diet is approximately 250 mg in contrast to a vegetable diet, which would provide double that amount. Although having no nutritional value to humans, phytosterols have recently received a great deal of attention due to their possible anti-cancer properties and their ability to decrease cholesterol levels when fed to a number of mammalian species, including humans. Phytosterols aid in limiting cholesterol absorption, enhance biliary cholesterol excretion and shift cholesterol from atherosclerotic plaque. While many of the mechanisms of action remain unknown, the relationship between cholesterol and phytosterols is apparent. This is perhaps not surprising given that chemically, phytosterols closely resemble cholesterol in structure.

The major phytosterols are β-sitosterol, campesterol and stigmasterol. Others include stigmastanol (β-sitostanol), sitostanol, desmosterol, chalinasterol, poriferasterol, clionasterol and brassicasterol. (Gould R. G., Jones R. J., LeRoyu G. V., Wissler R. W., Taylor C. B.; Absorbability of B-sitosterol in humans; Metabolism, (August) 1969; 18
(8): 652-662; Tabata T., Tanaka M., Lio T.; Hypocholesterolemic activity of phytosterol. II; Yakugaku Zasshi, 1980; 100 (5): 546-552. Hepstall R. H., Porter K. A.; The effect of β-sitosterol on cholesterol-induced atheroma in rabbits with high blood pressure; Br. J. Experimental Pathology, 1957; 38: 49-54.) Several novel applications of phytosterols including β-sitosterol have been reported. The U.S. Patent 5,965,449 to Novak describes a method of assessing risk for cardiovascular disease and other disorders and phytosterol-based compositions useful in preventing and treating cardiovascular disease and other disorders. The level of serum campesterol and β-sitosterol are determined and their ratio is correlated with the risk of cardiovascular or a related disorder. The U.S. Patent 5,523,087 to Shlyankevich is for a pharmaceutical composition for the treatment of diabetic male sexual dysfunction; it contains physostero gens, phosphatidyl choline, β-sitosterol, Damiana leaf extract and vitamins and minerals. The U.S. Patent 5,486,510 to Bouic, et al., is for a mixture of β-sitosterol glucoside and β-sitosterol is administered to persons for the modulation or control of immune responses. The U.S. Patent 5,747,464 to Sec is for a composition for inhibiting absorption of fat and cholesterol from the gut and a method for making and using the composition. The composition comprises β-sitosterol bound irreversibly to pectin to form a β-sitosterol and pectin complex. The U.S. Patent 5,118,671 to Bombardelli, et al., is for complexes formed between aescin, cholesterol or β-sitosterol and phospholipids and a method for producing an anti-inflammatory effect is also described.

As used herein, the term "acne" includes the various known types of acne and related skin disorders, including acne vulgaris, acne conglobata, acne fulminans, pyoderma faciale, acne keloidalis, chloracne, and steroid acne. The most common form
of acne is acne vulgaris, which is characterized by two types of lesions, inflammatory and noninflammatory. Noninflammatory lesions include open comedones (blackheads) and closed comedones (whiteheads) and are characterized by a lymphocytic infiltrate. Inflammatory lesions can be superficial or deep. Superficial inflammatory lesions include papules and pustules, and deep inflammatory lesions consist of cysts and nodules. Inflammatory lesions include those characterized by rupture of the follicular wall and aggregation of neutrophils and mononuclear cells. Acne vulgaris and the other forms of acne which may be treated by administering a therapeutically effective amount of the invention are described in more detail in Principles and Practice of Dermatology, Chapter 70: Acne and Related Disorders, W. Mitchell Sams, Jr. and Peter J. Lynch eds., 1990, which is incorporated herein by reference.

K. Drawings: None

L: Sequence Listing: Not Applicable.
Claims

What is claimed is:

1. A composition for topical application to a human body surface comprising:
   1-25% of each of the herbs namely Scutellaria baicalensis, Phellodendron amurense, and Coptis chinensis Franch, Optunia ficus-indica.
   1-25% of hydro-alcoholic extract of the animal tissue, Pheretima aspergillum.
   1-40% β-sitosterol.
   2-20% Polyethylene Glycol
   1-10% Acetone
   70-95% Alcohol.

2. The composition of claim 1 used in treatment of prevention of acne in humans including acne vulgaris, acne conglobata, acne fulminans, pyoderma faciale, acne keloidalis, chloracne, and steroid acne.

3. The composition of claim 1 used in the cleansing of skin for the purpose of removal of sebum from skin.

4. The composition of claim 1 wherein the herbal and animal issues are extracted in aqueous or alcoholic solvent.

5. The composition of claim 1 wherein β-sitosterol is obtained from any vegetable source, in its preferred embodiment from the soybean.

6. The composition of claim 1 wherein the preparation is used as solution, suspension, spray, gel bandage, compress, or an impregnated gauze.
7. A homogenized composition for topical application to a skin surface including:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
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<tr>
<td>β-sitosterol</td>
<td>50.0 G</td>
</tr>
<tr>
<td>Opuntia ficus-indica</td>
<td>50.0 G</td>
</tr>
<tr>
<td>Pheretima aspergillum</td>
<td>50.0 G</td>
</tr>
<tr>
<td>Phellodendron amurnese</td>
<td>50.0 G</td>
</tr>
<tr>
<td>Coptis chinesis franch</td>
<td>50.0 G</td>
</tr>
<tr>
<td>Polyethylene glycol NF Low Color</td>
<td>100.0 G</td>
</tr>
<tr>
<td>Acetone NF</td>
<td>65.00 G</td>
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<tr>
<td>Ethanol (Use Alcohol SD 23 A, 92.6%)</td>
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INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61K 35/56, 35/78
US CL : 424/195.1, 198.1, 401, 520; 514/859

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
U.S. : 424/195.1, 198.1, 401, 520; 514/859

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
West

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
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<tbody>
<tr>
<td>Y</td>
<td>US 6,124,274 A (SCHEHLMANN et al) 26 September 2000 (26.09.2000), column 1, lines 14-18, column 2, lines 41-54.</td>
<td>1, 2, 7</td>
</tr>
<tr>
<td>Y</td>
<td>US 6,060,863 A (LANSKY) 09 May 2000 (09.05.2000), column 2, lines 24-40, column 6, line 35-column 8, line 61.</td>
<td>4</td>
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<tr>
<td>Y</td>
<td>US 5,766,614 A (YONG) 15 June 1998 (15.06.1998), column 1, lines 24-38, column 2, lines 34-41, column 3, lines 14-19.</td>
<td>1, 6, 7</td>
</tr>
<tr>
<td>Y</td>
<td>Database JPAB on WEST, AN JP 41005995A, YOU et al 'New Flavonoid Derivative'. 03 March 1998 (03.03.1998), abstract.</td>
<td>1, 2, 6, 7</td>
</tr>
<tr>
<td>Y</td>
<td>US 5,405,608 A (XU) 11 April 1995 (11.04.1995), column 5, lines 1-50.</td>
<td>1, 7</td>
</tr>
<tr>
<td>Y</td>
<td>US 4,588,717 A (MITCHELL) 13 May 1986 (13.05.1986), column 6, lines 16 - 29.</td>
<td>5</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent published on or after the international filing date
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"i" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search: 12 July 2002 (12.07.2002)

Date of mailing of the international search report: 12 SEP 2002

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Form PCT/ISA/210 (second sheet) (July 1998)