Australian Government
IP Australia

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Date of issue: 27 June 2013

Patent Examination Report No. 1

Application Details

Patent Application No.: 2009313865

Applicant/s: Xeros Pharmaceuticals, LLC, VDF Futureceuticals, Inc.

Your reference: 33946VDF

Earliest Priority Date: 13 November 2008

Examination Request Date: 06 December 2012

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 **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. Information about fees may be obtained by phoning 1300 651 010 or by visiting www.ipaustralia.gov.au.

Basis of the report

In examining your application I have taken into account:

- the PCT pamphlet and amendments already made under the PCT Articles

I have examined this application on the basis of the claims as amended under Article 19. However, you may wish to correct the non-sequential page numbering caused by the Article 19 amendments

Statement of Novelty, Inventive Step and Patentable Subject Matter

Novelty/Inventive Step	Claim No. NONE Claim No. 1-20	**Yes** **No**
Patentable Subject Matter	Claim No. 1-20 Claim No. NONE	**Yes** **No**

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

1 Claim 1 is not clear. The claim defines a method of providing relief from a symptom associated with hyposalivation which comprises the following steps:
1) Formulate a topical composition for oral administration that includes as a sialagogue a combination of at least one proanthocyanidin and a grape seed extract, wherein the sialagogue is present at a concentration effective to provide relief from the symptom;
2) Obtain a test result that indicates that the at least one of the proanthocyanidin and a grape seed extract provide relief from the symptom; and
3) Provide the composition in association with the test result.

It is not clear how to obtain the test result as there is no indication as to how perform the test or what test to perform.

It is not clear how the method will provide relief from a symptom. The phrase "provide the composition in association with the test result" is not clear and does not specifically indicate that the composition is administered to the person in need of it.

The phrase "provide the composition in association with the test results" is not clear. It is not clear what the scope of the term 'association' is. It is also not clear to whom the composition is to be provided, presumably the patient, but it is not clear how the provision of results will provide relief.

It is not clear if the composition must contain at least two components, ie a proanthocyanidin and a grape seed extract or it only need to contain one of them. The wording of the claim suggests that for there must be two components, in particular the term combination implies more than one component. But the dictionary definition at page 14 the bottom of paragraph [0044] states that "where the specification **claims** refers to at least one of something selected from the group consisting of A,B, C. **AND** N the text should be interpreted as requiring only one element from the group not A plus N or B plus N. The use of the term "and/or", with regard to proanthocyanidin and/or grape seed extract, throughout the description also indicates that the substances can be in the composition alone.

Following on from above: Claims 5, 6 and 14 are construed as meaning that either the proanthocyanidin or the grape seed extract must be present at a concentration of equal or less than 1% (or 0.1%) not the combination of both in accordance with paragraph [0044]. And Claim 8 that the citrus extract with either the proanthocyanidin or the grape seed extract form a synergistic combination.

2 Claims 10 and 16 are not clear. It is not clear how the phrase "to provide" is intended to limit the

product. Both claims are directed to 'An oral care product'. The product can only provide oral comfort and treat the symptoms when it is administered to a patient in need of treatment. In the absence of an administration step in the claim or treatment method steps the claim can only be construed as to the composition per se'.

Therefore claims 10 and 16 are construed to be directed to the composition per se' that must only be suitable for relief of a symptom of hyposalivation.

Similarly the term "for" with regard to oral topical administration is not limiting on the product per se' as the term "for" is construed as meaning suitable for oral topical administration. Therefore a solution, liquid or food substance would be considered to be suitable for oral topical application even in light of the definition of paragraph [0031] as the solution, liquid or food substance could be spat out after contact with the surfaces within the mouth. As often occurs with mouthwashes or gargles.

3 Claim 16 is further not clear with regard to the phrase "comprising a plant extract that is demonstrated to have M3 receptor agonist activity, wherein the plant extract is present as a sialagogue active ingredient". If the plant extract activates the M3 receptor then it would inherently be present as a sialagogue active ingredient according to paragraph [0030] that states "the fruit/seed extract/proanthocyanidins as well as the citrus extract act as M3 receptor agonists. Therefore, it should be recognised that all plant extracts that activate the M3 receptor are deemed suitable for use herein". It is not clear if the wording of the claim is intended to impart another construction.

