



Australian Government

IP Australia

Best Practice Guide for Filing a Patent Application in Australia

*A practical guide to preparing a patent application for Australia based on
international standards and best practice*

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1. Introduction

This best practice guide has been established based upon, and should be read in conjunction with, the formality requirements of Schedule 3 of Australian Patent Regulations. It is also based on the requirements under the Patent Cooperation Treaty (PCT), recommendations provided by WIPO Standard ST.22 and the common application formats (CAF) accepted by the Trilateral Offices (USPTO, EPO and JPO).

It however does not cover all the requirements of schedule 3, particularly those relating to terminology and signs, and matter that may be considered scandalous. If you are in doubt about these requirements, or wish to depart from the recommended format provided in this guide, you should consult the schedule directly.

Guidance for the preparation and filing of international applications under the PCT (including using the PCT-safe software) is available from the WIPO website. Information on filing international applications with IP Australia is provided on IP Australia's website, under "The international (or PCT) application process".

1.1. ***Benefits of following this Best Practice Guide***

- Following this guide will help you draft an application that is in the form approved by the Commissioner and conforms to the requirements of Schedule 3 of the Australian Patent Regulations.
- A specification drafted according to this best practice guide will also be consistent with the format of applications required in other IP Offices such as the USPTO, EPO and JPO. This will assist you to prepare a specification that will be acceptable in other offices without requiring further major modifications.
- New specifications filed in Australia in paper form can be accurately captured using Optical Character Recognition (OCR) technology. The resulting electronic digitized records will facilitate application processing and enhanced searching capabilities across Australian specifications.
- The best practice guide provides an ideal basis for future developments of applications filed electronically using text-based XML.

2. Preparing your Application

2.1. Sections of the Application

2.1.1. The parts of the application should be placed in the following order:

- a. Patent Request
- b. Description
- c. Claim/s
- d. Abstract
- e. Drawing/s (if applicable)
- f. Sequence listing (if applicable)

2.1.2. Each part must commence on a new page.

2.2. Patent Requests

2.2.1. Patent Request forms can be obtained from IP Australia's website, available under "Patent Forms & Publications".

2.2.2. The official forms reflect the form for requests approved by the Commissioner of Patents. A request not on the relevant official form must nevertheless conform to it. In particular, any instructions on the approved form must be followed and information indicated as mandatory must be provided.

2.2.3. If not using the official form, the following requirements for page layout, margins and fonts apply unless otherwise indicated.

2.3. Page Layout

2.3.1. The size of the sheets must be A4 (21cm x 29.7cm).

2.3.2. Landscape orientation must not be used unless for pages containing embedded drawings, tables, chemical or mathematical formulae that would not fit in a portrait orientation.

2.3.3. Pages must be printed on only one side of the sheet.

- 2.3.4. Pages of a specification must be sequentially numbered with Arabic numerals beginning with “1”.
- 2.3.5. Page numbers must be centred at the top of each page and should be located 0.5cm from the margin (See Appendix I).
- 2.3.6. Paragraphs in a specification should be sequentially numbered from the first paragraph of the description, contained within brackets and indicated with Arabic numerals beginning with “[0001]”. See Appendix II for an example of description page
- 2.3.7. Paragraphs should be left aligned. Each paragraph number should align to the first line of each paragraph. See Appendix II for an example of a description page.
- 2.3.8. The space between the paragraphs should be at least twice the intra-paragraph line spacing.
- 2.3.9. Line numbering should not be used.
- 2.3.10. All pages should contain only one direction of text
- 2.3.11. Text must be set at 1½ line spacing
- 2.3.12. Handwritten text paragraphs or annotations should not be used.
- 2.3.13. All characters should be solid black on a white background

2.4. Margins

- 2.4.1. Each sheet of Abstract, description and claims must have the left hand margin set at least at 2.5 cm and all other margins set at least at 2cm (see Appendix I)
- 2.4.2. Each sheet of drawing must have the top and the left margins set at least at 2.5 cm, right margin set at least at 1.5 cm and bottom margin set at least at 1cm.

2.5. Fonts

2.5.1. All text must be presented in letters the capitals of which are not less than 0.21 cm high, in a dark colour and be indelible. As a guide, a minimum font size of 12 points is acceptable.

2.5.2. The fonts should be in solid black.

2.5.3. The preferred fonts are:

- Monospaced family: OCR-B, Courier New, Free Mono
- Serif family: ITC Officina Serif, Times New Roman, Free Times
- Sans serif family: Verdana, ITC Officina Sans, Arial, Helvetica, DejaVu Sans

2.5.4. Narrow and cursive fonts should not be used.

2.5.5. Bold and italic styles, and underlined text should not be used.

2.6. Description

2.6.1. The list below shows the titles, sub-titles (indicated by indentation) and order which should be used within the description. The titles in bold should be included in the application. If due to the nature of the invention, the section titles are not suitable, alternative titles may be used.

