



**Australian Government**

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**IP Australia**

**AUSTRALIAN OFFICIAL JOURNAL**

**OF**

**PATENTS**



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## General Information

For information on the following please see our website [www.ipaustralia.gov.au](http://www.ipaustralia.gov.au) or contact our Customer Service Network on 1300651010

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INID (Internationally agreed Numbers for the Identification of Data)

## GUIDE TO THE USE OF THIS JOURNAL

The Australian Official Journal of Patents (AOJP) reports all major events and actions which take place during the life cycle of an Australian patent and provides certain details of these actions as they relate to the patent or patent application involved. This guide sets out to teach the reader how to use the journal to access this information.

While there are many possible actions in the life of a patent, the majority of actions reported relate to the following events, which are the main stages in the progression of a patent application to a sealed patent:

### (i) FILING -

This is the act of making an application. When the application is first filed certain details are published.

### (ii) OPEN-TO-PUBLIC-INSPECTION (OPI) -

Approximately 18 months after first filing of an Australian or a corresponding foreign application, certain application documents, including the complete specification, become available to the public (Open-to-Public-Inspection or "OPI"). Relevant application details are published.

### (iii) NATIONAL PHASE ENTRY (NPE) -

For an application filed under the PCT to have full effect, it must move from the international phase of processing into the National phase of processing, by complying with the requirements of s.89(3). For PCT applications that were filed after 1 January 2004 which have entered the National Phase certain details are published.

### (iv) ACCEPTANCE -

This is the Commissioner's acceptance of a patent application. Once the Commissioner has accepted a patent application, certain details of the application are published in the AOJP. Notice of opposition may be filed within three months of advertisement of acceptance.

### (v) OPPOSITION -

If an opposition action is commenced against the grant of the patent, the six-figure acceptance number and the name of the opponent are published. If the opposition is to the Certification of an Innovation Patent, the patent number and the name of the opponent are published.

### (vi) SEALING -

Most accepted applications are not opposed. These proceed to sealing and become granted patents. Of the few that are opposed (less than 1%) most of these, after resolution of the opposition, proceed to sealing and become granted patents. Sealed patents are simply listed in order of their application number.

### (vii) CERTIFICATION-

This is the Commissioner's Certification after passing examination of a previously granted unexamined Innovation Patent.

In addition to the actions related to these stages, other actions reported include: assignments, lapsing or withdrawal of applications and ceasing or expiry of patents, voluntary amendments, extensions of time for certain actions and registration of licences.

## How To Identify Information Using "INID" Numbers

Patents are published in many different countries and in many different languages. As a result, finding the information that you want (eg the filing date) on a patent document or in a journal can be quite difficult. There is an international system operating, however, which codifies this information in an unambiguous way, by assigning a specific number to each piece of information about the history of a patent. These numbers are called the **Internationally agreed Numbers for the Identification of Data** or INID numbers.

These numbers appear on all published patents and abstracts and are used throughout this journal to identify particular items of information. For example, the date on which a document is filed has the INID number (22), while the name of the applicant has the INID number of (71). These numbers are always expressed in parentheses and always immediately precede the information to which they relate. For example:

(22) 12.10.91

means that the filing date of the document which contains this reference is 12 October 1991. Learning the INID numbers for the information you want will help you find it quickly and easily.

A complete list of the INID numbers and the items to which they relate is provided at the end of this Guide.

## How Australian Patent Documents are Numbered

**Patent applications** in Australia are assigned a number at the filing stage in their processing. Each Australian application will retain the same number throughout its life, though different numbers may be associated to the application. The number will incorporate the year of lodgment then a unique number within the appropriate range.

There will be number ranges for types of patents:

100,000 – 199,999	Innovation
200,000 – 799,999	Standard
800,000 – 899,999	Petty
900,000 – 999,999	Provisional

When searching for information and ordering documents it is vital that you understand the numbering systems.

1. **Provisional Applications** are given a ten-figure number

e.g. 2002901123

A provisional application number is identified by the INID number (21).

2. **Complete and Innovation Applications** are also given a ten-figure application number

e.g. 2002200345 Standard  
2002100123 Innovation

There are prefixes applied to this number which indicate whether the application has been accepted:

A document corresponding to an unaccepted application has the prefix, AU-A; eg AU-A-2002200234.  
A document corresponding to an accepted application carries the prefix AU-B; eg AU-B-2002200234.

