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A Review of United States Patents (US Patents) on Aloe

HUMAN



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ABSTRACT

The study aimed to collect data about several US Patents granted on Aloe from the year 1976 till date 23 Sep. 2020 and to study (observe and analyze) details of claims of some of the US Patents on Aloe. 800 US Patents are observed on Aloe vera. 12 US Patents are observed on Aloe ferox, 02 US Patents are observed on Aloe perryi, and 00 (zero) on Aloe socotrina. A significant rise in patenting activity to get US Patents on Aloe is observed between the year 2001 to 2020. In some of the US Patents, processing of Aloe to enhance stability and to minimize undesirable constituents is the main subject matter. In some of the US Patents, Aloe is the major active ingredient of composition and the method of usage of the composition is the main subject matter. However, in most of the US Patents, Aloe is one of the active ingredients in combination with other active ingredients and adjuvant in a composition, usage of the composition is specified. The search yielded several results, some results were featuring merely names of Aloe or Aloe vera in US patents without any actual relevance and such US Patents were excluded from the study.

INTRODUCTION

The objective of this review was to find out several United States Patents granted on Aloe and to study claims of some of the United States Patents on Aloe. In the United States, commercially *Aloe vera* is a commonly used term for Aloe rather than using it as a botanical name of Aloe. Till the year 2001 more than 80% of the inventors in USPTO database belonged to the USA and the remaining were from other countries like Germany, UK, Korea, Denmark, China, Canada, and Argentina. More than 50% of the patents on *Aloe vera* were product patents and 15% were process patents, rest of the patents were on extraction isolation and machinery or equipment developed for the processing of *Aloe vera*.^[1]

The commercial significance of Aloe led to the formation of the International Aloe Science Council (IASC) in the USA, it encourages research in Aloe and certifies raw materials and products containing Aloe.

In the United States *Aloe vera* is used mainly in food products and in beverages. This market segment is projected to witness a Cumulative Annual Growth Rate (CAGR) of 7.5% during the forecast period 2015-2021.^[3,4] From the previous few decades the growth trend in *Aloe vera* food products is maintained in the US market. Most of the expired and active US Patents involve steps that aim to remove constituents of Aloe that are undesirable in food products eg. Chlorophyll causes the color change, Phenols cause a bitter taste, Anthraquinones cause laxative action, and bitter taste. On the other hand, the process steps aim to preserve constituents of Aloe that are desirable in food products eg. Polysaccharides, heat-labile nutritive constituents like vitamins.

The constituents of aloe which are undesirable in food products are desirable in traditional systems of medicines eg. Anthraquinone glycosides. In Indian traditional systems of medicines, Aloe is used to treating digestive disorders due to its laxative, purgative and hepatoprotective activities attributed to the presence of Anthraquinone glycosides. In India Aloe is used in the form of Whole leaf juice (Juice obtained without removing leaf rind) and in the form of dried whole leaf juice (Aloin, Kanyasara).^[6]

MATERIALS AND METHODS (Methodology: Data collection and study)

The aim was to collect data about several US Patents granted on Aloe from the year 1976 till date 23 Sep. 2020 and to collect details of claims of some of the US Patents granted on Aloe from 1975 till date 23 Sep. 2020 and to study (observe and analyze) the patent claims.

Step 1: Google search was conducted by using keywords "US Patents on Aloe" and "US Patents on Aloe PDF". Free PDFs of some US Patents on Aloe were downloaded out of them ten PDFs were selected for the study. PDFs of International Application published under the Patent Cooperation Treaty (PCT) and PDFs of United States Patent Application were excluded as the aim was to collect data from granted US Patents only. During Google search two most useful websites were identified 1. https://patents.justia.com 2. http://patft.uspto.gov

Step 2: Search was conducted on website https://patents.justia.com by using keywords "Patent on Aloe" and "Aloe Patent". This was done to read abstracts of different US Patents on Aloe and to note down the Patent Number of relevant US Patents on Aloe.

The search yielded several results; some results (US Patent abstracts) were featuring merely the name of *Aloe vera* in the patent without any actual relevance such patients were excluded.

Step 3: Data about numbers of US Patents granted on Aloe from 1976 till date 23 Sep. 2020 was obtained from USPTO PATENT FULL TEXT AND IMAGE DATABASE available on the website http://patft.uspto.gov. The data about numbers were collected by using the Quick Search option on the website by using different keywords based on various names used for Aloe and by selecting "Claim(s)" as a field for quick search. The numerical data (Results of Quick Search) is represented in Table No.1.

