

 Australian Government IP Australia		Search Information Statement (SIS)			
		Application Number	2006294491		
IPC Classification	A23L 1/28, A01N 65/00				
Examiner	Ling Choo Chew	Section	B2	SIS completion date	4 August 2011
I. Earlier search results relied on					
Search results relied on	ISR corresponding EP 1942919 search report dated 21 July 2010 third party in corresponding EP 1942919 observation dated 24 May 2010				
II. Australian Search Details					
Reasons for search	Original search	<input type="checkbox"/>			
	Additional search	<input type="checkbox"/>	Claims amended	<input type="checkbox"/>	
			Update	<input type="checkbox"/>	
			Claims not covered by earlier search	<input type="checkbox"/>	
	Other reasons				
Claims not searched and reasons	Lack of unity	<input type="checkbox"/>	Excluded subject matter		<input type="checkbox"/>
	No meaningful search possible	<input type="checkbox"/>	Other reasons		
Additional search team members					
III. Documents considered to be relevant (from items I and/or II)					
Category*	Citations			Relevant to Claims	
X	PREUSS H G et al., "Protective effects of a novel niacin-bound chromium complex and a grape seed proanthocyanidin extract on advancing age and various aspects of syndrome X" ANNALS OF THE NEW YORK ACADEMY OF SCIENCES, vol. 957, (2002-01-01) , pages 250-259			1-40	
X	PREUSS H G et al., "Long-term effects of chromium, grape seed extract, and zinc on various metabolic parameters of rats" MOLECULAR AND CELLULAR BIOCHEMISTRY vol. 223, no. 1-2, (2001-07), pages 95-102			1-40	
X	US 2004/0247714 A1 (ROE et al.) 09 December 2004			1-40	
X	US 2002/0192314 A1 (CHO et al.) 19 December 2002			1-40	
X	PENG NING et al., "Grape seed extract improves glucose handling and decreases plasma cholesterol level in fructose-induced diabetes in spontaneously hypertensive rats (SHR)" FASEB JOURNAL, vol. 19, no. 5, Suppl. S, Part 2, March 2005 (2005-03) page A1479			1-40	
X	VAGBHATA, "Mardvikamadyagunaah", Astanga Samgraha, TKDL Abstract No. AT/2145, Knowledge known since 1000 years			1-40	
X	KAIYADEVA, "Draksa Sura", Kaiyadevanighamau, TKDL Abstract No. RS6/866, Knowledge known since 500 years			1-40	
X	KANNUSAMY PILLAI, "Thiraakshaadhi Nei", Chikithsa Rathna Deepam, TKDL Abstract No. SK03/209, Knowledge known since 200 years			1-40	

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X	THERAYAR, "Ratha Pithanoi Kundineer 1", Therayar Kudineer, TKDL Abstract No. BS01/77, Knowledge known since 1000 years	1-40
Citation Relevance Category "A, X, Y, P, T, E, L, O, &" is as per PCT standard		



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Examiner's first report on patent application no. 2006294491
by The Regents of the University of California

Last proposed amendment no. 2

Dear Madam/Sir,

I am replying to the request for examination. I have based this report on the pamphlet and the statement of proposed amendments under S104 of 25 August 2010. I have examined the application and I believe that there are lawful grounds of objection to the application. These grounds of objection are:

1. There is no Notice of Entitlement on file. You will need to file one because an application without a Notice of Entitlement cannot be accepted.
2. Claims 1-40 lack an inventive step in light of the following documents:

D1[^]: PREUSS H G et al., "Protective effects of a novel niacin-bound chromium complex and a grape seed proanthocyanidin extract on advancing age and various aspects of syndrome X" ANNALS OF THE NEW YORK ACADEMY OF SCIENCES, vol. 957, (2002-01-01), pages 250-259

D2[^]: PREUSS H G et al., "Long-term effects of chromium, grape seed extract, and zinc on various metabolic parameters of rats" MOLECULAR AND CELLULAR BIOCHEMISTRY vol. 223, no. 1-2, (2001-07), pages 95-102

[^] cited in corresponding EP 1942919 search report dated 21 July 2010

D1 discloses the protective effects of Grape Seed Proanthocyanidin Extract (GSPE) on various aspects of Syndrome X (also known as metabolic syndrome). In particular Tables 1 and 2 show the effect on metabolic parameters in normotensive and hypertensive rats which received a short term (21-30 days) and long-term (1 year) supplementation of GSPE. In addition, a human clinical study is reported on pages 256-257.

D2 discloses the above mentioned long-term study with GSPE in normotensive rats (fig 3, table 2).

The claimed invention differs from D1-D2 in that it recites a phenolic profile of grapes comprising 2% by weight or less epicatechin-gallate terminal units.

It is well known in the art that grapes or grape seed extracts comprise polyphenols in different forms. It would appear from the current specification that the extracts of D1 and D2 contain epicatechin gallate terminal units in an amount above 2%. However, grape seed extracts comprising 2% or less epicatechin gallate terminal units are known within the art and it is not clear from the current specification that having epicatechin gallate units in an amount of 2% by weight or less would bring new or surprising results in treating metabolic syndrome to lower blood pressure, as compared to the prior art.

Therefore, in absence of any evidence to the contrary, this difference is considered a mere obvious alternative in the art which would be available for use by a person skilled in the art.

Therefore claims 1-40 lack an inventive step.