Users need to be aware that an accepted document may differ from the corresponding unaccepted document. This is because amendment may occur between first publication (OPI) and second publication (acceptance).

A ten-figure application number is identified by the INID number (21).

**NOTE:** When ordering any patent document from us, whether accepted or not, please quote the ten-figure application number preceded by the appropriate prefix.

## Arrangement of Information in the Journal

For each of the categories

- (i) Provisional Applications Filed,
- (ii) Complete Applications Filed,
- (iii) Applications Open to Public Inspection
- (iv) Applications Entered National Phase
- (v) Applications Accepted, and
- (vi) Innovation Patent Certified.

The Journal lists the information published in that category in an alphabetical Name Index list based on the name of the applicant. These indices are useful if you wish to find information about applications made by a particular applicant.

In addition to the Name Index there is provided, for each of these categories, a Numerical Index. This index lists the applications either in order of their five-figure Application Numbers, in the case of complete applications filed and applications OPI, or in order of their six-figure Document Number in the case of accepted applications. It provides, for each number, the name of the applicant. These indices are useful if you wish to track the progress of a particular patent application.

There are also IPC Indices provided for applications which are OPI, for applications which have entered national phase and for applications which have been accepted. IPC stands for International Patent Classification. Each IPC "mark" is an alpha-numerical representation of a particular area of technology. These indices are in order of IPC mark, and within each mark provide either the five-figure application numbers of the application which are now OPI or the six-figure numbers of the cases now accepted. These indices are useful if you wish to check on patent activity in a particular technology.

## Using the Indices

### 1. To Find Patent Information if You Know the Name of the Applicant.

Use the Name Indices. They will give you the following information identified by their INID number:

<u>ITEM</u>	<u>INID</u> <u>No.</u>	<u>ITEM</u>	<u>INID</u> <u>No.</u>
<b>A) Provisional applications filed - Name Index</b>		<b>B) Complete applications filed - Name Index</b>	
The <u>name</u> of the applicant	(71)	The <u>name</u> of the applicant	(71)
The Provisional application <u>number</u>	(21)	The <u>number</u> assigned to the application	(21)
The <u>date</u> of filing	(22)	The <u>date</u> of filing	(22)
The <u>title</u> of the invention	(54)	<u>Title</u> of the invention	(54)
		<u>Number</u> of priority document(s) if any	(31)
		<u>Date(s)</u> of filing of priority documents	(32)
		<u>Country</u> of which priority documents filed	(33)
		PCT application <u>number</u>	(86)
<u>ITEM</u>	<u>INID</u> <u>No.</u>	<u>ITEM</u>	<u>INID</u> <u>No.</u>
<b>C) Applications open to public inspection - Name Index</b>		<b>D) Applications entered National Phase - Name Index</b>	
The <u>name</u> of the applicant	(71)	The <u>name</u> of the applicant	(71)
The <u>number</u> of the document	(11)	The <u>number</u> of the document	(11)
The <u>number</u> assigned to the application	(21)	The <u>number</u> assigned to the application	(21)

The <u>date</u> of filing	(22)	The <u>date</u> of filing	(22)
The <u>title</u>	(54)	The <u>title</u>	(54)
The <u>classification marks</u>	(51)	The <u>classification marks</u>	(51)
Priority document <u>number(s)</u>	(31)	PCT publication <u>number</u>	(87)
<u>Date</u> of filing of priority document(s)	(32)	Priority document <u>number</u>	(31)
<u>Country</u> in which priority document filed	(33)	<u>Date</u> of filing of priority document(s)	(32)
Publication <u>date</u> of unexamined document	(43)	<u>Country</u> in which priority document filed	(33)
Inventors <u>names</u> if known	(72)	Publication <u>date</u> of unexamined document	(43)
<u>Patent Attorneys</u>	(74)	Inventors <u>names</u> if known	(72)
Related by addition	(61)	<u>Patent Attorneys</u>	(74)
Related by division	(62)		