Documents Cited or Considered Relevant

D1 : US 6299925 B1 (Xiong et al) 09 October 2001 #
Category: X Claims: 10-15

D2 : US 2006/0024248 A1 (Spengler et al) 02 February 2006 #
Category: X Claims: 1-6, 9-14
Category: Y Claims: 7, 8, 15

D3 WO 2006/135785 A2 (Medical College of Georgia Research Institute) 21 December 2006 #
Category: X Claims: 1-15

D4 : AU 2008221548 A1 (GreenTaste Pty Ltd) 04 August 2010 ****
Category: P,X Claims: 10-20

D5 : TKDL KS01-110 Anuboga Vaithya Navaneetham, Part - 8, Ed:Mohammad Abdullah Shahib, Publisher: Thamarai Noolagam, Chennai. (Edn: 2nd, 2002) *
Category: X Claims: 1-20

D6 : TKDL ME02-167 Pulippani Vaithyam - 500. Ed:S.P.Ramachandhiran, Publisher: Thamarai Noolagam, Chennai. (Edn: 1st, 1999) *
Category: X Claims: 1-15

D7 : TKDL NA 4-248A Qaraabaadeen Najm-al-Ghani (20th century AD), Munshi Nawal Kishore, Lucknow, (Second Edition) 1928 AD *
Category: X Claims: 1-3, 5, 6, 10-12, 14
Category: Y Claims: 7, 8 , 15

D8 : TKDL AA27-5G1 Al-Abnia-'an-Haqaayiq-al-Advia (11th century AD), Tehran, Iran, 1992 AD *
Category: Y Claims: 7, 8, 15

D9 : TKDL RG13-29C Nighaṇṭuratnākara* - Edited and Marathi Translation by GRS Datar, BAS Tamankar, KS Mahabal, VV Patel; Part-2, Vishnu Vasudev Godbole, Bombay, Edn. 1887 *
Category: X Claims: 1-3, 5, 6, 10-13, 14
Category: Y Claims: 7, 8, 15

D10 : TKDL RS15-476 Madanapālanighaṇṭu* - Translated by Rama Prasad; Khemaraj Shri Krishnadas Prakashan, Bombay, Edn. 1998 *
Category: Y Claims: 7, 8, 15

D11 : TKDL RS6-112 Madanapālanighaṇṭu* - Translated by Rama Prasad; Khemaraj Shri Krishnadas Prakashan, Bombay, Edn. 1998 *
Category: Y Claims: 7, 8, 15

D12 : US 2006/115468 A1 (Morrison K) 01 June 2006 *****
Category: X Claims: 10-12, 14- 16-18, 20

D13 : US 2006/0024385 A1 (Pedersen M) 02 February 2006 *****
Category: X Claims: 10-15

D14 : US 2006/88643 A1 (Fugal et al) 27 April 2006 *****
Category: X Claims: 10-12, 14

D15 : Ghayur MN et al "Ginger facilitates cholinergic activity possibly due to blockade of muscarinic autoreceptors in rat stomach fundus" PAK J Pharm Sci 2007 Jul ; 20 (3):231-5 & Pubmed Abstract 17545109 *****
Category: A Claims: 16-20

* Cited in the International Search Report and the IPRP/PRPII
* Cited in the EP Examination report dated 14 August 2012 for Application No. 09760382.
***** Document found in an original search. See attached Search Information Statement for details.

Note that this report has cited non-patent literature document/s. Copies of non-patent literature document/s can be requested for a fee (see Patent Regulations, schedule 7, fee item 234) by emailing assist@ipaustralia.gov.au.

Please provide the citation details and associated patent application number with your request. Note that because of copyright restrictions we can only provide copies of hard copy books, journals and newspapers (see the Australian Patent Office Manual of Practice and Procedure at part 2.13.14 Copying of Material and Copyright Implications). However copies of any remaining documents should be readily obtainable from known electronic database sources.

Special categories of cited documents:

X: The claimed invention cannot be considered novel under subsection 7(1) in light of the document and/or cannot be considered to involve an inventive step under subsection 7(2) of the Act in light of the common general knowledge considered together with the document.
Y: The claimed invention cannot be considered to involve an inventive step under subsection 7(2) of the Act in light of the common general knowledge when considered together with a combination of the document and one or more other such documents.
A: Document defining the general state of the art which is not considered to be of particular relevance.
P: Document published prior to the filing date but later than the priority date claimed

Novelty and Inventive Step

4 The claims in general lack clarity, which is compounded by dictionary definitions in the description (Please see objections 1-3 above). In considering novelty and inventive step the claims have been

construed to require one proanthrocyanidin source, not a pure compound of proanthocyanidin as there is no disclosure of the pure compound in the description. That source is considered to include any substance that contains proanthocyanidin, that source may be grape seed extract as it is well known in the literature that grape seed extract is extremely high in proanthocyanidins. The claims therefore have been construed to require **either** a proanthocyandin source **or** grape seed extract. Having stated this, documents have been cited which disclose compositions comprising both a source of proanthocyanidins and grape seed extract.

