Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <http://www.tga.gov.au/about/tga-information-to.htm>.

Certificate regarding proposed patent infringement proceedings in relation to therapeutic goods

Required under subsection 26C(2) of the *Therapeutic Goods Act 1989* for commencing proceedings under the *Patents Act 1990* against a person who provides a certificate under subsection 26B(1) of the *Therapeutic Goods Act 1989*

I, _____
[Name, and where applicable, relationship to patentee/licensee]

_____
[Patentee/licensee name]

_____
[Patentee/licensee address]

understand that the certificate below is required under subsection 26C(2) of the *Therapeutic Goods Act 1989* to be given to the Secretary of the Commonwealth Department of Health, or his or her delegate, and to the person who has given the certificate under subsection 26B(1) of the *Therapeutic Goods Act 1989* (the applicant), in order to provide certain information in relation to proposed patent infringement proceedings by the patentee/licensee prior to commencing proceedings against the applicant.

a) The applicant is _____
[Name of applicant]

b) The therapeutic goods in question are _____
[Description of therapeutic goods]

It is hereby certified that the proceedings:

(i) are to be commenced in good faith; and

(ii) have reasonable prospects of success; and

(iii) will be conducted without unreasonable delay.

Note 1: For the purposes of this certificate, proceedings have reasonable prospects of success if:

a) the patentee/licensee had reasonable grounds in all the circumstances known to the patentee/licensee, or which ought reasonably to have been known to the patentee/licensee (in

addition to the fact of grant of the patent) for believing that he or she would be entitled to be granted final relief by the court against the person who provided the certificate under subsection 26B(1) of the Act in relation to the therapeutic goods; and

b) the patentee/licensee had reasonable grounds in all the circumstances known to the patentee/licensee, or which ought reasonably to have been known to the patentee/licensee (in addition to the fact of grant of the patent) for believing that each of the claims, in respect of which infringement is alleged, is valid; and

c) the proceedings are not otherwise vexatious or unreasonably pursued.

Note 2: The certificate must be signed by the patentee/licensee or a person on behalf of the patentee/licensee. If signing on behalf of the patentee/licensee, the person signing must be authorised to do so. If a person signing on behalf of the patentee/licensee is not a Company Director, please provide documentary evidence of the authority to sign on behalf of the patentee/licensee.

A company may execute this certification in accordance with section 127 of the *Corporations Act 2001*. Therefore, the document may be signed without using a common seal by, or with a common seal fixed and witnessed by:

a) 2 directors of the company; or

b) a director and a company secretary of the company; or

c) for a proprietary company that has a sole director who is also the sole company secretary – that director.

Note 3: The person who provided the certificate under subsection 26B(1) in relation to the therapeutic goods, with leave of the court, or the Attorney-General, may apply to a prescribed court for an order that the patentee pay to the Commonwealth a pecuniary penalty if the patentee gives a certificate required under subsection 26C(3) of the Act and:

a) the certificate is false or misleading in a material particular; or

b) the patentee breaches an undertaking given in the certificate.

Maximum Penalty: $10,000,000.

Ref: Subsection 26C(5) of the *Therapeutic Goods Act 1989.*

Witnessed by:

Applicant's signature or authorised person signing on behalf of applicant or Signature 1	Witness' Signature
Name 1/ Position	Witness' Name
Date	Date

Witnessed by:

Signature	Witness' Signature
Name 2/ Position	Witness' Name
Date	Date

Amendments to the *Therapeutic Goods Act 1989*

Implementation of the Australia-US Free Trade Agreement

Commencement

Amendments to the *Therapeutic Goods Act 1989* (the Act) for the purpose of implementing obligations under the Australia-US Free Trade Agreement took effect on 1 January 2005. These amendments apply to applications for the registration or listing of a therapeutic good (other than devices), under section 23 of the Act made on or after 1 January 2005.

However, subsequent amendments made by the *Therapeutic Goods Amendment Act (No.2) 2006* have restricted the application of the patent certification requirements.

The amendments in relation to legal proceedings under section 26C and 26D apply to proceedings commenced on or after 1 January 2005.

Certificates required in relation to patents (subsection 26B(1) of the Act)

From 1 January 2005 an applicant seeking to include therapeutic goods, other than devices, in the Australian Register of Therapeutic Goods (ARTG) under section 23 of the Act must provide a certificate required under subsection 26B(1) of the Act.

Note that this new requirement does not apply to applications for inclusion in the ARTG of therapeutic devices under Chapter 3 of the Act or medical devices under Chapter 4 of the Act.