Title of Invention or Title

Technical Field or Field

Background Art or Background

Summary of Invention or Summary

Technical Problem

Solution to Problem

Advantageous Effects of Invention

Brief Description of Drawings (if applicable)

Description of Embodiments

Examples

Industrial Applicability

Reference Signs List (If applicable)
Reference to Deposited Biological Material (if applicable)
Sequence Listing Free Text (if applicable)
Citation List (if applicable)
Patent Literature (If applicable)
Non-Patent Literature (If applicable)

2.6.2. Paragraphs should be left aligned. Each paragraph number should align to the first line of each paragraph. See Appendix II for an example of a description page.

2.6.3. Description must not include drawings but may include chemical or mathematical formulae and/or tables where necessary.

2.6.4. The section titles and titles within the description should not be numbered

2.7. Claims

2.7.1. Claims must commence on a separate page.

2.7.2. Each claim must be numbered sequentially in Arabic numerals beginning with "1".

2.7.3. Each claim number should align to the first line of each claim.

2.7.4. The first line of text of each claim should be right-indented with respect to the claim number by at least 1cm allowing for a clean separation between the first line of the text of the claim and the claim number (see Appendix III).

2.7.5. Claims must not include drawings but may include chemical or mathematical formulae and/or tables where necessary.

2.8. Abstract

2.8.1. Abstract should be between 50-150 words (see Appendix V).

2.8.2. Abstract must not include drawings but may include chemical or mathematical formulae and/or tables where necessary.

2.8.3. Abstract page should not be numbered

2.9. Drawings

2.9.1. Drawings must commence on a separate page.

2.9.2. Images and drawings must be executed in durable, black, dense, dark, uniformly thick and well-defined, lines and strokes without colouring.

2.9.3. Grayscale images should not be used as information is lost when scanning them or converting them to black and white.

2.9.4. Each drawing or figure should be numbered separately and labelled by a sign to indicate that it is a drawing (i.e. Fig. 1 or Figure 1) (see Appendix IV).

2.9.5. The sheet of a specification that contains drawings must be numbered by means of 2 Arabic numerals separated by an oblique stroke, the first numeral in each set being the consecutive number of each sheet, beginning with the Arabic number "1", and the second being the total number of the sheets containing the drawings.

2.9.6. Drawings must not be included in the description, claims or abstract.

2.9.7. Drawings must not contain a frame surrounding the drawings

2.9.8. A drawing must not include text, other than a word or words indispensable to the understanding of the drawing

2.10. Tables and Formulae

2.10.1. Tables, chemical formulae and mathematical formulae should be separated from text paragraphs (see Appendices VI to VIII).

2.10.2. Tables, chemical formulae and mathematical formulae should be separated above and below text paragraphs by a clear space of at least 1 cm across the width of the page.

2.10.3. Tables should contain one direction of text

2.10.4. Tables should have borders. The borders should be solid lines having a minimum thickness of 1.5 points.

2.10.5. Each Table, formula or mathematical equation should be labelled by a sign to indicate that it is a table, formula or equation together with an Arabic numeral (i.e. Fig. 1, Table 1, Math. 1, Chem. 1, Formula 1, Equation 1 or Compound 1).

2.11. Nucleotide and/or Amino Acid Sequence Listings

2.11.1. Sequence listings should be submitted in electronic text format on physical media. The format should be consistent with that of the PCT Administrative Instruction Annex C.

2.12. Amending your Application

2.12.1. Form for amendments

- Amendments to the patent request and specification (including drawings) must be made by means of substituting one page or document for another page or document. Amendments specifying deletions and/or insertions by page and line numbering or otherwise are not permitted.
- A statement of proposed amendment on a separate sheet or sheets is also required. This must include the application number and an itemised list of the amendments proposed, numbered consecutively. The consecutive

numbering must continue in any further statements filed for the application to ensure that amendments ultimately allowed can be clearly identified.

- For amendments to the specification, an additional copy of each substitute page marked to indicate the nature and location of the proposed amendments is required. It should not merely indicate that the page is new or substituted unless it is impractical to indicate where each change has been made to the page.

2.12.2. Amendments made to description:

- Where amendments require new paragraphs to be inserted then the new paragraphs should be allocated the same Arabic numeral as the preceding paragraph followed by an alphabet starting with letter (a). For example, if two new paragraphs are inserted between paragraphs [0001] and [0002] then the new paragraph numbering between paragraphs [0001] and [0002] should be [0001a] and [0001b] (see Appendix II-A).
- Where amendments require paragraphs to be deleted than a comment stating “paragraphs [number/s] intentionally deleted” should be placed in place of those deleted paragraphs. For example, if two paragraphs after paragraph [0001] are to be deleted then the new paragraph numbering should be [0001], [paragraphs 0002-0003 intentionally deleted], [0004] (see Appendix II-B).
- Where additional pages are required as a result of amendments, then additional pages should be allocated the same Arabic numeral number as the preceding page followed by an alphabet starting with letter (a). For example 1a, 1b, 1c etc. If a page is deleted, then a blank page with a statement “page intentionally left blank” should be inserted in place of the deleted page.

