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Date of issue: 3 June 2015

Patent Examination Report No. 1

Application Details

Patent Application No.:	2014201901
Applicant/s:	Scott & White Healthcare
Your reference:	997587
Earliest Priority Date:	07 September 2006
Examination Request Date:	26 June 2014

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 **12 months** from the date of this report to overcome all my objection(s) otherwise your application will lapse.

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 considered:

- the specification as filed

Note the present claims are identical to the claims originally filed for parent application **2007293047**

Statement of Novelty, Inventive Step and Patentable Subject Matter

Novelty/Inventive Step	Claim No. NONE Claim No. 1-69	**Yes** **No**
Patentable Subject Matter	Claim No. 1-69 Claim No. NONE	**Yes** **No**

Section 40 (Support, Disclosure, Clarity, Lack of Unity)

1 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 claims into distinct groups:

Claims **1, 3, 5-33, 35-39, 41-45, 48-61** directed to methods of inhibiting IL-3R expressing cells with a conjugate of (IL-3)-diphtheria toxin wherein the cells are ***not*** AML cells, wherein the cells express both alpha and beta subunits of the receptor.

Claims **2, 4, 34, 40, 46 and 47** are directed to methods of inhibiting IL-3R expressing cells with a conjugate of (IL-3)-diphtheria toxin at a concentration of 4µg/kg, wherein the cells express only the alpha subunit of the receptor.

Claims **62-69** directed to methods purging/transplanting bone marrow with a conjugate of (IL-3)-diphtheria toxin to purge the sample of IL-3R expressing cells wherein the cells express both alpha and beta subunits of the receptor.

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.

The only feature common to all of the claimed inventions and which provides a technical relationship among them is methods of inhibiting IL-3R expressing cells with a conjugate of (IL-3)-diphtheria.

However this feature does not make a contribution over the prior art because it is disclosed in:

FRANKEL AE et al, Blood, American Society of Haematology, 2001, vol. 98, page 328A

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 : FRANKEL ARTHUR E ET AL: "Diphtheria toxin-interleukin 3 fusion protein (DT3881L3) prolongs survival of leukemic SCIO mice", BLOOD, AMERICAN SOCIETY OF HEMATOLOGY, US, vol. 98, no. 11 Part 1, 11 December 2001 (2001-12-11), page 328A *

Category: **X** Claims: 2, 4, 34, 40, 46 and 47

D2 : FRANKEL ARTHUR E ET AL: "The AML recombinant toxin, DT3881L3, consisting of a truncated diphtheria toxin (DT388) linked to human interleukin 3 (IL3), shows safety at therapeutically active doses

in cynomolgus monkeys", BLOOD, AMERICAN SOCIETY OF HEMATOLOGY, US, vol. 102, no. 11, 9 December 2003 (2003-12-09), page 386A *
Category: **X** Claims: 2, 4, 34, 40, 46 and 47

D3 : COHEN KA et al, "Safety evaluation of $DT_{388}IL3$, a diphtheria toxin/interleukin 3 fusion protein, in the cynomolgus monkey." Cancer Immunology Immunother, 2005, vol 54, pp 799-806 *
Category: **X** Claims: 2, 4, 34, 40, 46 and 47

D4 : VALLERA DANIEL A ET AL: "Targeting myeloid leukemia with a DT390-mIL-3 fusion immunotoxin: Ex vivo and in vivo studies in mice", PROTEIN ENGINEERING, vol. 12, no. 9, September 1999 (1999-09), pages 779-785 *
Category: **X** Claims: 1-69

D5 : VALLERA D A ET AL: "Ex vivo purging of myeloid leukemia cells from murine BM with a fusion immunotoxin recognizing the interleukin-3 receptor", BLOOD, AMERICAN SOCIETY OF HEMATOLOGY, US, vol. 90, no. 10 Suppl. 1 Part 1, 9 December 1997 (1997-12-09), page 187A *
Category: **X** Claims: 1-69

D6 : CHAN et al. Reactivity of Murine Cytokine Fusion Toxin, Diphtheria Toxin390-Murine 1-69 Interleukin-3 (DT390-mIL-3), With Bone Marrow Progenitor Cells. Blood. 15 August 1996, pages 1445-1458 #
Category: **X** Claims: 1-69

Cited in the International Search Report and the IPRPI/IPRPII
* Cited in the EP SUPPLEMENTARY EUROPEAN SEARCH REPORT dated 19 July 2011 for Application No. EP 07 83 7840.

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) through IP Australia's eServices at http://www.ipaustralia.gov.au/get-the-right-ip/eservices/

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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.

Novelty and Inventive Step

2 Claims 1-69 lack an inventive step in light of the prior art document **D6** discussed in Box V of the IPRP1 of parent application **2007293047** dated 10 March 2009.

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.

A similar inventive step objection applies with regards to each of documents **D4 and D5.**

3 Claims 2, 4, 34, 40, 46 and 47 do not involve an inventive step in light of any one of prior art documents D1-D3.

D1 to D3 disclose methods of inhibiting IL-3R expressing AML cells with a conjugate of (IL-3)-diphtheria toxin. They further disclose the diphtheria toxin consisting of 388 amino acids which inherently includes the catalytic and translocation domains of the diphtheria toxin.

The claimed invention differs from the cited art in that it specifies that the leukemia cells express specific (alpha/beta) subunits for IL-3R. D1 to D3 are silent on this requirement. However given that IL-3R contains only alpha and beta subunits, the cells would have to express either one or both these subunits.

The specification describes no particular problem to be overcome which would act as a barrier in applying such a known alternative without an inventive solution, nor is such a solution described. Additionally the particular selection provides no new or surprising result.

Therefore this is merely an obvious choice which the PSA would arrive at by a routine and non-inventive process.

How to contact us

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