Step 4: Details of claims were obtained from PDFs downloaded during Step 1 and by using the Number Search option on the website http://patft.uspto.gov using Patent Numbers obtained during Step 2.

Step 5: Claims of some US Patents on Aloe were studied (observed and analyzed).

OBSERVATIONS

Observation 1: In the case of some US Patents, processing of Aloe to remove undesirable constituents and to enhance stability is the main subject matter in patent claims. Following are highlights observed from some of such US Patents on Aloe.

US Patent 3878197 (1975), Inventor R.H. Maret: It was granted for a process for extracting and stabilizing gel from leaves of *Aloe vera* plant. It included the Separation of the gel layer of the leaf by trimming the rind, cutting away the rind and adjacent layers to a depth of 1/8th inch. Sterilizing separated gel layer by washing in a chlorine solution. Addition of amine (Glycine), phosphorus ions (Phosphoric acid), potassium ions (Potassium chloride) ions,

Citric acid, Ascorbic acid, Potassium gluconate, and a Surfactant. Digestion under ultraviolet radiation at ambient temperature by maintaining P^H between 3 to 4.5 for about 4 hours. Filtration to remove residual cellulose. This process is intended to produce a biologically sterile and chemically stable composition having characteristics similar to fresh *Aloe vera*.^[7]

The advantage of this process is that it does not involve heating hence suitable to preserve heat labile constituents in *Aloe vera* gel which are desirable in food products and beverages etc. This patent is expired in the year 1995, today industries producing stabilized *Aloe vera* gel are using similar processing steps.

US Patent 4446131 (1984), Inventor R.G. Maughan (Assignee: Aloe Vera of America Inc.): It was granted for controlled temperature process for manufacturing of stabilized *Aloe vera* gel to improve shelf life. It included heating *Aloe vera* gel in two ways one within temperature range 35°C to 70°C for more than 10 minutes and another at about 49°C for about 10 min. Addition of 0.05% to 0.5% ascorbic acid, 0.01% to 0.5% citric acid, 1.0% to 6.0% sorbitol powder, 0.05% to 0.5% sodium benzoate, 0.001% to 0.05% cetyl alcohol, 0.006% to 0.01% tocopherol (any of Vitamin E, Alpha-tocopherol, Beta tocopherol, Gamma tocopherol, Delta tocopherol and mixtures thereof). Maintaining the mixture at any temperature between 35°C to 70°C for sufficient time to kill bacteria. Cooling *Aloe vera* gel mixture to ambient temperature (25°C) or lower in less than one hour. Patent claim mention that it also includes products in which *Aloe vera* gel used is stabilized by using this patented process.^[8]

US Patent 6713095 (2004), Inventors R.G. Maughan *et.al* (Assignee: Aloe Vera of America Inc.): It includes, rapidly heating *Aloe vera* gel within temperature range 35^oC to 80^oC. Addition of tocotrienol-tocopherol blend, rosmarinic acid, polyphenols, ascorbic acid, at least one stabilizing agent selected from the group consisting of sodium benzoate/citric acid/potassium sorbate/phosphoric acid/glucono-delta-lactone. Rapidly cooling the *Aloe vera* gel mixture to a temperature between 20^oC to 30^oC. Patent claim mention that it also includes products in which *Aloe vera* gel used is stabilized by using this patented process.^[9]

US Patent 6869624 (2005), Inventors R.G. Maughan *et.al.* (Assignee: Aloe Vera of America Inc.): It is granted for a process for stabilizing *Aloe vera* gel. It includes, rapidly heating *Aloe vera* gel in two ways one within temperature range 35° C to 80° C and another within temperature range 60° C to 75° C. Addition of rosmarinic acid derived from herbs belonging to Labiatae family, polyphenols, ascorbic acid, at least one stabilizing agent selected from the

group consisting of sodium benzoate/citric acid/potassium sorbate/phosphoric acid/gluconodelta-lactone, tocotrienol-tocopherol. Rapidly cooling the *Aloe vera* gel mixture to a temperature between 20^oC to 30^oC and further to 5^oC. Patent claim mention that it also includes products in which *Aloe vera* gel used is stabilized by using this patented process.^[10]

US Patent 7033620 B2 (2006), Inventors R.G. Maughan et.al. (Assignee: Aloe Vera of America Inc.): It is granted for product and process for stabilizing *Aloe vera* gel. It includes a process comprising rapidly heating *Aloe vera* gel in two ways one within temperature range 350° C to 80° C and another within temperature range 60° C to 75° C. Addition of a compound selected from the chemical group consisting of procyanidin/proanthocynidine/cinnamic acid/caftaric acid/phenolic acid/gallic acid, tocotrienol/tocopherol blend, ascorbic acid, at least one stabilizing agent selected from the group consisting of sodium benzoate/citric acid/potassium sorbate/phosphoric acid/glucono-delta-lactone, a compound from grapes. Rapidly cooling the *Aloe vera* gel mixture to temperature 20° C to 30° C. Patent claim mention that it also includes products in which aloe vera gel used is stabilized by using this patented process.^[11]