2.12.3. Amendments made to claim/s:

Where amendments have been introduced to add or delete one or more claims, claim numbers and page numbers should be re-numbered consecutively.

2.12.4. Amendments made to drawing/s:

Where amendments have been introduced to add or delete one or more drawings, the drawing numbers and page numbers should be re-numbered consecutively.

3. Filing your Specification

3.1 *Means of Filing your Specification*

Specifications should be filed using one of the following means of filing:

- In person at IP lodgement points located in each state and territory
- Via post
- Via fax
- Via IP Australia's online submission facility as electronic attachments.

3.2 *Electronic Attachment Formats*

Specifications filed online as attachments should be in acceptable electronic formats, which include PDF (for Abstract, description and claims) and TIFF or JPEG (for drawings). Electronic files must not be locked or password protected. PDF format is obtained using a PDF converter (a tool which converts a word-processing document to PDF format).

3.3 *Use of Physical Media*

Specifications in paper form exceeding 1000 pages or specifications in electronic form exceeding 30 MB in size should be sent to IP Australia as physical media such as DVD, CD or USB. Specifications stored in physical media should be in the form of PDF, TIFF or JPEG.

4. Appendices

Appendix I-A: Margins of description, claims & abstract page

Appendix I-B: Margins of drawings & figures page

Appendix II: Example of description

Appendix II-A: Example of amendments to description (Addition of paragraphs)

Appendix II-B: Example of amendments to description (Deletion of paragraphs)

Appendix III: Example of claims

Appendix IV: Example of drawings

Appendix V: Example of abstract

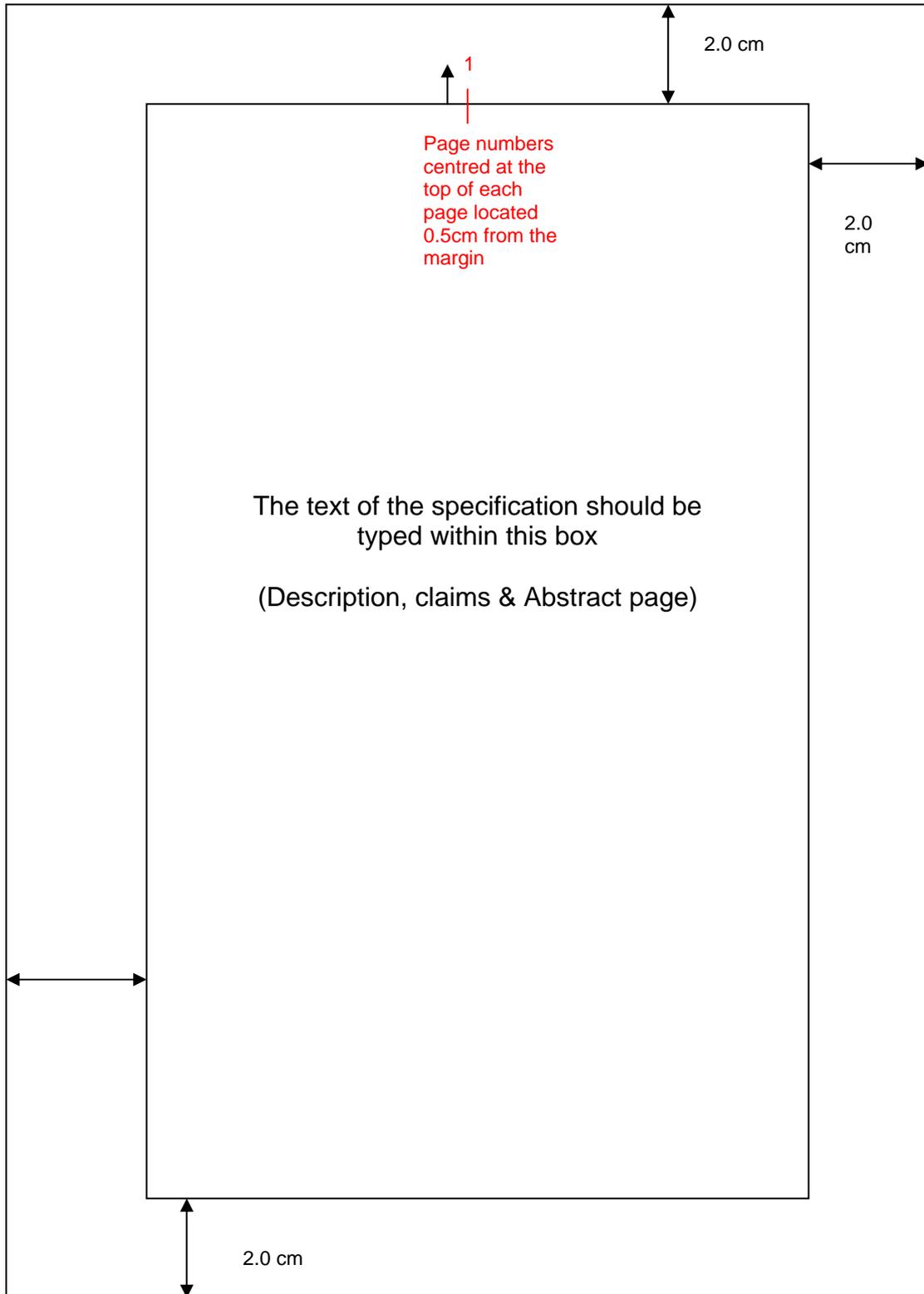
Appendix VI: Example of description page with chemical formulae

