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PATENTS / DESIGNS / TRADE MARKS
GEOGRAPHICAL INDICATIONS

No. 4913/CHENP/2007

Dated the : 18/11/2010

To

M/s DePenning & DePenning,
31, South Bank Road,
Chennai-600028.

SUB : **First Examination Report**

REF :- Patent Application No. **4913/CHENP/2007**

NAME OF APPLICANT :- **MORINAGA MILK INDUSTRY CO LTD**

a) This report is the First/ Consequent Examination Report prepared on the basis of the examination conducted on the instant application under Section 12 and 13 of the Patents Act 1970.

b) The report contains the official requirements broadly on the following grounds:

i. Whether the application and the specification and other documents relating thereto are in accordance with the requirements of this Act and of any rules made thereunder.

ii. Whether there is any lawful ground of objection to the grant of the patent under this Act in pursuance of the application.

iii. The result of investigations made under section 13; and

iv. Other prescribed matters.

c) The application under reference will be treated as deemed to have been abandoned under Section 21(1) of the Act unless all the requirements imposed by the Act and rules made there under are complied with within prescribed period of 12 months from the issuance of this report.

2. Detailed Examination Report:

(Dr SP Subramanian)

Controller of Patents & Designs

Encl:-

1. Provisional/Complete Specification
2. Statement & Undertaking

3. Declaration as to Inventorship

NOTE : All Communications to be sent to the Controller of Patents at the above address.

Serial
Number Objections

- 1 Distinguishing features as compared with prior art given is not clear.
 Invention claimed in claims lacks Novelty and Inventive step see for instance

D1.WO2004105770

D2.JP2000319190

D3.JP2003-286185, A

D4.JP10036283

D5. Khimiya Prirodnikh Soedinenii, 1977, No. 3, p. 353-360

D6. US6506387

D7.photochemistry,1978,vol17,no.5 , p 971-977

Document 1 relates to the utilization of a plant sterol, and also refers to therapy for visceral obesity (page 7).

Documents 2 and 4 relate to utilization of an aloe extract. Document 3 relates to utilization of an aloe pressed liquid.

Document 5 describes that as a result of analyzing a substance contained in B. Alba, the presence of a compound represented by the chemical formula (1) is confirmed.

Document 7 describes as a plant sterol,4-methylcholest-7-en-3-ol,4-methylergost-7-en-ol, and 4-methylstigmast-7-en-3-ol

- 2 The subject matter of claim 1 is used for inhibiting visceral fat accumulation using a compound represented by the chemical formula (1) as an active ingredient. Documents 2 and 4 describe food and drink containing an aloe extract. Document 3 describes food and drink containing an aloe pressed liquid. Documents 2-4 do not describe the content of a compound of the chemical formula (1) in food and drink described in these documents. However, the extraction method in documents 2 and 4 and the extraction method in the subject matters of claims 4-5 are considered to overlap with each other, and document 3 uses an aloe pressed liquid, so it is highly probable that the content of a compound of chemical formula (1) in the inventions described in documents 2-4 is also within the range of claims 4-5. Furthermore, the description "a visceral fat accumulation inhibitor" in claims 4-5 is considered to explain an action (property) of the extract or pressed liquid of a plant such as aloe, which does not allow the distinction from food and drink containing the same component. So the subject matters of claims 4-5 cannot be distinguished from the inventions described in documents 2 and 4 in their containing aloe extract, and cannot be distinguished from the invention described in document 3 in its containing aloe pressed liquid. Therefore, claims 4-5 do not appear to be novel or to involve an inventive step. Therefore, the subject matter of claim 1 -9 appears to be not novel and to involve an inventive step.
- An active ingredient of the subject matters of claims 2-3 and 6-7 is an extract or a pressed liquid of a plant such as an aloe. Therefore an active ingredient of the subject matters of these claims 2-3 and 6-7 corresponds to that of an aloe pressed liquid described in document 2. Document 2 describes that an aloe pressed liquid is used as an obesity preventing/improving agent. Preventing/improving obesity is also considered to be closely related to the inhibition of visceral fat accumulation, so the subject matters of claims 2-3 and 6-7 do not appear to be novel or to involve an inventive step in view of the description of document 2.
- The subject matters of claims 10-11 relate to food and drink. In claims 10-11, a restriction that "containing a visceral fat accumulation inhibitor described in one of claims 1 -3" is given. Among the claims cited here, claims 5-6 use an extract or pressed liquid from a plant such as aloe as an active ingredient. Therefore the food and drink of claims 10-11 include the case of food and drink containing an extract or pressed liquid or a plant such as aloe.. Furthermore, the description a visceral fat

accumulation inhibitor" in claims 10-11 is considered to explain an action (property) of an extract or pressed liquid from a plant such as aloe. Hence the claims

In addition to that, According to the D6 and applicant claims a method of inhibiting visceral fat accumulation comprising administering either a hot water extract or organic solvent extract (ethyl acetate or butanol or ethyl acetate/butanol mixture) of Aloe vera wherein the extract contains the claimed compound in various amounts therein.

