

**BALDWIN SHELSTON WATERS**  
SYDNEY NSW 2000

**Speed Dial 508**

Contact: Ivan Rajkovic

20 December, 1999

The Commissioner of Patents  
PO Box 200  
WODEN ACT 2606

Sir

Australian Patent No. 600650  
Applicant: Kirin-Amgen Inc.  
Our reference: 11860.80 IAR:mnb

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We submit herewith a Request for Extension of Term of the abovementioned patent.

Please find enclosed:

- Request for Extension of Term
- Certificate of Registration for product EPREX
- Print-out from the Australian Register of Therapeutic Goods (ARTG)

We look forward to receiving confirmation of acceptance of the application.

Yours respectfully  
BALDWIN SHELSTON WATERS



Encl.

**IP Australia**  
Documents received

21 DEC 1999

Amgen

Batch NO:

11860.80

AUSTRALIA

PATENTS ACT 1990

Request for an Extension of Term (S.70) where there is NO Pre-TGA Marketing Approval

(Subject to the provisions of the Patents Act, information provided on this form may be made publicly available, including on the Internet)

We KIRIN-AMGEN, INC., of One Amgen Centre Drive, Thousand Oaks, CA 91320-1789, United States of America, the patentee of Patent No. 600,650 request an extension of the term of the patent.

- 1. Goods containing, or consisting of, pharmaceutical substance EPREX are currently included in the Australian Register of Therapeutic Goods (ARTG).
2. The substance as it occurs in the goods registered on the ARTG, is identified in the complete specification as: (claim 1)

A purified and isolated polypeptide having the primary structural conformation and possessing a biological property as herein defined of naturally-occurring erythropoietin and characterized by being the product of procaryotic or eucaryotic expression of an exogenous DNA sequence.

- 3. The first regulatory approval date for a good containing, or consisting of, a pharmaceutical substance that is in substance disclosed in the specification and in substance falls within the scope of a claim of the specification, is 24 April 1991
4. There was no pre-TGA marketing approval for this substance.
5. There are no relevant proceedings in relation to this patent.
6. In support of this application, attached hereto are:

A copy of the certificate of registration of the relevant goods;

AND A copy of a print out from the ARTG indicating that the pharmaceutical is registered on the ARTG.

Address for service is: BALDWIN SHELSTON WATERS
60 MARGARET STREET
SYDNEY NSW 2000

Attorney Code: SW

Dated this 20 Day of December, 1999.
BALDWIN SHELSTON WATERS

by [Signature]
Fellow Institute of Patent and Trade Mark Attorneys of
Australia of BALDWIN SHELSTON WATERS

IP Australia
Documents received on

21 DEC 1999

SYDNEY

To: The Commissioner of Patents
WODEN ACT 2606

Batch No:

[Empty rectangular box for Batch No.]

File: 11860.80 IAR/mnb
Fee: \$400.00

 Therapeutic  
Goods  
Administration

PO Box 100, Woden, ACT 2606, Australia  
Telephone: (06)232 8444. Fax: (06)232 8581

TGAIN: 137

## CERTIFICATE OF REGISTRATION

**Registration Name of Therapeutic Goods:**

EPREX human recombinant erythropoietin 2,000 U/1mL  
injection vial

**ARTG Registration Number:**

AUST R 9999

**Commencement Date of Registration:**

24 April 1991

**Sponsor:**

JANSSEN-CILAG P/L

**Sponsor Enterprise ID: 268**

The above Therapeutic goods are registered in the Australian Register  
of Therapeutic goods subject to the following conditions: -

1. *Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.*
2. *Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.*
3. *Conditions specified in the letter of 27 March 1991 from Dr Brian Hillcoat advising of the approval for registration of the goods.*
4. *Changes to this registration as described in the letter of 27 January 1993 from John Cable.*
5. *Change as described in the letter of 25 August 1993 by E Walker DEB.*
6. *Changes as described in the letter of 27 January 1994 from Dr L. Hunt.*
7. *Changes as described in the letter of 14 March 1996 from R Baker.*

CERTIFIED ORIGINAL  
CERTIFICATE  
ARTG

Therapeutic  
Goods  
Administration

PO Box 100, Woden, ACT 2606, Australia  
Telephone: (06)232 8444. Fax: (06)232 8581