Appendix VII: Example of description page with mathematical formulae

Appendix VIII: Example of description page with table

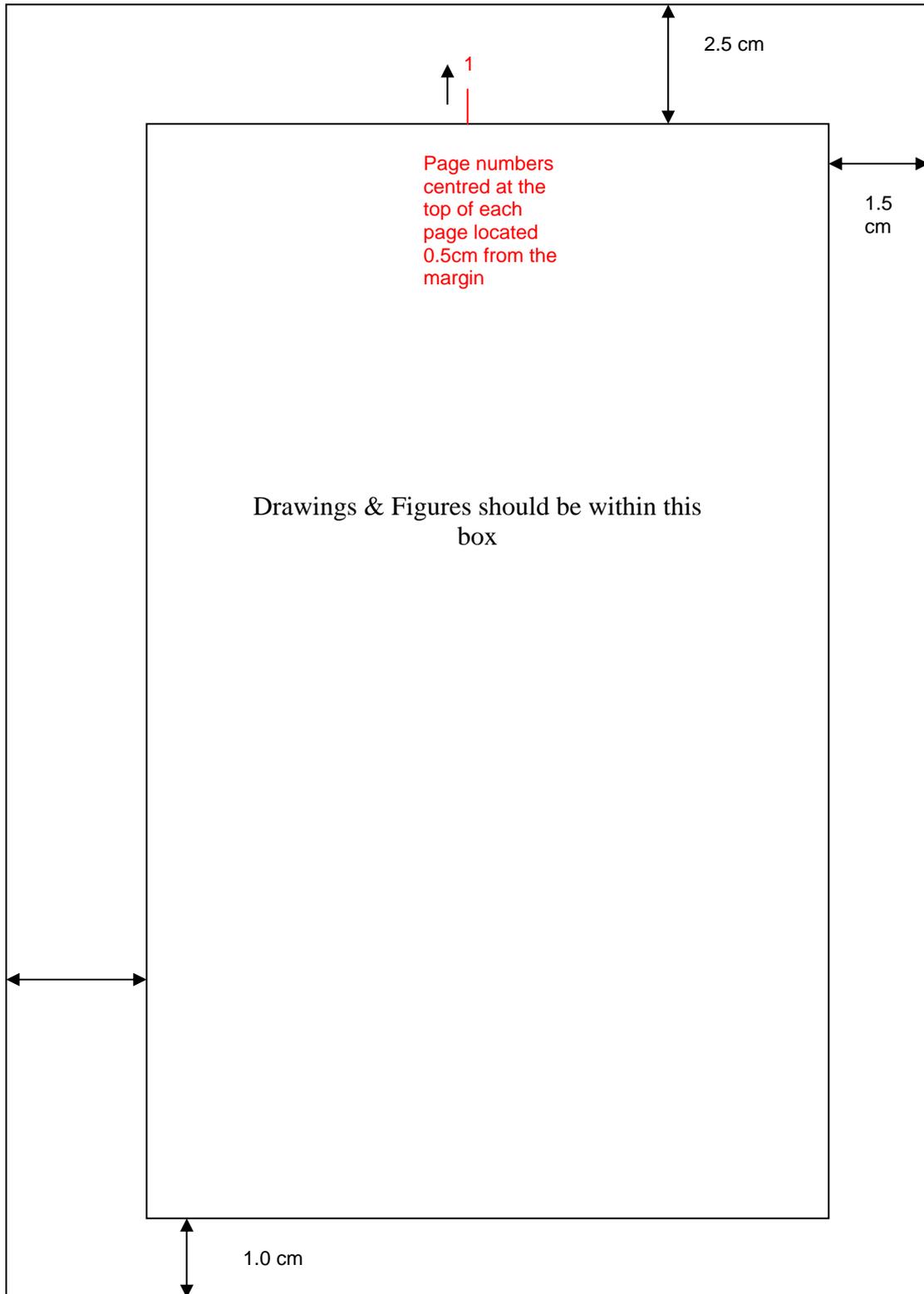
APPENDIX 1-A

Page Size = A4



APPENDIX 1-B

Page Size = A4



Appendix II: Example of description page

1

CONJUGATES HAVING A DEGRADABLE LINKAGE AND POLYMERIC REAGENTS USEFUL IN PREPARING SUCH CONJUGATES

BACKGROUND OF THE INVENTION

[0001] The present invention relates generally to polymeric reagents useful in providing a conjugate having a degradable linkage between a polymer and another moiety. In addition, the invention relates to, among other things, conjugates of the polymeric reagents, methods for synthesizing the polymeric reagents and methods for conjugating the polymeric reagents to active agents and other moieties.

