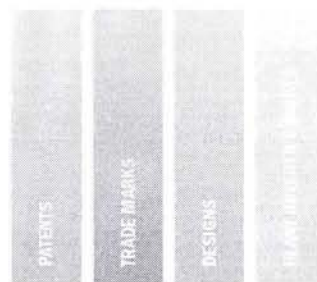




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Date of issue: 29 October 2012

Patent Examination Report No. 3

Application Details

Patent Application No.: 2009222618
Applicant/s: Life Science Nutrition AS
Your reference: 795459D1:ANB:AAO
Earliest Priority Date: 19 July 2004
Examination Request Date: 13 April 2010

Your application has been examined under Section 45 of the *Patents Act 1990*. I consider that the application does not meet the requirements of the Act for the reasons indicated below.

Actions you can take

NOTE: There is a current postponement of acceptance in place. If you overcome all other objections before the expiration of that postponement, the Commissioner will only accept the application at that time if you have filed a clear and unambiguous statement requesting the withdrawal of that postponement. Otherwise, a further adverse report will be issued.

You have until 23 November 2012 to overcome all my objection(s) otherwise your application will lapse.

You will need to pay a monthly fee for any response you file after 12 months from the date of the first report.

You will also need to pay any annual continuation fees that apply. Information about fees may be obtained by phoning 1300 651 010 or by visiting www.ipaustralia.gov.au.



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This data, for application number 2009222618, is current as of 2012-10-31 23:17 AEST

Basis of the report

Last amendment item no. 1 .

In examining your application I have taken into account:

- the specification as filed
- the proposed amendments under S104 filed on 19 October 2012

Statement of Novelty, Inventive Step and Patentable Subject Matter

Novelty/Inventive Step	Claim No. NONE	Yes
	Claim No. 1-13	No
Patentable Subject Matter	Claim No. 1-13	Yes
	Claim No. NONE	No

Section 40 (Fair Basis, Full Description, Clarity, Lack of Unity)

- 4 The specification does not comply with Section 40(4) because the claims do not relate to one invention only. I have found different inventions based on the following features that separate the parts of the claims into distinct groups:

Claims 1-13 are directed to at least 10 inventions according to the second component to be administered in combination with 99 percent pure n-glycolylneuraminic acid to induce alleviation of the symptoms of viral induced obesity, increasing energy, increasing the feeling of well-being and/or alleviation of cold symptoms in a subject comprising: providing a composition comprising an enterically coated capsule or tablet containing n-glycolylneuraminic acid that is ninety-nine percent pure and an agent selected from the group consisting of:

Invention 1: catechins;

Invention 2: flavenoids;

Invention 3: Echinacea;

Invention 4: cascara;

Invention 5: soy/red clover;

Invention 6: rosemary/lemon balm;

Invention 7: selenite;

Invention 8: barley grass;

Invention 9: lauric acid;

and Invention 10: Phyllanthus amarus/niruri;

and administering said composition to said patient under conditions such that said physiological effect is induced. The second component to be mixed with n-glycolylneuraminic acid is specific to each respective invention.

Unity of invention is only fulfilled when there is at least one "special technical feature" present in the claims that both:

provides a technical relationship among all the claims; and,

makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified distinguishing features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. The only feature common

to all of the claimed inventions and which provides a technical relationship among them is administering 99% pure n-glycolyl neuraminic acid and a second agent to alleviate the symptoms of viral induced obesity, increasing energy, increasing the feeling of well-being and/or alleviation of cold symptoms via enterically coated capsules or tablets. However this feature does not make a contribution over the prior art because it is disclosed in D1.

Therefore in the light of this document this common feature cannot be a special technical feature. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied *a posteriori*.

Documents Cited or Considered Relevant

D1 : WO 2000/038697 A1 (SHARMA, Y.) 06 July 2000 *

Category: Y Claims: 1-13

D2 : Bhavamisra; Bhavaprakasa - Edited & translated by Brahmashankara Misra & RupaLalaji Vaisya, ParH : Chaukhambha Sanskrit Sanslhan, Varanasi, Edn. 9th, 1999. [Time of origin 16th century] Pg 525
Formulation ID: RS/3383

Formulation Name: Khadiragunah

^

Category: Y Claims: 1-13

D3 : Madanapala; Madanapalanighauhj- Translated by Rama Prasad; Khemaraj Shri Krishnadas
Prakashan, Bombay, Edn. 1998 Pg 113

Formulation ID: RS15/382A

Formulation Name: Khadira Nirayasa Guna

^

Category: Y Claims: 1-13

D4 : Kaiyadeva; Kaiyadevanighantau – (Pathyapathyavibodhakah.) Edited and translated by P.V.
Sharma and Guru Prasad Sharma,

Chaukhambha Orientalia, Varanasi, Edn. 1st, 1979 Pg 430-431

Formulation ID: RS6/981

Formulation Name: Yava Saktu Guna

^

Category: Y Claims: 1-13

D5 : Govt of India; The Ayurvedic Pharmacopoeia of India - Part I ,Vol II Ed. First 1999, Govt of India,
Ministry of Health & Family Welfare.