TGAIN: 138

## CERTIFICATE OF REGISTRATION

**Registration Name of Therapeutic Goods:**

EPREX human recombinant erythropoietin 4,000 U/1mL  
injection vial

**ARTG Registration Number:**

AUST R 9998

**Commencement Date of Registration:**

24 April 1991

**Sponsor:**

JANSSEN-CILAG P/L

**Sponsor Enterprise ID: 268**

The above Therapeutic goods are registered in the Australian Register of Therapeutic goods subject to the following conditions: -

1. *Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.*
2. *Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.*
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6. *Changes as described in the letter of 27 January 1994 from Dr L. Hunt.*
7. *Changes as described in the letter of 14 March 1996 from R Baker.*

CERTIFIED ORIGINAL  
CERTIFICATE  
ARTG

Therapeutic  
Goods  
Administration

PO Box 100, Woden, ACT 2606, Australia  
Telephone: (06)232 8444. Fax: (06)232 8581

TGAIN: 139

## CERTIFICATE OF REGISTRATION

**Registration Name of Therapeutic Goods:**

EPREX human recombinant erythropoietin 10,000  
U/1mL injection vial

**ARTG Registration Number:**

AUST R 9997

**Commencement Date of Registration:**

24 April 1991

**Sponsor:**

JANSSEN-CILAG P/L

**Sponsor Enterprise ID: 268**

The above Therapeutic goods are registered in the Australian Register of Therapeutic goods subject to the following conditions: -

*Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.*

*Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.*

*Conditions specified in the letter of 27 March 1991 from Dr Brian Hillcoat advising of the approval for registration of the goods. Changes to this registration as described in the letter of 27 January 1993 from John Cable.*

*Change as described in the letter of 25 August 1993 by E Walker DEB.*

*Changes as described in the letter of 27 January 1994 from Dr L. Hunt.*

*Changes as described in the letter of 14 March 1996 from Robyn Baker.*

CERTIFIED ORIGINAL  
CERTIFICATE  
ARIO

ARTG Registration:

9997 EPREX human recombinant erythropoietin 10,000  
U/1mL injection vial  
Drug Only

ELF Number:

Sponsor:

268 JANSSEN-CILAG P/L  
LOCKED BAG 2070, NORTH RYDE, NSW, 1670, AU  
1-5 KHARTOUM ROAD, NORTH RYDE, NSW, 2113, AU

ARTG STATUS:

23/04/91 RE Registered

Charge Level:

09/04/91 RH Registered Medicines (S4 and S8) Annual Charge for Financial Year 98/9

TGAIN:

139

ADG Code:

NIL

Shelf Life:

02Y 2-8 SL 2 years Store at 2 to 8 degrees Celsius Do not Shake, Protect from Light

Indications:

1. For the treatment in adults of symptomatic or transfusion-requiring anaemia associated with chronic renal failure.
2. Indications as at 27 January 1994: For the treatment of patients with symptomatic or transfusion-requiring anaemia associated with chronic renal failure to improve their quality of life by improving energy levels, exercise performance, fatigue and sleep patterns, and by reducing the need for blood transfusions.

Conditions & Limitations:

1. Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.
2. Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.
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4. Change as described in the letter of 25 August 1993 by E Walker

- DEB.  
5. Changes as described in the letter of 27 January 1994 from Dr L. Hunt.  
6. Changes as described in the letter of 14 March 1996 from Robyn Baker.  
7. Conditions specified in the letter of 9 September 1996 from Dr B L  
8. Hillcoat advising of approval for registration of the goods.

Alias/Export Names:  
NIL

Drug Product: 61276 EPREX 10000U/1mL injection

Purpose: SU Supply in Australia.

Pack Size and Poison Schedule:  
6 x 1mL vials 4

ATC Codes:  
B03XA OTHER ANTIANEMIC PREPARATIONS

Drug Evaluation Numbers:  
91 513 4

Drug Component:  
1

Dosage Form:  
INJSOL Injection - solution

Admin Route:  
IVENOS INTRAVENOUS, SCUTAN SUBCUTANEOUS

Visual Identification:  
colourless solution

Container:  
VIAL vial

Sterility:  
FT Filtration

Animal Origin/Body Part:  
HUMAN  
HAMSTER

Active Ingredients:  
erythropoietin 10000 U/mL (recombinant human equiv 84 microgram/mL)

ARTG Registration:

9998 EPREX human recombinant erythropoietin 4,000 U/1mL  
injection vial  
Drug Only

ELF Number:

Sponsor:

268 JANSSEN-CILAG P/L  
LOCKED BAG 2070, NORTH RYDE, NSW, 1670, AU  
1-5 KHARTOUM ROAD, NORTH RYDE, NSW, 2113, AU

ARTG STATUS:

23/04/91 RE Registered

Charge Level:

09/04/91 RH Registered Medicines (S4 and S8) Annual Charge for Financial Year 98/9

TGAIN:

138

ADG Code:

NIL

Shelf Life:

02Y 2-8 SL 2 years Store at 2 to 8 degrees Celsius Do not Shake, Protect from Light

Indications:

1. For the treatment in adults of symptomatic or transfusion-requiring anaemia associated with chronic renal failure.
2. Indications as at 27 January 1994: For the treatment of patients with symptomatic or transfusion-requiring anaemia associated with chronic renal failure to improve their quality of life by improving energy levels, exercise performance, fatigue and sleep patterns, and by reducing the need for blood transfusions.

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2. Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.
3. Conditions specified in the letter of 27 March 1991 from Dr Brian Hillcoat advising of the approval for registration of the goods.
4. Changes to this registration as described in the letter of 27 January 1993 from John Cable.
5. Change as described in the letter of 25 August 1993 by E Walker DEB.
6. Changes as described in the letter of 27 January 1994 from Dr L. Hunt.



7. Changes as described in the letter of 14 March 1996 from R Baker.  
8. Conditions specified in the letter of 9 September 1996 from Dr B L Hillcoat advising of approval for registration of the goods.

Alias/Export Names:  
NIL

Drug Product: 61275 EPREX 4000U/1mL injection

Purpose: SU Supply in Australia.

Pack Size and Poison Schedule:  
6 x 1mL vials 4

ATC Codes:  
B03XA OTHER ANTIANEMIC PREPARATIONS

Drug Evaluation Numbers:  
91 513 4

Drug Component:  
1

Dosage Form:  
INJSOL Injection - solution

Admin Route:  
IVENOS INTRAVENOUS, SCUTAN SUBCUTANEOUS

Visual Identification:  
colourless solution

Container:  
VIAL vial

Sterility:  
FT Filtration

Animal Origin/Body Part:  
HUMAN  
HAMSTER

Active Ingredients:  
erythropoietin 4000 U/mL (recombinant human equiv 33.6 microgram/mL)

ARTG Registration:  
9999 EPREX human recombinant erythropoietin 2,000 U/1mL

injection vial  
Drug Only

ELF Number:

Sponsor:

268 JANSSEN-CILAG P/L  
LOCKED BAG 2070, NORTH RYDE, NSW, 1670, AU  
1-5 KHARTOUM ROAD, NORTH RYDE, NSW, 2113, AU

ARTG STATUS:

23/04/91 RE Registered

Charge Level:

09/04/91 RH Registered Medicines (S4 and S8) Annual Charge for Financial Year 98/9

TGAIN:

137

ADG Code:

NIL

Shelf Life:

02Y 2-8 SL 2 years Store at 2 to 8 degrees Celsius Do not Shake, Protect from Light

Indications:

1. For the treatment in adults of symptomatic or transfusion-requiring anaemia associated with chronic renal failure.
2. Indications as at 27 January 1994: For the treatment of patients with symptomatic or transfusion-requiring anaemia associated with chronic renal failure to improve their quality of life by improving energy levels, exercise performance, fatigue and sleep patterns, and by reducing the need for blood transfusions.

Conditions & Limitations:

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2. Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.
3. Conditions specified in the letter of 27 March 1991 from Dr Brian Hillcoat advising of the approval for registration of the goods.
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5. Change as described in the letter of 25 August 1993 by E Walker DEB.
6. Changes as described in the letter of 27 January 1994 from Dr L. Hunt.
7. Changes as described in the letter of 14 March 1996 from R Baker.
8. Conditions specified in the letter of 9 September 1996 from Dr B L Hillcoat advising of approval for registration of the goods.

Alias/Export Names:  
NIL

Drug Product: 61274 EPREX 2000U/1mL injection

Purpose: SU Supply in Australia.

Pack Size and Poison Schedule:  
6 x 1mL vials 4

ATC Codes:  
B03XA OTHER ANTIANEMIC PREPARATIONS

Drug Evaluation Numbers:  
91 513 4

Drug Component:  
1

Dosage Form:  
INJSOL Injection - solution

Admin Route:  
IVENOS INTRAVENOUS, SCUTAN SUBCUTANEOUS

Visual Identification:  
colourless solution

Container:  
VIAL vial

Sterility:  
FT Filtration

Animal Origin/Body Part:  
HUMAN  
HAMSTER

Active Ingredients:  
erythropoietin 2000 U/mL (recombinant human equiv 16.8 microgram/mL)

\*\*\*\*\* END OF REPORT \*\*\*\*\*

THIS REPORT CONTAINED:

3 REGISTRATIONS  
0 DEVICES  
3 DRUGS  
3 COMPONENTS  
3 INGREDIENTS

Karen,

Your advice is sought for this S.70 application.