<u>ITEM</u>	<u>INID</u> <u>No.</u>	<u>ITEM</u>	<u>INID</u> <u>No.</u>
<b>E) Applications accepted - Name Index</b>		<b>F) Patents Certified – Name Index</b>	
The <u>name</u> of the applicant	(71)	The <u>name</u> of the applicant	(71)
The <u>number</u> of the document	(11)	The <u>number</u> of the accepted document	(10)
The <u>number</u> of the accepted document	(10)	The <u>number</u> assigned to the application	(21)
The <u>number</u> assigned to the application	(21)	The <u>date</u> of filing	(22)
The <u>date</u> of filing	(22)	The <u>title</u>	(54)
The <u>title</u>	(54)	The <u>classification marks</u>	(51)
The <u>classification marks</u>	(51)	Priority document <u>number</u>	(31)
PCT publication <u>number</u>	(87)	<u>Date</u> of filing of priority document(s)	(32)
Priority document <u>number</u>	(31)	<u>Country</u> in which priority document filed	(33)
<u>Date</u> of filing of priority document(s)	(32)	Publication <u>date</u> of granted patent	(45)
<u>Country</u> in which priority document filed	(33)	Inventors <u>names</u>	(72)
Publication <u>date</u> of unexamined document	(43)	<u>Patent Attorneys</u>	(74)
Publication <u>date</u> of examined document	(44)	Related by division	(62)
Publication <u>date</u> of granted patent	(45)		
Inventors <u>names</u>	(72)		
<u>Patent Attorneys</u>	(74)		
Related by addition	(61)		
Related by division	(62)		

You will notice at each stage of following application through that all applications are in alphabetical order of **Applicant**, not inventor.

## 2. To Find Information About a Patent Application if You Know its Number.

Use the appropriate numerical index. This will give you the name of the applicant from the number. You will then need to use the appropriate Name Index as above to find out other information about the Patent Application you are interested in.

The following Numerical Indices are available:

- A) **Provisional** Applications filed.
- B) **Complete** Applications filed.
- C) **Innovation** Applications filed.
- D) Applications **Open to Public Inspection**.
- E) Applications **Entered National Phase**
- F) Applications **Accepted**.
- G) Innovation Patent **Certified**

## 3. To Find Information About Patent Documents in the Area of Technology in which You are Interested if You Know the International Patent Classification Mark for that Area.

All patent applications are classified according to their subject matter using the International Patent Classification (IPC). Although the system is very detailed and covers all technologies, knowledge of the IPC marks of the technologies you are interested in will allow you to find patent documents in these technologies quite easily. To identify the IPC marks of technologies you are interested in, you can inspect relevant documentation in any of IP Australia's state offices.

The indices to use are

- A) Applications **OPI** - IPC Index
- B) Applications **accepted** - IPC Index
- C) Applications **Entered National Phase** – IPC Index

These indices give you the numbers of the applications which are either OPI, Entered National Phase or Accepted and are listed in order of their IPC marks.

Once you have the numbers of the documents that interest you, consult the relevant Number Index (see 2. above) to find the applicant's name, and then the Name Index (see 1. above) to find out the details of that application.



## 'INID' NUMBERS in use on Australian Patent Documents

'INID' is an acronym for 'Internationally agreed **N**umbers for the **I**dentification of **D**ata'.

### (10) Document identification

- (11) Number of the document
- (12) Plain language designation of the kind of document
- (19) WIPO country code, or other identification, of the country publishing the document.

### (20) Document filing data

- (21) Number(s) assigned to the application(s).
- (22) Date(s) of filing application(s)
- (23) Other date(s) of filing, including exhibition filing date and date of filing complete specification following provisional specification.
- (24) Date from which industrial property rights may have effect.

### (30) Priority data

- (31) Number(s) assigned to priority application(s)
- (32) Date(s) of filing priority application(s)
- (33) Country (countries) in which the priority application(s) was (were) filed.

### (40) Date(s) of making available to the public

- (43) Date of publication by printing or similar process of an unexamined document, on which no grant has taken place on or before the said date.
- (44) Date of publication by printing or similar process of an examined document, on which no grant has taken place on or before the said date.
- (45) Date of publication by printing or similar process of a document, on which grant or certification has taken place on or before the said date.

### (50) Technical Information

- (51) International Patent Classification
- (52) Domestic or national classification
- (54) Title of invention
- (56) List of prior art documents, if separate from descriptive text
- (57) Abstract or claim

### (60) Reference(s) to other legally related domestic document(s)

- (60) Related by cognate(s).
- (61) Related by addition(s).
- (62) Related by division(s).