[This book contains back references from 1000 B.C. to 20th century] Pg 175-176

Formulation ID: RG/3656

Formulation Name: Yava (Phala)

^

Category: Y Claims: 1-13

D6 : Mohammad Shareef Khan; Ilaaj-al-Amraaz (18th century AD), Afzal-al- Matabe, Barqi Press, Delhi,
1921 AD Pg 322

Formulation ID: MH1/3711

Formulation Name: Maa-ush- Shaeer Mulaaham

^

Category: Y Claims: 1-13

D7 : Gopalakrsna Bhatta; Rasendrasarasamgrahah.- Commentary by Indradeva Tripathi, Chaukhambha
Orientalia, Varanasi, Edn. 3rd 2003 Pg 23

Formulation ID: HG/1020

Formulation Name: Sarvailgasundararasah. [081] [pitabhasma]

^

Category: Y

Claims: 1-13

D8 : Abdulla Sahib; Anuboga Vaithiya Navaneetham, Pub:Palani Thandayuthapani Devasthanam publications, Directorate of Indian systems of Medicine, Chennai.(1975). Pg 37

Formulation ID: GR01/49

Formulation Name: Ayapodi Dagam-I

^

Category: Y

Claims: 1-13

D9 : Bharata Bhaisajya Ratnakara -Compiled by Naginadasa Chaganalala Saha, Translated by Gopinath Gupta - Vol-I: B. Jain Publishers, New Delhi, Edn. 2nd. Reprint, August 1999. [This book contains back references from 1000 B.C.to 20th century] Pg 160

Formulation ID: AB/456

Formulation Name: Iksvadimodakah

^

Category: Y

Claims: 1-13

D10 : Bharata Bhaisajya Ratnakara - Compiled by Naginadasa Chaganalala Saha, Translated by Gopinath Gupta - Vol.-II : B. Jain Publishers, New Delhi, Edn. 2nd. Reprint, August 1999. [This book contains back references from 1000 B.C.to 20th century] Pg 41

Formulation ID: BP/207

Formulation Name: Guggulurasayanam (01)

^

Category: Y

Claims: 1-13

* Cited in the EP Examination Report dated 04 January 2010 for Publication No. 5773215.

^ Section 27 Notice 21 January 2011

New Documents

Documents D2-D10 were brought to my attention by a section 27(1) notice now particularly relevant due to the proposed amendments.

I apologise for any inconvenience that raising new citation/s at this stage may have caused.

Special categories of cited documents (based on PCT standard):

Y: 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.

Novelty and Inventive Step

- 5 Objection 3 is maintained in part. That is, the invention claimed in claims 1-13 does not involve an inventive step when the disclosures of the following documents are combined: D1 when read in the light of each of D2-D10.

In D1, see page 1, lines 18-20 which discloses treatment of viral infections and pathogenic infections.

See page 2, lines 17-20 which discloses treatment of immune mediated diseases.

See page 7, lines 1-7 where the administration is orally, by capsules or tablets. There is no inventive step in enterically coating capsules or tablets.

In D1, at page 13, line 21 to page 14, line 6, no treatment related clinical signs were observed with administration on N-glycolyl neuraminic acid. Therefore only positive benefits (feelings of increased well being, etc.) are to be expected as an illness is treated.

See page 4, line 31 to page 5, line 14, for purification steps to produce at least 99% pure N-glycolyl neuraminic acid.

See page 6, lines 23-28 which discloses administering N-glycolyl neruraminic acid with other therapeutic agensts such as antibiotics and other antivirtal agents. The selected agents to be co-administered are well known to treat coughs, bronchitics and obesity.

See (i) D2, D3 and D10 each of which discloses acacia catechu as a source of catechins to promote strength, and removing tiredness, and therefore increased energy and well being;

(ii) D4 - D6 which disclose *Hordeolum vulgare* (barley grass) for oral administration for strength promotion and removing tiredness, treating obesity, coughs and bronchitis and as a general tonic; and

(iii) D7-D9 which disclose *Phyllanthus niruri* for strength promotion, lethargy and as a vitaliser (increasing energy and feeling of well being).

It is considered that a person skilled in the art would, in seeking a solution to the problem being addressed, be motivated, with a reasonable expectation of success, to combine the disclosures of each of documents D1 and any of D2-D10 and arrive at a solution which is the same as the claimed inventions.

Additional Comments

This report has been reviewed by the Supervising Examiner responsible for this section.

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Website QR code

View your application in AusPat by going to <http://www.ipaustralia.gov.au/auspat/> and entering your application number.