Could you please clarify if the complete filing date of 11-12-84 or the date of sealing, 24-6-99.

If neither of these two dates are to be used, according to the marketing date, I believe it is unable to apply for S.70.

Please clarify. Thankyou.

Tracey

Patent sealed (granted) on 24/06/99.  
S.70 appan made on 22/12/99.

07/01/00

PATENT ENQUIRY SYSTEM

08:29:44  
PAEN02MH

Application Id : 37467 / 85      Serial Number : 600650  
PCT Number :      PCT/US84/02021      WIPO Number :      WO85/02610  
Patentee : Kirin-Amgen, Inc.  
Title :      Polypeptides of erythropoietin  
57504 / 90 is Dvsnl ; 10074 / 95 is Dvsnl ; 46867 / 97 is Dvsnl ;  
Status : Patent Sealed

Complete Filing Date :      11/12/84      Earliest Priority Date :      13/12/83  
Australian OPI Date:      26/06/85      National Phase Date :      10/10/85  
Direction Date :      11/09/86  
Request Lodgement Date :      09/03/87  
Exam Section/Examiner :      H3 -- J.WHITE  
First Report Date :      15/09/88  
Date Sent to Examination :      29/01/90      Further Report Date :      08/02/90  
Date Accepted :      14/06/90      Acceptance Advertised Date      23/08/90  
Opposition Date:      23/11/90      Result :      D  
Date Sealed :      24/06/99  
Priority Date/Country:      13/12/83      UNITED STATES OF AMERICA  
Cont./Ren. Fee paid to :      11/12/00      Option > \_\_      Relevant Act > \_

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PAEN02EC V3.5 ( 2.7 ) CPAMOA Command  
4-©      1 Sess-1      10.0.6.28      IPAU45      22/50



# CHECK LIST FOR EXTENSION OF TERM APPLICATION

## PATENT SUPPORT

Patent Number 600650

Application for extension of term filed on 22-12-99

Application for extension made by patentee:  YES  NO

Is application after and within six months of the latest date of either:  
 grant of the patent - Jan 1998 20/6/97  
 marketing approval or  
 the 27 January 1999

YES  NO

Application fee paid: amount \$400 date paid 22-12-99

**If fee not paid or underpaid send out section 227 letter requiring payment in 28 days and DO NOT advertise or send to exam branch**

Patent in force until 11-12-00

Has the term of the patent been previously extended under the current or previous extension of term scheme  YES  NO

a) Date of marketing approval: 24-4-91

b) Date of patent: 11-12-84 <sup>complete filing date</sup> 24-6-99 <sup>seating date</sup>

### Extension calculation

Is the difference between (a) & (b) above,

- 1) Less than 5 years
- 2) 5 to 10 years
- 3) greater than 10 years

If the difference is 1 then no extension

If the difference is 2 then the extension is 15 years from the date of marketing approval.

If the difference is 3 then the extension is 25 years from the date of the patent.

Calculated extension date: 24-4-2006

If no response or response inadequate please refer case to DCC or Supervising Examiner CC for advice. Please provide summary

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If conditions are okay to accept then fill out below and send to patent support for acceptance to be advertised.

**Please ensure that Exam Branch database has been updated.**

**ACCEPTANCE OF EXTENSION OF TERM APPLICATION**

**Patent Examination:**

I have considered the application for extension of term and am satisfied that the requirements of section 70 and 71 are satisfied in relation to the application. I therefore accept the application for extension of term until the calculated date above.

Could you please advertise the acceptance in the journal and inform the patentee of the advertisement date.

Please enter the extension of term date on Patadmin

Signed A. S. Moore Date 7 JAN 2000

Name of delegate A. S. MOORE

Has Exam Branch database been updated  YES  NO

**Patent support:**

Advertised in the journal: 3-2-00

Entered on Patadmin DATE 7-1-00



Discovery House, Phillip ACT 2606  
PO Box 200, Woden ACT 2606  
Australia  
Phone +61 -2 6283 2211  
Facsimile +61 -2 6285 3593  
Internet <http://www.ipaustralia.gov.au>

5 January, 2000

BALDWIN SHELSTON WATERS  
Level 21  
60 Margaret Street  
SYDNEY NSW 2000

Re: Serial Number 600650 in the name of  
Kirin-Amgen, Inc.