### (70) Identification of parties concerned with the document

- (71) Name(s) of applicant(s)
- (72) Name(s) of inventor(s) if known to be such
- (74) Name(s) of attorney(s) or agent(s)
- (75) Name(s) of inventor(s) who is (are) also applicant(s)

### (80) Identification of data related to International Conventions other than the Paris Convention

- (86) PCT Application Number
- (87) PCT Publication Number

### NOTE

- (1) Australian patent documents published on or after 26 October 1978 should be referred to by the application number preceded by the prefix AU-A or AU-B.  
  
    **AU-A** = Pre-examination                      **AU-B** = Post-examination
- (2) The classification used is the International Patent Classification and is identified by the INID code (51). Further editions of the classification are identified as (51)<sup>2</sup>, (51)<sup>3</sup>, (51)<sup>4</sup> and (51)<sup>5</sup>.
- (3) INID code 74 provides for the name of the patent attorney, or firm of attorneys, prosecuting an application.

## Proceedings under the Patents Act 1990

### Extensions of Time, Section 223

#### Applications Received

Notice of opposition under Section 223(6) to the undermentioned application(s) for an extension of time may be lodged at the Patent Office within the prescribed time.

677021 **Strathayr Pty. Ltd.** An application to extend the time from 1 Nov 2008 to 1 Jul 2009 in which to pay a renewal fee has been lodged . Address for service in Australia - Griffith Hack GPO Box 1285K MELBOURNE VIC 3001

705378 **Penwest Pharmaceuticals Co.** An application to extend the time from 21 Mar 2008 to 21 Aug 2009 in which to pay a renewal fee has been lodged . Address for service in Australia - Shelston IP Level 21 60 Margaret Street SYDNEY NSW 2000

724161 **AdVec, Inc.** An application to extend the time from 7 Jun 2008 to 7 Sep 2009 in which to pay a renewal fee has been lodged . Address for service in Australia - Griffith Hack GPO Box 1285K MELBOURNE VIC 3001

753992 **Turbo Trac Systems ULC** An application to extend the time from 3 Aug 2009 to 3 Sep 2009 in which to pay a renewal fee has been lodged . Address for service in Australia - Blake Dawson Locked Bag N6 Grosvenor Place SYDNEY NSW 2000

784051 **Law, R.R.** An application to extend the time from 27 Sep 2007 to 27 Aug 2009 in which to pay a renewal fee has been lodged . Address for service in Australia - SPRUSON & FERGUSON GPO Box 3898 SYDNEY NSW 2001

#### Applications Allowed - Section 223(2)

676839 **Musacus International Ltd.** The time in which to pay a renewal fee has been extended to 10 Jun 2009 . Address for service in Australia - Ellis Verboeket Terry PO Box 10932 Wellington 6143 New Zealand

689883 **Afra Star Pty Ltd** The time in which to pay a renewal fee has been extended to 26 Apr 2009 . Address for service in Australia - Griffith Hack Level 19 109 St Georges Terrace PERTH WA 6000

697212 **Dickey-John Corp.** The time in which to pay a renewal fee has been extended to 3 Jun 2009 . Address for service in Australia - Callinans PO Box 1189 HARTWELL VIC 3124

700019 **Greystone Medical Group, Inc.** The time in which to pay a renewal fee has been extended to 4 Jul 2009 . Address for service in Australia - Davies Collison Cave GPO Box 3876 SYDNEY NSW 2001

709268 **Assistance S.R.L.** The time in which to pay a renewal fee has been extended to 26 May 2009 . Address for service in Australia - Davies Collison Cave Level 15 1 Nicholson Street MELBOURNE VIC 3000

735484 **Auspex Pty Ltd.** The time in which to pay a renewal fee has been extended to 6 Jun 2009 . Address for service in Australia - Callinans PO Box 1189 HARTWELL VIC 3124

### Extensions of Time, Section 223 -cont'd

739455 **International Metalizing Corp.** The time in which to pay a renewal fee has been extended to 4 Jun 2009 . Address for service in Australia - SPRUSON & FERGUSON GPO Box 3898 SYDNEY NSW 2001

751244 **Carrier Corp.** The time in which to pay a renewal fee has been extended to 16 Jun 2009 . Address for service in Australia - Griffith Hack GPO Box 1285K MELBOURNE VIC 3001