The applicant must either certify to the effect that:

a) the applicant, acting on good faith, believes on reasonable grounds that it is not marketing, and does not propose to market the therapeutic goods, in a manner or in circumstances, that would infringe a valid claim of a patent that has been granted in relation to the therapeutic goods; or

b) a patent has been granted in relation to the therapeutic goods, and the applicant proposes to market the therapeutic goods before the end of term of the patent for such goods, and that the applicant has given the patentee notice of the application for registration or listing of the therapeutic goods under section 23 of the Act.

Subsequent amendments were introduced in the Act to restrict the application of the patent certification requirements under subsection 26B(1) of the Act to only those applicants who are required to submit safety or efficacy data of the goods as part of the process of applying for registration or listing, and who rely on the safety or efficacy data previously submitted to the Therapeutic Goods Administration (the TGA) by another person to establish the safety or efficacy of other goods that have already been registered or listed, as part of the process for applying for the registration or listing of that product.

These amendments have been implemented by the *Therapeutic Goods Amendment Act (No.2) 2006* (the Amendment Act). The Amendment Act received its Royal Assent on 1 March 2006 and commenced on 3 April 2006 by Proclamation.

These changes mean that requirements for patent certificates will not apply to applicants for registration or listing of medicines who are not required to submit evidence or information to establish the safety or efficacy of the goods as part of the registration or listing process. In these circumstances, the applicants are only required to notify the Secretary in the approved form that the subsection 26B(1) patent certificate is not required in relation to the application.

As a consequence of that restriction, amendments were also introduced in the Act to require applicants for registration or listing of medicines to either:

a) 26B(1) is not required; **or**

b) provide a certificate required under subsection 26B(1) of the Act.

These new requirements apply to all applications for registration or listing lodged on or after 3 April 2006.

All applicants for registration or listing under subsection 23 of the Act lodged on or after 1 January 2005 and before 3 April 2006 are required to provide a patent certificate required under subsection 26B(1) of the Act. The option of providing a notice to the Secretary that a patent certificate is not required in relation to the application is not open to these applicants (ie applications lodged from 1 January 2005 to 2 April 2006).

The patent certificate must be signed by, or on behalf of the applicant. The applicant must use the form of the certificate approved by the Secretary of the Department of Health. The requirements under subsection 26B(1) are not satisfied if a certificate other than those approved by the Secretary is used by the applicant. Copies of the approved form can be downloaded from the TGA or the Department of Health's website.

Notification to the Secretary that a patent certificate is not required in relation to the application should be made using the approved form which can be downloaded from the TGA website.

Applications for registration

The subsection 26B(1) certification or a notification that the patent certificate under subsection 26B(1) is not required is a mandatory requirement for the registration of therapeutic goods and can be provided at any time prior to registration.

However, the subsection 26B(1) patent certificate or the notification is only required once the evaluation of the safety, efficacy and quality of the goods has been completed under section 25 of the Act and the decision is to register the goods. At this stage of the process the Secretary will notify the applicant in writing that the goods will be included in the ARTG once the applicant gives the Secretary the certificate required under subsection 26B(1) or a notice (in accordance with a form approved in writing by the Secretary) that a certificate under that subsection is not required in relation to the application.

Applications for listing

In contrast to applications for the registration of therapeutic goods, the listing of medicines under sections 26 and 26A requires that the subsection 26B(1) certificate or the notification (in accordance with a form approved, in writing, by the Secretary) that a patent certificate is not required, be lodged at the time of application. As the listing of goods under section 26A occurs electronically and listing can be effected almost immediately, the applicant is therefore required to lodge their subsection 26B(1) certificate or the notification at the same time as the lodgement of their section 26A application. If the subsection 26B(1) patent certificate is not required, the

applicant is required to notify the Secretary online on their ELF application. No evaluation relating to the safety, efficacy and quality is required for listable goods under section 26A prior to inclusion in the ARTG. The applicant is required to hold information or evidence to support any claim the applicant makes relating to the medicine.

As no evaluation is required under Section 26A, automatic listing may occur if applicants lodge their subsection 26B(1) certificates at the same time as lodgement of their application, or fill in the required online notification.

A new part has been added to the online ELF application entitled "**Subsection 26B(1) Notification**" to electronically notify the Secretary that the certification requirements to Subsection 26B(1) do not apply to the application.

For further advice on using ELF please call the ELF Helpdesk on 1800 773 312.

Assuming all other requirements for inclusion of the goods in the ARTG are met under sections 25, 26 and 26A of the Act and the subsection 26B(1) certificate has been provided by the applicant, the Secretary will include the goods in the ARTG without inquiring into the correctness of the certificate. The responsibility to ensure the correctness of the certificate lies on the applicant.

Civil proceedings do not lie against the Secretary (or a delegate of the Secretary) in respect of loss, damage or injury of any kind suffered by another person as a result of the Secretary (or the delegate) including the therapeutic goods in the ARTG in reliance on the subsection 26B(1) certificate given by the applicant.