[0002] Scientists and clinicians face a number of challenges in their attempts to develop active agents into forms suited for delivery to a patient. Active agents that are polypeptides, for example, are often delivered via injection rather than orally. In this way, the polypeptide is introduced into the systemic circulation without exposure to the proteolytic environment of the stomach. Injection of polypeptides, however, has several drawbacks

[0003] For example, many polypeptides have a relatively short half-life, thereby necessitating repeated injections, which are often inconvenient and painful. Moreover, some polypeptides can elicit one or more immune responses with the consequence that the patient's immune system attempts to destroy or otherwise neutralize the immunogenic polypeptide. Of course, once the polypeptide has been destroyed or otherwise neutralized, the polypeptide cannot exert its intended pharmacodynamic activity. Thus, delivery of active agents such as polypeptides is often problematic even when these agents are administered by injection. Some success has been achieved in addressing the problems of delivering active agents via injection.

[0004] Some success has been achieved in addressing the problems of delivering active agents via injection. For example, conjugating the active agent to a water-soluble polymer has resulted in polymer-active agent conjugates having reduced immunogenicity and antigenicity. In addition, these polymer-active agent conjugates often have greatly increased half-lives compared to their unconjugated counterparts as a result of decreased clearance through the kidney and/or decreased enzymatic degradation in the systemic circulation. As a result of having a greater half-life, the polymer-active agent conjugate requires less frequent dosing, which in turn reduces the overall number of painful injections and inconvenient visits with a health care professional.

Page number centred and positioned at the top of the page

Paragraph numbered

1.5 line spacing

Left aligned

Font size is 12 points

Inter-paragraph spacing is twice the intra-paragraph line spacing

Appendix II-A: Example of amendments to description page (Addition of paragraphs)

13

CONJUGATES HAVING A DEGRADABLE LINKAGE AND POLYMERIC REAGENTS
USEFUL IN PREPARING SUCH CONJUGATES

BACKGROUND OF THE INVENTION

**Numbering of additional
paragraphs**

[0001] The present invention relates generally to polymeric reagents useful in providing a conjugate having a degradable linkage between a polymer and another moiety. In addition, the invention relates to, among other things, conjugates of the polymeric reagents, methods for synthesizing the polymeric reagents and methods for conjugating the polymeric reagents to active agents and other moieties.

[0001a] Scientists and clinicians face a number of challenges in their attempts to develop active agents into forms suited for delivery to a patient. Active agents that are polypeptides, for example, are often delivered via injection rather than orally. In this way, the polypeptide is introduced into the systemic circulation without exposure to the proteolytic environment of the stomach. Injection of polypeptides, however, has several drawbacks.

[0001b] For example, many polypeptides have a relatively short half-life, thereby necessitating repeated injections, which are often inconvenient and painful. Moreover, some polypeptides can elicit one or more immune responses with the consequence that the patient's immune system attempts to destroy or otherwise neutralize the immunogenic polypeptide. Of course, once the polypeptide has been destroyed or otherwise neutralized, the polypeptide cannot exert its intended pharmacodynamic activity. Thus, delivery of active agents such as polypeptides is often problematic even when these agents are administered by injection. Some success has been achieved in addressing the problems of delivering active agents via injection.

[0002] Some success has been achieved in addressing the problems of delivering active agents via injection. For example, conjugating the active agent to a water-soluble polymer has resulted in polymer-active agent conjugates having reduced immunogenicity and antigenicity. In addition, these polymer-active agent conjugates often have greatly increased half-lives compared to their unconjugated counterparts as a result of decreased clearance through the kidney and/or decreased enzymatic degradation in the systemic circulation. As a result of having a greater half-life, the polymer-active agent conjugate requires less frequent dosing, which in turn reduces the overall number of painful injections and inconvenient visits with a health care professional.

Appendix II-B: Example of amendments to description page (Deletion of paragraphs)

14

CONJUGATES HAVING A DEGRADABLE LINKAGE AND POLYMERIC REAGENTS
USEFUL IN PREPARING SUCH CONJUGATES

BACKGROUND OF THE INVENTION

[0001] The present invention relates generally to polymeric reagents useful in providing a conjugate having a degradable linkage between a polymer and another moiety. In addition, the invention relates to, among other things, conjugates of the polymeric reagents, methods for synthesizing the polymeric reagents and methods for conjugating the polymeric reagents to active agents and other moieties.