US Patent 8877265 (2014), Inventors M. Tanaka, M. Yamada (Assignee: Morinaga Milk Industry Co.): It is granted for a process for producing *Aloe vera* extract which is safe to ingest and intended to be used in food products and drugs. It includes supercritical fluid extraction of dried *Aloe vera* leaf mesophyll using carbon dioxide as solvent at temperature 50 to 69°C and at pressure 15 to 24 MPa for 50 to 70 minutes, mixing the extract (>0.01%) with a pharmaceutical carrier or with food/drink material. The supercritical fluid extract obtained consists of cyclolanostane compound (9,19-cyclolanostan-3-ol and or 24-mrthylene-9,19-cyclostan-3-ol), lophenol compound (4-methylcholest-7-en-3-ol, 4-methylergost-7-en-3-vol, 4-methylstigmast-7-en-3-ol) and very low concentration of anthraquinones (<0.001%).^[12]

US Patent 6117247 (2000), Inventor X. Huang: It is granted for *Aloe vera* gel extracting apparatus. The apparatus consists of a body, a transmission system, a peeling device, and a driving mechanism. The peeling device consists of an edge cutting blade, an upper peeling blade, and a lower peeling blade. The apparatus is simple structured, efficient in operation, and capable of producing complete bars of *Aloe vera* gel.^[13]

Observation 2. In the case of some US Patents, Aloe is the sole active ingredient with other adjuvant substances in composition, and the method of treatment by using the composition is the main subject matter in patent claims. Following are highlights observed from some of such US Patents.

U.S. Patent 4670265 (1987), Inventor R.J. Sydiskis: It was granted for the treatment of type 1 and type 2 herpes simplex virus. It included a method of treatment involving the topical application of Anthraquinone (Aloe-emodin) containing extract obtained from *Aloe vera* (leaf, gel, sap) by using methanol or ethanol or ethyl acetate or acetone or glycerin as a solvent.^[14]

US Patent 8945637 (2015), Inventor I.E. Danhof (Assignee: Aloe Bioscience LLC): It is grated for Decubitus treatment system that comprises a kit containing three types of Aloe compositions. It includes a First container containing a wound cleansing solution comprising *Aloe vera* long-chain polysaccharides (gel) having an average of 5000 saccharides per chain and a balanced salt solution comprising NaCl, KCl, CaCl₂, NaHCO₃, and Na₂HPO₄ adjusted to P^H 4.5. A second container containing wound healing gel comprising *Aloe vera* long-chain polysaccharides (gel) having an average of 10000 saccharides per chain, thickening agent (xanthan gum and or guar gum and or locust bean gum), preservatives (benzoate salts and or benzonium salts and or sorbate salts). A third container containing moisture barrier cream comprising *Aloe vera* long-chain polysaccharides (gel) having an average of 2000 saccharides per chain, vegetable-based emulsifier (diiosostearoyl polyglyceryl-3 dimer dilinoleate, polyglyceryl-4 isostearate, polyglyceryl-3 oleate), low occlusivity cosmetic ester (cetearyl ethyl hexanoate), beeswax, hydrogenated castor oil, glycerin.^[15]

US Patent 9750781 (2017), Inventor I.E. Danhof (Assignee: Aloe Bioscience LLC): It is grated for a method of treatment for Decubitus ulcer using compositions containing *Aloe vera* polysaccharides. It includes Cleaning one or more decubitus ulcers with the first composition containing *Aloe vera* long-chain polysaccharides (gel) having an average of 5000 saccharides per chain and a balanced salt solution comprising NaCl, KCl, CaCl₂, NaHCO₃, and Na₂HPO₄ adjusted to P^H 4.5. Coating one or more decubitus ulcers with a second composition containing *Aloe vera* long-chain polysaccharides (gel) having an average of 10000 saccharides per chain and thickening agent (xanthan gum and or guar gum and or locust bean gum) and preservatives (benzoate salts and or benzonium salts and or sorbate salts).