The test results obtained in claim 1 is considered to include placing the composition in the patients mouth and accessing if relief is found.

As noted in the clarity objections above claims 10 and 16 have been construed to be limited to the compositions per se' please refer to those objections for further reasoning.

The invention defined in claim 1 is not novel (and does not involve an inventive step) when compared with either of the following prior art documents that disclose all the essential features of the invention claimed:
D2 which discloses dry mouth relieving compositions comprising grape seed extract [0069], [0074], flavour extracts of cinnamon and citus based flavours [0054]. Tests results on the effectiveness of compositions are recorded in table III and example 3.
and
D3 which discloses compositions and methods of treating symptoms of Sjogren's Syndrome in particular Xerostomia (page 2 lines 6-35). The composition comprising green tea polyphenyols such as proanthocyanidins (page 3 line 31), dosage forms include oral formulations such as tablets, pastes, powders etc (page 14 line 31- page 15 line 9).

5 The invention defined in Claim 10 is not novel (and does not involve an inventive step) when compared with the disclosure of many patent specifications of which the following are a selection:
D1: Discloses compositions comprising grape seed extract and green tea extract (known to be a source of proanthocyanidins), the formulations are in a powder form (see examples V and VI).
D2: Disclosure discussed in previous objection.
D3: Disclosure discussed in previous objection.
D4:This document discloses apple, cinnnamon, cranberry and ginger in liquid herbal formulations. All these substances are known to be souces of proanthocyanidins.
D12: Discloses compositions suitable for oral topical administration which comprises, red wine extract, grapeseed extract, green tea extract and ginger root (claim 1).
D13: Discloses a composition suitable for oral topical administration which comprises grape seed extract, cranberry extract and bilberry extract [0112].
D14:This document discloses a composition comprising buckthorn extract, apple fruit extract, grape seed extract and green tea extract which is suitable for oral topical use (see claims, in particular 11-12).

6 The invention defined in claim 16 is not novel (and does not involve an inventive step) when compared with any of the following prior art documents that disclose all the essential features of the invention claimed:
D3 and D12 both disclose ginger in compositions. Ginger has a M3 receptor agonist activity. This activity is demonstrated in D15 which is cited as representative of common general knowledge at the time of the invention.

7 The invention defined in claims 1, 10 and 16 is not novel (and does not involve an inventive step) when compared with the following prior art document that discloses all the essential features of the invention claimed:
D5: A traditional knowledge citation which discloses a syrupy formulation for oral administration for the treatment of tastlessness and dry mouth. The formulation comprises ginger, cinnamon and citrus lemon. Ginger and cinnamon are known as a source of proanthocyanidins and ginger has a demonstrated M3 agonist activity.

8 The invention defined in claims 1 and 10 is not novel (and does not involve an inventive step) when compared with the following prior art document that discloses all the essential features of the invention claimed:
D6 which discloses wine grape extract and citrus lemon in the form of a pill or tablet traditionally used to treat dryness of the tongue.

9 It is considered that the features of the dependant claims 11 and 17 add nothing to the independent claim. The independent claim is directed to the composition per se', the further limitation of the symptoms does not further limit the composition. Claims 12 and 18 lack an inventive step in light of common general knowledge where the topical formulations are well within the knowledge and skills of the person skilled in the art to formulate without any inventive faculty.
Features of the remaining dependant claims are disclosed in one or more of the cited documents or a combination of the cited documents. These have been discussed in Box V2 of the IPER dated 29 June 2011 and in points 1.2, 1.3, 1.4, 5 and 6 of the European examination report on Application Number 09760382 dated 14 August 2012.

While the objection regarding these documents was not made under Australian law, I agree with the reasons given in that report and consider that they support a corresponding objection against the Australian claims.

10 Further to the above novelty objections it appears that the compositions of claims 10 and 16 are not novel in light of the known, commercially available products discussed on page 9, para [0032] of the description. VDF FutureCeutical products FC-03, FC-06 and FC-09 all comprise proanthocyanidin sources and are demonstrated to have M3 receptor agonist activity in a form suitable for oral topical administration.

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