Paragraphs 0002 to 0003 have been intentionally deleted

[0004] Some success has been achieved in addressing the problems of delivering active agents via injection. For example, conjugating the active agent to a water-soluble polymer has resulted in polymer-active agent conjugates having reduced immunogenicity and antigenicity. In addition, these polymer-active agent conjugates often have greatly increased half-lives compared to their unconjugated counterparts as a result of decreased clearance through the kidney and/or decreased enzymatic degradation in the systemic circulation. As a result of having a greater half-life, the polymer-active agent conjugate requires less frequent dosing, which in turn reduces the overall number of painful injections and inconvenient visits with a health care professional.

**A comment should be
included where paragraphs
have been deleted**

Appendix III: Example of claims page

CLAIMS

Claims numbered using Arabic numerals

2

Claim page numbered

1. An outlet vent for delivery of fan-forced air from a duct into a room, said vent being adapted for mounting on a horizontal surface to deliver air upwards through an opening in the plane of the surface, and said vent comprising a flange portion and an air delivery flap, wherein: the flange portion in use rests against said horizontal surface, the flap lays horizontally covering the opening when the room pressure is the same or higher than the duct pressure and is caused to tilt about an axis when the duct is pressurised, a major portion of the flap tilts upwards from said plane of the surface, and a minor portion of the flap tilts downwards from said plane of the surface into the vent.
2. A vent according to claim 1 wherein said opening in the plane of the surface is elongated and the axis about which the flap tilts extends in the direction of the opening's elongation.
3. A vent according to claim 2 wherein said axis is positioned from the side of the opening in the range of 10% to 40% of the width of the opening.
4. A vent according to claim 3 wherein said axis is positioned from the side of the opening in the range of 20% to 30% of the width of the opening.
5. A vent according to any one of the previous claims wherein a weight of dense material is affixed to the minor portion of the flap to partly counterbalance the major portion of the flap about said axis.
6. A vent according to any one of the previous claims further comprising: - a vent body defining an air flow channel, through which said air is delivered, and an auxiliary chamber through which said air is substantially not delivered.