758454 **Trustees of Boston University and Sequenom, Inc.** The time in which to pay a renewal fee has been extended to 23 Feb 2009 . Address for service in Australia - SPRUSON & FERGUSON GPO Box 3898 SYDNEY NSW 2001

782415 **Auspex Pty Ltd.** The time in which to pay a renewal fee has been extended to 13 Jun 2009 . Address for service in Australia - Callinans PO Box 1189 HARTWELL VIC 3124

### Opposition Proceedings

(The name in the parentheses is that of the opponent)

### Notice of Opposition under Section 223(6) and Chapter 5

623144

A Notice of Opposition to the Request for an Extension of Time for an Extension of Term was filed on 21 August 2009 by Sandoz Pty Ltd

### Letters Patent Sealed

#### Standard Patents

782548

### Surrender and Revocation of Letters Patent

It is hereby notified that the offer by the Patentee **Novartis Vaccines and Diagnostics, Inc.** to surrender Letters Patent 694760 dated 12 November 1998 for an invention titled 'B7-1-specific ligands, and their use for the induction of T cell anergy' (as advertised in the Official Journal of 16 July 2009) has been accepted and the Letters Patent has been revoked in accordance with Section 137 of the Patents Act.

**Assignments Registered**

622405 The Liposome Company, Inc. The patent has been assigned to **Cephalon Limited**

651720 Clouth Gummiwerke AG The patent has been assigned to **Calenberg Ingenieure, planmaBig elastisch lagern, GmbH**

662163 Moduline Pty Ltd The patent has been assigned to **Clipsal Australia Pty Ltd**

662530 Clouth Gummiwerke AG The patent has been assigned to **Calenberg Ingenieure, planmaBig elastisch lagern, GmbH**

669668 The Babraham Institute The patent has been assigned to **Crescendo Biologics Limited**

673943 Sealand Technology, Inc. The patent has been assigned to **Dometic Corporation**

681036 The Liposome Company, Inc.; B. Braun Medical, Inc. The patent has been assigned to **B. Braun Medical, Inc.; Cephalon Limited**

695373 BresaGen Limited; St. Vincent's Hospital (Melbourne) Limited The patent has been assigned to **St. Vincent's Hospital (Melbourne) Limited**

696184 Moduline Pty Ltd The patent has been assigned to **Clipsal Australia Pty Ltd**

696420 Westway Trading Corporation The patent has been assigned to **Westway Feed Products, Inc.**

711144 BresaGen Limited; St. Vincent's Hospital (Melbourne) Limited The patent has been assigned to **St. Vincent's Hospital (Melbourne) Limited**

712666 Pharmacia & Upjohn Company LLC; Boehringer Ingelheim KG The patent has been assigned to **Boehringer Ingelheim Pharma GmbH & Co. KG**

716341 NEC Corporation The patent has been assigned to **AU Optronics Corporation**

729843 Pentapharm AG The patent has been assigned to **DSM IP Assets B.V.**

731637 Cecina Establishment The patent has been assigned to **Uretek Worldwide Oy**

743729 Environmental Technologies Capital Partners, LLC The patent has been assigned to **Unity Envirotech LLC**

750791 BAE Systems (Defence Systems) Limited The patent has been assigned to **BAE SYSTEMS PLC**

753220 RuleBurst Limited The patent has been assigned to **Oracle International Corporation**

756525 Progressive Gaming International Corporation The patent has been assigned to **IGT**

759735 Witex AG The patent has been assigned to **Witex Flooring Products GmbH**

760422 Dong-A Pharmtech Co., Ltd. The patent has been assigned to **Dong-A Pharm. Co., Ltd.**

761884 Progressive Gaming International Corporation The patent

**Assignments Registered - cont'd**

has been assigned to **IGT**

763846 Progressive Gaming International Corporation The patent has been assigned to **IGT**

767049 BAE SYSTEMS Integrated System Technologies Limited The patent has been assigned to **BAE SYSTEMS PLC**

782155 King's College London; MGI PHARMA Biologics, Inc The patent has been assigned to **King's College London; Eisai Corporation of North America**

784442 LG Electronics Inc. The patent has been assigned to **LG-Nortel Co., Ltd.**

**Mortgages Registered**

(The name in the parentheses is that of the mortgagee)

711374 **Recochem Inc.** (Business Development Bank of Canada; (MG Stratum Fund III, Ltd. Partnership, by its General Partner, McKenna Gale Management III Ltd; (Royal Bank of Canada and (La Caisse Populaire Desjardins de Saint-Laurent)

**Extensions of Term of Standard Patents, Section 70**

**Grant**

The following application(s) for Extension of Term have been granted under Section 74.