3. Additionally claims 1-40 lack an inventive step in view of a large number of documents. The art is replete with suggestions and disclosures of treatments comprising a polyphenol extract from grapes. The following documents are provided as examples chosen from many in a well traversed art:

D3*: US 2004/0247714 A1 (ROE et al.) 09 December 2004

D4*: US 2002/0192314 A1 (CHO et al.) 19 December 2002

D5^: PENG NING et al., "Grape seed extract improves glucose handling and decreases plasma cholesterol level in fructose-induced diabetes in spontaneously hypertensive rats (SHR)" FASEB JOURNAL, vol. 19, no. 5, Suppl. S, Part 2, March 2005 (2005-03) page A1479

D6#: VAGBHATA, "Mardvikamadyagunaah", Astanga Samgraha, TKDL Abstract No. AT/2145, Knowledge known since 1000 years

D7#: KAIYADEVA, "Draksa Sura", Kaiyadevanighamau, TKDL Abstract No. RS6/866, Knowledge known since 500 years

D8#: KANNUSAMY PILLAI, "Thiraakshaadhi Nei", Chikithsa Rathna Deepam, TKDL Abstract No. SK03/209, Knowledge known since 200 years

D9#: THERAYAR, "Ratha Pithanoi Kundineer 1", Therayar Kudineer, TKDL Abstract No. BS01/77, Knowledge known since 1000 years

* cited in ISR

^ cited in corresponding EP 1942919 search report dated 21 July 2010

cited by a third party in corresponding EP 1942919 observation dated 24 May 2010

D3 discloses a method of improving vascular function comprising administering to a subject in need thereof a grape seed extract, wherein said extract contains polyphenols as oligomeric and polymeric proanthocyanidins (abstract). D3 further discloses that the entities present in polymeric grape components include epicatechin gallate ([0009]).

D4 discloses a dietary supplement comprising a grape skin extract and grape seed extract for inhibiting platelet aggregation or LDL cholesterol oxidation in a mammal (abstract). D4 also discloses said grape seed extract comprises monomeric, oligomeric and polymeric flavanols, wherein oligomeric flavanols include dimers, trimers, tetramers etc ([0020]).

D5 discloses the positive effect of Grape Seed Extract on glucose tolerance in spontaneously hypertensive rats (abstract).

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D6 (pg. no. 3-4) discloses a formulation containing wine grape (*Vitis vinifera* Linn.) as a single ingredient used for the treatment of Diabetes Mellitus, wherein mode of administration is as directed by physician.

D7 (pg. no. 5-7) discloses a formulation containing wine grape (*Vitis vinifera* Linn.) as a single ingredient used for the treatment of Obesity through oral administration.

D8 (pg. no. 8-10) discloses a formulation containing wine grape (*Vitis vinifera* Linn.) as a single ingredient used for the treatment of hypertension through oral administration.

D9 (pg. no. 11-12) discloses a formulation containing wine grape (*Vitis Vinifera* Linn.) along with few other ingredients used for the treatment of Hypertension through oral administration.

The current specification defines Metabolic Syndrome as a syndrome characterised by an accumulation of risk factors for cardiovascular disease, stroke and/or diabetes mellitus type II (para [0006]). Therefore it is considered that symptoms and diseases as disclosed in D3-D9 would constitute risk factors that define Metabolic Syndrome, and grape seed extracts used for treatment of said symptoms and diseases would be inherently capable of alleviating Metabolic Syndrome.

The claimed invention differs from D3-D9 in that it recites a phenolic profile of grapes comprising 2% by weight or less epicatechin-gallate terminal units. As there is no indication of epicatechin gallate terminal units or commercial sources of grape seed extracts in these documents, it is considered that the grape seed extracts disclosed therein may comprise commercially available products known to have such a profile.

For similar reasons outlined in Objection No. 2, this difference is considered a mere obvious alternative in the art which would be available for use by a person skilled in the art.

Therefore claims 1-40 lack an inventive step.

You have 21 months from the date of this report 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. These will normally be first due five years from the filing date. Please note however that earlier commencement dates apply for divisional applications.

Information about fees may be obtained by phoning 1300 651 010.

Yours faithfully,

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Bibliographic Details at Acceptance

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National Phase Entry Date: 9 April 2008
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Title: Method for lowering blood pressure in pre-hypertensive individuals and/or individuals with metabolic syndrome
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Prior Art Documents:

THERAYAR, "Ratha Pithanoi Kundineer 1", Therayar Kudineer, TKDL Abstract No. BS01/77, Knowledge known since 1000 years
PENG NING et al., "Grape seed extract improves glucose handling and decreases plasma cholesterol level in fructose-induced diabetes in spontaneously hypertensive rats (SHR)" FASEB JOURNAL, vol. 19, no. 5, Suppl. S, Part 2, March 2005 (2005-
VAGBHATA, "Mardvikamadyagunaah", Astanga Samgraha, TKDL Abstract No. AT/2145, Knowledge known since 1000 years
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PREUSS H G et al., "Long-term effects of chromium, grape seed extract, and zinc on various metabolic parameters of rats" MOLECULAR AND CELLULAR BIOCHEMISTRY vol. 223, no. 1-2, (2001-07), pages 95-102
US 2004/0247714 A1 (ROE et al.) 09 December 2004
US 2002/0192314 A1 (CHO et al.) 19 December 2002

Priority Details:

Date	Application Number	Country
28 September 2005	60/721,720	United States of America

Int. Cl.

A23L 1/28 (2006.01)
A01N 65/00 (2006.01)

Continuation Fee Due Date: 26 September 2012