D6 teaches a hot water extract of the plant Aloe vera whereas D6 extraction process also includes other claimed extraction and/or purification organic solvents of Aloe vera such as the claimed organic solvents of ethyl acetate and butanol therein. Furthermore, when D6's same hot water extract of the plant Aloe vera that also includes other claimed extraction organic solvents of Aloe vera such as ethyl acetate and butanol therein as the claimed invention's hot water extract solvent and/or organic extract solvent of the plant Aloe vera, both D6's same hot water and/or organic solvent extraction process as the claimed invention's extraction process would also intrinsically contain the same claimed compound therein. Moreover, when D6's same claimed hot water extract and/or organic solvent extract of the plant Aloe vera as the claimed invention's hot water extract and/or organic solvent extract of the plant Aloe vera is administered to any and/or all claimed subject, both D6's same claimed hot water extract and/or organic solvent extract of the plant Aloe vera and the claimed invention's hot water extract and/or organic solvent extract of the plant Aloe vera would intrinsically obtain the same claimed functional effect of inhibiting visceral fat accumulation in any and/or all claimed subject, (see, e.g. entire patent including abstract, claims, column 1 lines 65-66 and examples). D6, however, does not expressly teach a hot water extract and/or organic solvent extract of the plant Aloe vera whereas either the hot water extract and/or organic solvent extract expressly contains the claimed compound in various amounts therein.

However, based on the overall teachings of above documents, it would have been obvious to one of ordinary skill in the art to modify D6's extraction method to include result-effective adjustment of these type of conventional working conditions therein (e.g., determining appropriate amounts/ranges of such a bioactive extract and also to produce the claimed organic solvent mixture of an ethyl acetate/butanol mixture with organic solvents that are well known in the art to be beneficial extraction solvents of Aloe vera such as ethyl acetate and/or butanol as readily disclosed within D6), which is deemed merely a matter of selection and routine optimization which is well within the purview of the skilled artisan. Meanwhile, claims 4-5 in terms of a visceral fat accumulation inhibitor, it is considered that a person skilled in the art reading the description of document 2 could have understood that aloe contains a component having the action of preventing/improving obesity, and extracted an aloe component to make an obesity preventing/improving agent, and also expected an inhibiting effect toward visceral fat that is closely related to obesity, so claims 4-5 do not appear to involve an inventive step.

Invention claimed in claims lacks Novelty over the documents as mentioned in the Traditional knowledge digital library and the documents cited below

TKDL

Exhibit 1 : (pg. no. 4-6) refers to a formulation containing Aloe barbadensis Mill, along with few other ingredients used for the treatment of Obesity through oral administration.

Exhibit 2 : (pg. no. 7-9) refers to a formulation containing Aloe barbadensis Mill, along with few other ingredients used for the treatment of Obesity through oral administration.

Exhibit 3 : (pg. no. 10-12) refers to a formulation containing Aloe barbadensis Mill, along with few other ingredients used for the treatment of Obesity through oral administration.

Exhibit 4 : (pg. no. 13-15) refers to a formulation containing Aloe barbadensis Mill, along with few other ingredients used for the treatment of Obesity through oral administration.

Exhibit 5 : (pg. no. 16-19) refers to a formulation containing Aloe barbadensis Mill, along with few other ingredients used for the treatment of Obesity through oral administration.

Exhibit 6 : (pg. no. 20-25) refers to a formulation containing Aloe barbadensis Mill, along with few other ingredients used for the treatment of Obesity through oral administration.

Exhibit 7 : (pg. no. 26-28) refers to a formulation containing Aloe barbadensis Mill, along with few other ingredients used for the treatment of Obesity through oral administration.

To know more detail and the corresponding reprints of above TKDL documents applicant advised to refer IPER which available in Esp@ce online link

The alleged patent application claims the usefulness of a hot water extract of a Liliaceae plant (Aloe barbadensis) for the treatment of visceral fat accumulation as novel. However Aloe barbadensis (Liliaceae family) has been used for the treatment of Obesity through oral administration in the Indian system of medicine since long, as is evident from exhibits cited from the book namely Bayaaz-e-Kabir, Vol. II by Mohammad Kabiruddin(Unani,Exhibits, pg no 4-6), Rasendracintamanaih by Dundukanatha (Ayurveda,Exhibit:2, pg no 7-9), Rasatantrasarah Evam Siddhaprayogasamgrahah;-part (Ayurveda,Exhibit:3, pg no 10-12), Rasayoga Sagara (Ayurveda, Exhibit 4, pg no 13-15), Rasayoga Sagara (Ayurveda,Exhibit:5, pg no 16-19), Rasaratnakarah -Rasendra khandam (Ayurveda,Exhibit:6, pg no 20-25), Rasakamadhenu Samhita by Cudamani (Ayurveda,Exhibit:7 pg no 26-28). In addition to the aforesaid references, some other references also exist in TKDL wherein Aloe barbadensis has been used in combination with few other ingredients for the treatment of obesity. Hence, the said application is not novel as per the cited prior art and does not involve any inventive step, therefore cannot qualify for the grant of patent rights.

- 3 The subject matter of claim 12 -15 doesn't fall within the meaning of section 2 (1) (j) of the Patents Act 1970.
- 4 The subject matter of claim 1-15 attracts section 3 (d) of Patents Act 1970.
- 5 Priority document shall be filed.
- 6 Proof of right shall be filed with necessary petition.
- 7 Application number and date shall be mentioned in form 3.
- 8 Application number shall be mentioned in form 5.
- 9 Latest status of foreign filing particulars should be communicated to this office at the earliest.
- 10 Irrelevant portions indicated by pencil should be deleted in the complete specification
- 11 ?We claim? should be mentioned in the body of the complete specification.
- 12 Pages of the complete specification shall be serially numbered and mentioned at the bottom of each page.

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