Thank you for your application for extension of the above  
patent filed on 21/12/1999.

It will be advertised in the Official Journal dated 03/02/2000.

Tracey WATERS  
Patent Support  
Ext. 2020

7 January, 2000

BALDWIN SHELSTON WATERS  
Level 21  
60 Margaret Street  
SYDNEY NSW 2000

Re: Serial Number 600650 in the name of  
Kirin-Amgen, Inc.

The Commissioner has accepted the application for extension  
of term filed on 21/12/1999.

This will be advertised in the Official Journal dated 03/02/2000.

The provisions of Section 75 and Regulation 5.3 now apply.

Tracey WATERS  
Patent Support  
Ext. 2020

Discovery House, Phillip ACT 2606  
PO Box 200, Woden ACT 2606  
Australia  
Phone +61 -2 6283 2211  
Facsimile +61 -2 6285 3593  
Internet <http://www.ipaustralia.gov.au>

10 May, 2000

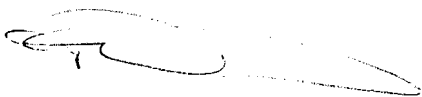
BALDWIN SHELSTON WATERS  
Level 21  
60 Margaret Street  
SYDNEY NSW 2000

Re: Patent Number 600650 in the name of  
Kirin-Amgen, Inc.

Your reference: 11860.80 IAR:mnb

I refer to your request under section 70 for extension of  
term of the above patent filed on 21/12/1999.

The opposition period to your request is now over and there was  
no opposition filed on your request. The Commissioner therefore  
can proceed to grant your request. However, before doing this,  
we need your advice whether relevant proceedings are pending.  
Please provide advice within 14 days of the date of this letter,  
irrespective of whether you have provided advice previously.



Tracey WATERS  
Patent Support  
Ext. 2020

**BALDWIN SHELSTON WATERS**  
SYDNEY NSW 2000

Speed Dial 508

Facsimile No. - 02 6285 3593  
Pages: 1  
CONFIRMATION via MAIL

Contact: Ivan Rajkovic

23 May, 2000

The Commissioner of Patents  
PO Box 200  
WODEN ACT 2606

**CONFIRMATION**  
**ORIGINAL SENT BY FAX**

Sir

Australian Patent No. 600650  
Applicant: Kirin-Amgen Inc.  
Our reference: 11860.80 IAR:mnb

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In response to your letter of 10 May 2000, to advise that no relevant proceedings are pending in relation to the above referenced Australian Patent.

In providing this advice we have taken note of the statutory definition of the term "relevant proceedings" and note that the current involvement of AU 600650 in the Johnson & Johnson vs Genetic Institute federal court appeal does not constitute a "relevant proceeding" as defined in the Patents Act 1990, as the proceedings are not in relation to infringement of the patent, the revocation of the patent nor is the validity of the patent currently in dispute.

We therefore look forward to receiving confirmation that the patent term has been extended.

Yours respectfully  
BALDWIN SHELSTON WATERS



*This letter and any accompanying documentation may contain privileged and confidential information. If you are not the intended recipient, you are hereby notified that any disclosure and distribution on the contents of this facsimile information is strictly prohibited. If you have received this facsimile in error, please immediately notify us by telephone to arrange for return of the original documents to us.*

**GRANT OF EXTENSION OF TERM APPLICATION**

No opposition has been filed by the due date: 3/5/2000

Letter regarding relevant proceedings sent: 10/5/2000

Advice received 23/5/2000

I grant the extension of term application under section 74. ✓

Signed V. Portella Date: 7/6/00  
Delegate SEB3

**PLEASE UPDATE PATADMIN AND THE PATEXAM DATABASE** Done ✓ 7/6/00

Note: I have knowledge of the fact that 600650 (this patent) is cited as the prime prior art in the TTT v G.I. action in the Federal Court. This is clearly not relevant proceedings in relation to this patent and does not in any way preclude the granting of the extension of term above.  
V. Portella 7/6/00

7 June, 2000

BALDWIN SHELSTON WATERS  
Level 21  
60 Margaret Street  
SYDNEY NSW 2000

Re: Serial Number 600650 in the name of  
Kirin-Amgen, Inc.

The Commissioner has granted an extension of the above patent.

Advertisement of this matter will appear in the Official  
Journal dated 22/06/2000.

The extension of term will expire on 24/04/2006.

Tracey WATERS  
Patent Support  
Ext. 2341