A person is guilty of an offence if the applicant gives a certificate required under subsection 26B(1) of the Act and the certificate is false or misleading in a material particular. The maximum penalty which can be imposed if a person is convicted of this offence is $110,000 for an individual and $550,000 for a body corporate.

Certificates required in relation to patent infringement proceedings (section 26C)

If a person ("the first person") gives a certificate under subsection 26B(1) in relation to therapeutic goods and another person ("the second person") intends to commence proceedings under the *Patents Act 1990* against the first person for infringement of a patent that has been granted in relation to the therapeutic goods, the second person is required to give the Secretary and to the first person before the commencement of the infringement proceedings ("the proceedings"), a certificate required under subsection 26C(3).

The certificate required under subsection 26C(3) is a certificate to the effect that the infringement proceedings:

a) are to be commenced in good faith;

b) have reasonable prospects of success; and

c) will be conducted without unreasonable delay.

The first person, with the leave of the Federal Court or the Attorney-General, can apply to a prescribed court ("the court") for an order that **the second person** pay to the Commonwealth a pecuniary penalty, if **the second person** gives a certificate required under subsection 26C(3) and the certificate given is false or misleading in material particular, or the second person breaches an undertaking given in the subsection 26C(3) certificate. The maximum pecuniary penalty that can be imposed by the court is $10 million. In determining the extent of the pecuniary penalty, the court may take into account any profit obtained by **the second person** and any loss or damage suffered by any person, by reason of **the second person** exploiting the patent during the infringement

proceedings. However, these are not the only considerations that the court may take into account in determining the level of pecuniary penalty to be imposed on **the second person.**

The subsection 26C(3) certificate must be signed in writing by **the second person** using the form approved by the Secretary of the Department of Health. Copies of the approved subsection 26C(3) certificate can be downloaded from the TGA or the Department of Health's internet website.

The second person may also be ordered by the court to pay to the Commonwealth, a State or Territory compensation for any damages sustained or costs incurred by the Commonwealth, a State or a Territory, as a result of the grant of an interlocutory injunction. This order is able to be made in circumstances where:

a) **the second person** has sought and obtained in the infringement proceedings an interlocutory injunction restraining the first person from infringing the patent; and

b) section 26D does not apply; and

c) the court has declared that **the second person** has given a certificate required under subsection 26C(3); and

d) the court declares that the certificate is false or misleading in a material particular or **the second person** has breached an undertaking given in the certificate.

Requirements for Interlocutory injunction (section 26D of the Act)

Section 26D applies where:

a) the applicant for the inclusion of a therapeutic good in the ARTG has notified the patentee of the application for registration or listing of the therapeutic goods under section 23 ("the applicant") in accordance with subparagraph 26B(1)(b)(iii); and

b) the patentee and/or its exclusive licensee applies for an interlocutory injunction to restrain the applicant from marketing the therapeutic goods (the subject of the application) on the ground that such conduct will constitute an infringement of its patent.

Before applying for interlocutory relief, the patentee is required to first notify the Attorney-General of the Commonwealth, or of a State or of a Territory, in writing of the application. The Attorney-General of the Commonwealth shall be deemed to be a party to the proceedings unless the Attorney-General gives written notice to the court that he or she does not desire to be a party.

Where section 26D applies, the court may, in addition to other relief which it believes should be granted to any person, make any other orders if the following circumstances occur after an interlocutory injunction is granted to a patentee:

a) the patentee subsequently discontinues the principal proceedings without the consent of the other parties; or

b) the principal proceedings are dismissed; and

c) in either case, the court declares that:

   (i) the patentee did not have reasonable grounds, in all the circumstances known to the patentee, or which ought reasonably have been known to the patentee to believe that it would be granted final relief by the court against the applicant for infringement by the applicant of the patent; or for believing that each of the claims, in respect of which infringement is alleged in the proceedings, would have reasonable prospect of being held to be valid if challenged by the applicant; or

   (ii) the application for the interlocutory injunction was vexatious or not reasonably made or pursued.

If the court makes a declaration pursuant to paragraph (c) immediately above, the court may, pursuant to the usual undertaking as to damages given by the patentee to the court to obtain the interlocutory injunction, order the following:

a) assess and award compensation to the applicant on the basis of an account of gross profits of the patentee arising from the patentee's sale of the therapeutic goods in Australia during the period of the interlocutory injunction, without requiring the applicant to establish or quantify actual loss, or on such other basis as the court determines to be appropriate; and

b) award to the Commonwealth, a State or a Territory, compensation for any damages sustained, or costs incurred, by it as a result of the grant of the interlocutory injunction.