Providing moisture barrier to one or more decubitus ulcers with a third composition containing *Aloe vera* long-chain polysaccharides (gel) having an average of 2000 saccharides per chain, vegetable-based emulsifier (diiosostearoyl polyglyceryl-3 dimer dilinoleate, polyglyceryl-4 isostearate, polyglyceryl-4 diisostearate, polyglyceryl-3 oleate), low occlusivity cosmetic ester (Cetearyl ethyl hexanoate), beeswax, hydrogenated castor oil, glycerin.^[16]

Observation 3. In the case of most of the US Patents, Aloe is one of the active ingredients with other active ingredients and adjuvants in a composition. Usage of the composition is specified. Following are highlights observed from some of such US Patents.

US Patent 5560913 (1996), Inventor P.L. Kupper (Assignee: The Proctor and Gamble Company): It included orally ingestible pharmaceutical composition containing an effective amount of *Aloe vera* component (*Aloe vera* gel/decolorized *Aloe vera*/whole leaf or mixtures thereof containing not more than 1% anthraquinones) for taste masking, 0.1% to 90% of at least one pharmaceutically active ingredient (analgesics/decongestant/expectorant/antitussive/ antihistamines/gastrointestinal actives), an orally acceptable pharmaceutical carrier, one or more sweetening agent, one or more releasing agent, one or more cooling agent, one or more flavoring agent. The composition is intended to administer orally to the patients having difficulty in swallowing tablets or capsules for treating symptoms of respiratory illness, allergy, and gastrointestinal disorder.^[17]

US Patent 6949262B1 (2005), Inventor D.L. Smothers (Assignee: LouSal Enterprises Inc.): It include, 35% to 80% *Aloe vera*, 0.5 to 3% allantoin, dimethicone, water, one or more additional components selected from group consisting of humectants/preservatives/ emollients/buffers/coloring agents/gel-forming agents/oils/antibiotics/herbal materials and vitamins. It is intended to use for skin and mucosal treatment.^[18]

US Patent 7569210B2 (2009), Inventor J.C. Doss: It includes, cleansing composition in soap bar form comprising Balm of Gilead: Chlorophyll: Olive oil: *Aloe vera*: Lemon juice in ratio 1:2:1:1:3. With respect to the weight of cleansing composition other ingredients are 0.4% to 0.6% zinc oxide, 0.15% to 0.3% titanium dioxide, further comprising one or more selected from group consisting of natural soap base/fragrance/oil/fat/water/bactericide /antiviral/ antifungal / colorant/antioxidant/foaming improvers. It is intended to use for UV protection through normal use for washing and rinsing and therapeutic purpose.^[19]

Citation: Vishal P. Nalamwar et al. Ijppr.Human, 2020; Vol. 20 (1): 232-242.

US Patent 8557264B2 (2013), Inventor G.L. Grune (Assignee: 3rd Rock Sunblock Inc.): It includes a composition comprising vegetable-derived glycerine, emulsifier (cetearyl glucoside, cetearyl alcohol) further comprise one or more ingredients selected from the group consisting of vitamin E, provitamins, *Aloe vera* gel, *Aloe vera* juice, beeswax, carnauba wax, orange wax, sunscreen agent, fragrance, zinc oxide, titanium dioxide. Method of preparation involves heating glycerine to about 70°C, mixing emulsifier until the emulsifier is no longer visible, and cooling to room temperature, this yields a stiff jelly base intended to be mixed with other ingredients.^[20]

US Patent 8623335B2 (2014), Inventor T.A. Waddington: It includes a composition first portion of which comprise by volume 25 to 40% *Aloe vera* gel, vegetable glycerine, royal jelly, vitamin E, witch hazel extract and second portion comprise up to coconut oil, almond oil, avocado oil, emu oil, and sesame oil. The first portion and second portion combined in appropriate ratio to yield composition containing *Aloe vera* gel in said proportion. It is intended to use for cleansing skin, removing dead skin cells, restoring alkali balance, shrinking skin pores, increasing water content in skin, reducing redness, reducing scar and rosacea.^[21]

US Patent 9750681 (2017), Inventor G. Giagnorio (Assignee: JG Skin Inc.): It includes a composition consisting of vegetal material *Aloe barbadensis* gel, marine material (Algae extract/Sea fennel extract/Sea kelp extract/Sea tangle extract/Sea buckthorn extract), Oil in water nano-emulsion comprising phospholipid (lecithin/lecithin derivative) stabilized submicron triglyceride (caprylic/capric triglyceride) particles, polycarboxylate polymer (linear copolymer of acrylic acid), phosphate ester type emulsifier, phosphatidylcholine, water-soluble solvents (alcohol/liquid polyol), a copolymer of two or more monomers of acrylic acid or one of their simple esters, isodecyl oleate, dimethicone, Cyclopentasiloxane, polyethoxylating moieties, polypropoxylating moieties. The composition is intended to be packed separately as part of a kit whose other component is color cosmetic. It is intended to use for skincare.^[22]