Text of claim right indented by at least 1cm

Appendix IV: Example of drawings page

1/1

Numbering of drawing page

DRAWINGS

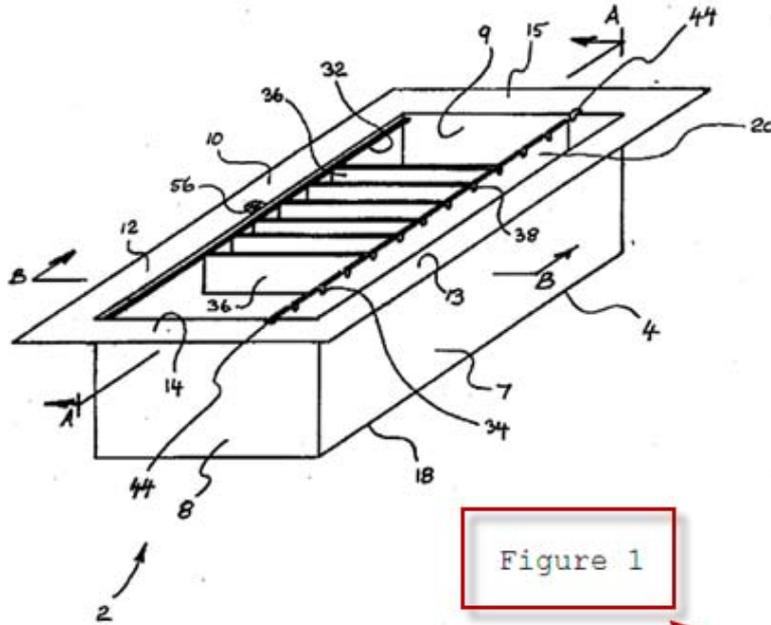


Figure 1

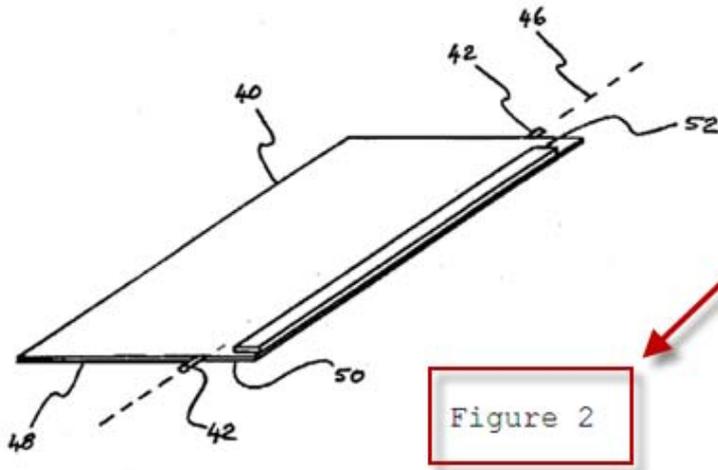


Figure 2

Labelling figures

Appendix V: Example of Abstract page

ABSTRACT

An apparatus for cooling overheated gas generated from a diesel particulate filter which is connected between a diesel engine (5) and an exhaust pipe of the diesel engine is disclosed. The apparatus includes a tail pipe (1) for discharging outwardly the overheated gas discharged from the diesel particulate filter (6), a cooling fan (3), provided at one side of an engine room (7), for generating an air stream by sucking ambient air, and a diffuser (4) enclosing an outer circumference of the tail pipe (1) in such a way a space is formed between the diffuser (4) and the tail pipe (1) to prevent the diffuser (4) from directly contacting the tail pipe (1). The engine room (7) is provided with a through-hole (2) penetrating one side of the engine room (7), and the tail pipe has one end connected to the diesel particulate filter (6), and the other end extended outwardly from the engine room (7) through the through-hole (2).

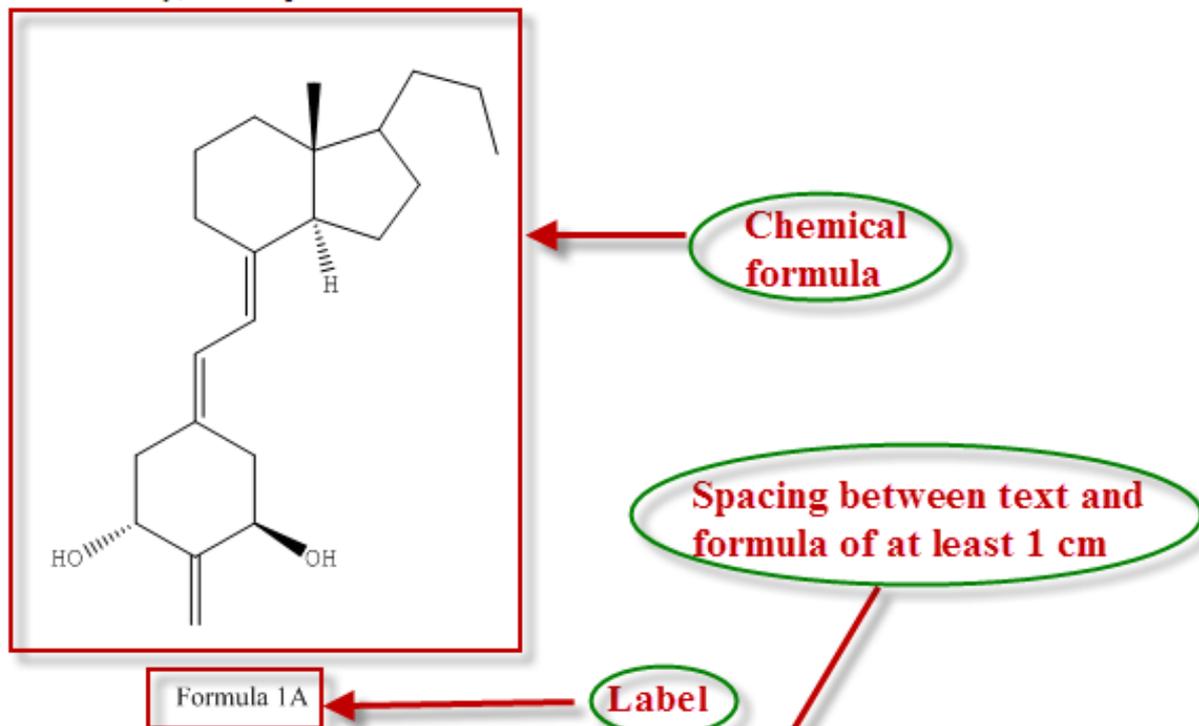
Abstract page should not be numbered

1.5 line spacing

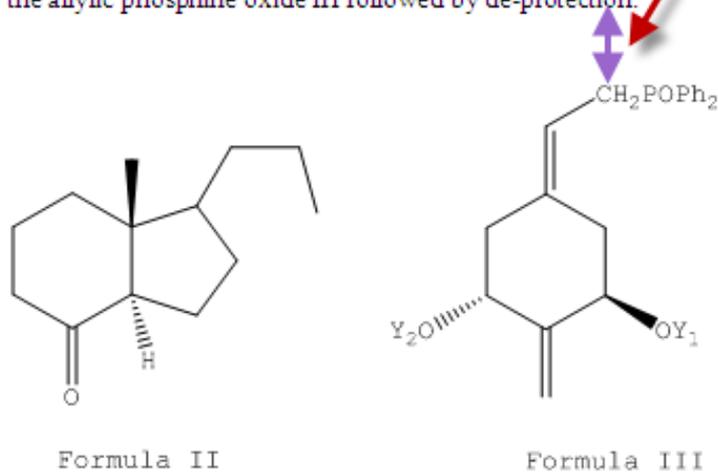
Appendix VI: Example of description page with chemical formula

17

[0023] 2-Methylene-19,21-dinor-1 α -hydroxy-bishomopregna calciferol was synthesised, and tested, and found to be useful in treating a variety of biological conditions as described herein. Structurally, this compound has the formula 1A as shown below:



[0024] Preparation of 2-methylene-19, 21-dinor-1 α -hydroxybishomopregnacalciferol can be accomplished by condensing an appropriate bicyclic Windaus-Grundmann type ketone (II) with the allylic phosphine oxide III followed by de-protection.