767725 **Amgen, Inc.**

NPLATE romiplostim (rbe)

Date extended term due to expire on 08/08/2023

**Notice of Intention to Amend pursuant to Order 58 Rule 10(1) of the Federal Court Rules**

Australian Patent 716747 in the name of CSL Limited and Monash University

**AUSTRALIA**  
**Patents Act 1990**  
**NOTICE**  
**OF**  
**APPLICATION TO AMEND LETTERS PATENT**  
**PURSUANT TO SECTION 105**

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CSL Limited  
of 45 Poplar Road  
PARKVILLE VIC 3052

and

Monash University  
of Clayton campus  
Wellington Road  
CLAYTON VIC 3800

hearby give notice that they intend to apply under sub-section 105(1) of the *Patents Act 1990* for an Order directing the amendment of the Australian Letters Patent No. 716747 for an invention entitled "Stabilised Growth Hormone formulation and method of preparation thereof" in accordance with the Advertisement lodged herewith.

The Applicant's address for service is C/O Davies Collison Cave Solicitors, Level 15, 1 Nicholson Street, Melbourne, VIC 3000.

DATED: 31 August 2009



**DAVIES COLLISON CAVE SOLICITORS**

Solicitors for the Applicants

TO: The Commissioner of Patents  
Australian Industrial Property Organisation  
PO Box 200  
WODEN ACT 2600

## SECTION 105 PATENTS ACT

**Advertisement pursuant to Order 58 r10(1) of the Federal Court Rules.**

### IDENTITY OF PROCEEDINGS

Court: Federal Court of Australia  
Victoria District Registry  
Proceeding No. VID 154 of 2009

Parties: CSL Limited and Monash University  
(Applicants)

and

Novo Nordisk Pharmaceuticals Pty Ltd and Novo Nordisk A/S  
(Respondents)

### PARTICULARS OF PROPOSED AMENDMENT

CSL Limited and Monash University, the registered proprietors of Australian Letters Patent No. 716747 (the "**Patent**"), will seek an Order under Section 105(1) of the Patents Act 1990 directing the amendment of the Patent as follows:

1. Page 22; add the words "wherein the pH of the formulation is from 5.0 to 6.8 and" at the start of line 7 of claim 1, as shown in annexure 2.
2. Page 22; Delete "0.1" where appearing in the first line of claim 3 and replace with "0.01" as shown in annexure 2.
3. Page 23; delete the words "from 5.0 to 7.5, preferably 5.0 to 6.8, more preferably" where appearing in claim 7 as shown in annexure 2.

### APPLICANTS' ADDRESS FOR SERVICE

Davies Collison Cave Solicitors  
Level 15, 1 Nicholson Street  
MELBOURNE VIC 3000  
Tel: (03) 9254 2888  
Fax: (03) 9254 2880

Attention: Ian Pascal and Penny Smith

### OPPOSITION

Any person or corporation intending to oppose the application not being a party to the proceedings must not later than 28 days after the publication of this advertisement, give written notice of that intention to each of the Commissioner of Patents, CSL Limited and Monash University at the above address for service.

## THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A method for the preparation of a stable, liquid formulation of growth hormone, comprising growth hormone, a buffer and a stabilising effective amount of a least one stabilising agent selected from the group consisting of:

- (i) polyoxyethylene-polyoxypropylene block copolymer non-ionic surfactants,
- 5 (ii) taurocholic acid or salts or derivatives thereof, and
- (iii) methyl cellulose derivatives,

wherein the pH of the formulation is from 5.0 to 6.8, and wherein the method comprises admixing the growth hormone with the buffer and the stabilising agent(s) under conditions such that the growth hormone is not exposed to concentrations of the buffer or stabilising agent(s) which are greater than 2x the final concentrations of the buffer or stabilising agent(s) in the formulation."