US Patent 1032156 (2019), Inventors M. Yatcilla and A. Bertocco (Assignee: Herbalife International of America Inc.): It is granted for a composition comprising purified (decolorized) *Aloe vera* leaf dry juice containing not more than 10 ppm aloin and at least about 5% acetylated acemannan. It include, purification decolourisation and drying of *Aloe*

vera leaf juice, addition and mixing of acidity modifier selected from group consisting of citric acid salt/malic acid salt/acetic acid/acetic acid salt/lactic acid/lactic acid salt/tartaric acid/tartaric acid salt/formic acid/formic acid salt/propionic acid/propionic acid salt/butyric acid/butyric acid salt/valeric acid/valeric acid salt/phosphoric acid/phosphoric acid salt, addition and mixing of one or more excipients selected from the group sorbic acid/sorbic acid salt/benzoic acid/benzoic acid salt/rosemary extract/lovage extract/chitosan/sage essential oil/thymol oil nisin/e-polylysine/grape seed extract/goji berry extract/honey/cruptose/dextrose /maltodextrin/cellulose powder/modified starch/microcrystalline cellulose/magnesium stearate/stearic acid/sodium croscarmellose/calcium carbonate/dicalcium phosphate. It is intended to use for improving the health of the animal or human gastrointestinal microflora.^[23]

RESULTS:

		Number of US Patents	Number of US Patents
Keyword(s)	Field	from 1976 till date	from 1 Jan. 2002 till date
		23 Sep.2020	23 Sep.2020
Aloe vera	Claim(s)	800	608 (76% of 800)
Aloe barbadensis	Claim(s)	125	113 (90% of 125)
Aloe chinensis	Claim(s)	00	00
Aloe indica	Claim(s)	00	00
Aloe perfoliata	Claim(s)	00	00
Aloe vera gel	Claim(s)	164	114 (69% of 164)
Aloe vera extract	Claim(s)	88	71 (80% of 88)
Aloe vera juice	Claim(s)	42	28 (66% of 42)
Aloe ferox	Claim(s)	12	09 (75% of 12)
Aloe perryi	Claim(s)	02	01 (50% of 02)
Aloe socotrina	Claim(s)	00	00

Table No. 1: Results of Quick Search in USPTO patent full text and image database

DISCUSSION

In the case of the United States Aloe does not find a major role as medicine in the treatment of disorders hence less importance is given to the presence of therapeutically important

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constituents of Aloe i.e. Anthraquinones in US Patent claims. These constituents are considered undesirable in most food products.

Aloe vera of America Inc., Aloe Biosciences LLC, Herbalife International of America Inc., Unigen Pharmaceuticals Inc. (Formerly known as Univera Pharmaceuticals Inc.) is the major USA based companies engaged in patenting and manufacturing of *Aloe vera* stabilized extracts and *Aloe vera* products.

From the observations, it is important to note that in 1984 US Patent 4446131 on Aloe was granted to inventor R.G. Maughan. Subsequently, some innovations in the processing steps and compositions were done year after year as a result of this inventors R.G. Maughan *et.al* (Assignee: Aloe Vera of America Inc.) could get more US Patents each in the year 2004, 2005 and 2006.

CONCLUSION

Based on the observations of results of Quick Search in USPTO Patent Full Text And Image Database and based on claims in US Patents on Aloe following conclusions are drawn.

Table No.1 indicates that for claims in US Patents, the most common term used for Aloe is "Aloe vera" followed by "Aloe barbadensis", "Aloe vera gel", "Aloe vera extract" and "Aloe vera juice". There are only 12 US Patents on "Aloe ferox" and 02 on "Aloe perryi" and none on "Aloe socotrina". There is a significant rise in patenting activity to get US Patents on Aloe between the years 2001 to 2020.

Based on claims, US Patents on Aloe can be broadly put into three categories.

Category 1: It includes US Patents on Aloe in which processing of Aloe to remove undesirable constituents and to enhance stability is the main subject matter in the patent claims.

Category 2: It includes US Patents on Aloe in which Aloe is the sole active ingredient with other adjuvants in composition and method of treatment for particular condition by using the composition is the main subject matter in the patent claims.

Category 3: It includes US Patents on Aloe in which Aloe is one of the active ingredients with other active ingredients and adjuvants in a composition. Usage of the composition is specified. Composition and its specific use are the main subject matter in the patent claims.

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