[0134] When performing the first iteration of step S9-4, the values of D_2 , A_2 , D_0 and A_0 are the values previously calculated at step S7-2, while all values of λ_n are zero.

Appendix VII: Example of description page with mathematical formula

Mathematical equations

18

Label

[0135] The equations used by solver 244 at step S9-6 comprise the following in this embodiment:

$$\text{if}(\lambda_{x,y,z-\max}^{n+1})_{\text{ang\&lin}} < 0 \text{ then } \lambda_{x,y,z-\max}^{n+1} = 0$$

$$\text{if}(\lambda_{x,y,z-\min}^{n+1})_{\text{ang\&lin}} > 0 \text{ then } \lambda_{x,y,z-\min}^{n+1} = 0$$

$$\lambda_{\text{lin}}^{n+1} = \lambda_{\text{lin}-\min}^{n+1} + \lambda_{\text{lin}-\max}^{n+1}$$

$$\lambda_{\text{ang}}^{n+1} = \lambda_{\text{ang}-\min}^{n+1} + \lambda_{\text{ang}-\max}^{n+1}$$

Equation 46

Equation 47

Equation 48

Equation 49

[0136] The equations used by solver 244 at step S9-8 comprise the following in this embodiment:

$$D_a^{n+1} = D_a^n + L \frac{(\lambda_{\text{lin}}^{n+1} - \lambda_{\text{lin}}^n)}{m_a}$$

Equation 50

$$A_a^{n+1} = A_a^n + I_a^{-1} [r_a^s] L (\lambda_{\text{lin}}^{n+1} - \lambda_{\text{lin}}^n) + I_a^{-1} T (\lambda_{\text{ang}}^{n+1} - \lambda_{\text{ang}}^n)$$

Equation 51

$$D_b^{n+1} = D_b^n - L \frac{(\lambda_{\text{lin}}^{n+1} - \lambda_{\text{lin}}^n)}{m_b}$$

Equation 52

$$A_b^{n+1} = A_b^n + I_b^{-1} [r_b^s] L (\lambda_{\text{lin}}^{n+1} - \lambda_{\text{lin}}^n) + I_b^{-1} T (\lambda_{\text{ang}}^{n+1} - \lambda_{\text{ang}}^n)$$

Equation 53

Minimum spacing of 1 cm between text and equations

[0137] Referring again to Figure 7, at step S7-6, solver 244 performs a convergence test. In this embodiment, solver 244 performs processing to determine whether the values of λ , calculated for the current iteration differ from the values of λ , calculated for the previous iteration by more than a predetermined threshold, in accordance with the following equation:

$$\sum_{\lambda} \frac{(\lambda^{n+1} - \lambda^n)^2}{\lambda^{n^2}} \leq \text{Threshold}$$

Equation 54

Appendix VIII: Example of description page with table

6

[0351] In the evaluation phase, the results from the feasibility phase were used to select the appropriate doses required to attain a sustained delivery of GLP-1 for a 3-5 day effect. Eight mice were used in each group. Data on the baseline glucose levels were gathered for each mouse three days prior to drug dosing. A time 0 day blood sample (5 to 10 μ L) was collected from the tail vein. The glucose level (mg/dL) was measured using a glucose analyser. Each animal was then dosed subcutaneously (SC) below the skin on the back. The amount of test article administered was based on the average body weight of the animal, and the total volume of the dose did not exceed 10 mL/kg. Blood samples of 5 to 10 μ L (<0.5% of 2 mL blood volume for a 35 g mouse) were removed at the following time points: -3, -2, -1, 0, 0.04, 0.16, 0.33, 0.5, 1, 2, 3, 6 days.

[0352] Table 2 below describes the test compounds and the dose for each group of animals.

TABLE 2

Test Compounds and Dose for Each Group of Animals

Treatment	Lot or Reference Nos.	Number of mice/group	Dose (μ g)
Negative control (saline)	Baxter, Lot C645028	8	-
Positive control 2 (GLP-1)	American Peptide, lot T05128191	8	60, 120
G2PEG2Fmo _{C20K} -Lys _(26 or 34) -GLP1	ZH 071805	8	420
G2PEG2Fmo _{C40K} -Lys _(26 or 34) -GLP1	ZH 072305	8	420
G2PEG2Fmo _{C20K} -N ^{ter} -GLP1	ZH 082405 ZH 092105	8	420
G2PEG2Fmo _{C40K} -N ^{ter} -GLP1	ZH 082505 CP2F1 ZH 082505 CP2F2	8	420

Space between text and table of at least 1 cm

Table border of at least 1.5 points