2. A method according to claim 1, wherein the growth hormone is human growth hormone.

3. A method according to claim 1 or 2, wherein the formulation comprises 0.01-5.0% w/v, preferably 0.05 – 2.0% w/v, more preferably 0.08-1.0% w/v, of the stabilising agent(s).

4. A method according to any of claims 1 to 3, wherein the stabilising agent(s) are selected from Pluronic polyols, taurocholic acid and its salts, and hydroxypropyl-methyl cellulose.

5. A method according to any of claims 1 to 4, wherein the formulation comprises 0.08% w/v of a Pluronic polyol as the stabilising agent(s).

6. A method according to claims 1 to 5, wherein the formulation comprises a pharmacologically acceptable buffer, preferably a phosphate or a citrate buffer, at a concentration of 2.5 to 50mM, preferably 10-20 mM.

7. A method according to any of claims 1 to 6, wherein the pH of the formulation is from 5.2 to 6.5, and most preferably from 5.4 to 5.8.
8. A method according to any of claims 1 to 7, wherein the stabilising agent(s) is added to the formulation immediately prior to final volume adjustment.
9. A stable, liquid formulation of growth hormone, prepared by a method according to any of claims 1 to 8.
10. A stable, liquid formulation of growth hormone, comprising growth hormone, a buffer and a stabilising effective amount of at least one stabilising agent selected from hydroxypropylmethyl cellulose and other methyl cellulose derivatives.
11. A formulation according to claim 10, wherein the growth hormone is human growth hormone.
12. A method of treatment of a human or animal patient in need of growth hormone, which comprises administration to said patient of a pharmaceutically effective amount of a formulation according to claim 9 or claim 10.
13. A method according to claim 1 or claim 12, or a formulation according to claim 9 or claim 10, substantially as hereinbefore described.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A method for the preparation of a stable, liquid formulation of growth hormone, comprising growth hormone, a buffer and a stabilising effective amount of a least one stabilising agent selected from the group consisting of:

- 5 (i) polyoxyethylene-polyoxypropylene block copolymer non-ionic surfactants,  
(ii) taurocholic acid or salts or derivatives thereof, and  
(iii) methyl cellulose derivatives,

10 wherein the pH of the formulation is from 5.0 to 6.8, and wherein the method comprises admixing the growth hormone with the buffer and the stabilising agent(s) under conditions such that the growth hormone is not exposed to concentrations of the buffer or stabilising agent(s) which are greater than 2x the final concentrations of the buffer or stabilising agent(s) in the formulation."

2. A method according to claim 1, wherein the growth hormone is human growth hormone.

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3. A method according to claim 1 or 2, wherein the formulation comprises ~~0.1~~0.01-5.0% w/v, preferably 0.05 – 2.0% w/v, more preferably 0.08-1.0% w/v, of the stabilising agent(s).

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4. A method according to any of claims 1 to 3, wherein the stabilising agent(s) are selected from Pluronic polyols, taurocholic acid and its salts, and hydroxypropyl-methyl cellulose.

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5. A method according to any of claims 1 to 4, wherein the formulation comprises 0.08% w/v of a Pluronic polyol as the stabilising agent(s).

6. A method according to claims 1 to 5, wherein the formulation comprises a pharmacologically acceptable buffer, preferably a phosphate or a citrate buffer, at a concentration of 2.5 to 50mM, preferably 10-20 mM.



7. A method according to any of claims 1 to 6, wherein the pH of the formulation is ~~from 5.0 to 7.5, preferably 5.0 to 6.8, more preferably~~ from 5.2 to 6.5, and most preferably from 5.4 to 5.8.

5 8. A method according to any of claims 1 to 7, wherein the stabilising agent(s) is added to the formulation immediately prior to final volume adjustment.

9. A stable, liquid formulation of growth hormone, prepared by a method according to any of claims 1 to 8.

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10. A stable, liquid formulation of growth hormone, comprising growth hormone, a buffer and a stabilising effective amount of at least one stabilising agent selected from hydroxypropylmethyl cellulose and other methyl cellulose derivatives.

15 11. A formulation according to claim 10, wherein the growth hormone is human growth hormone.

12. A method of treatment of a human or animal patient in need of growth hormone, which comprises administration to said patient of a pharmaceutically effective amount of a  
20 formulation according to claim 9 or claim 10.

13. A method according to claim 1 or claim 12, or a formulation according to claim 9 or claim 10, substantially as hereinbefore described.