

Proposal to relax patent certificates under the *Therapeutic Goods Act 1989*

The Government has introduced amendments to Parliament to reduce the scope of the application of the earlier amendments relating to patent certificates under the *Therapeutic Goods Act*.

29 September 2005

In August 2004 we reported on amendments to the *Therapeutic Goods Act 1989* which introduced a requirement for applicants to lodge a certificate (a *Section 26B Certificate*) certifying that:

- (a) the marketing of the proposed good would not infringe any third party patents; or
- (b) it had notified the patentee of the application.

These amendments commenced on 1 January 2005.

Earlier this month the Government introduced amendments to Parliament to reduce the scope of the application of these provisions. Under the proposed amendments a Section 26B Certificate will be required only if:

- (a) the applicant is required to submit evidence or information to establish the safety or efficacy of the goods as part of the process of applying for registration or listing; and
- (b) in order to satisfy that requirement, the applicant relies (in whole or in part) on evidence or information that another person submitted to the Secretary:
 - (i) to establish the safety or efficacy of other therapeutic goods that have already been registered or listed; and

- (ii) as part of the process of applying for the registration or listing of those other goods.

The effect of the amendments is to require a Section 26B Certificate to be lodged only where an applicant seeks to rely on data previously submitted by another person as part of that person's earlier application. A typical example of such a situation is an application to register a **generic** version of an existing drug.

As a result, **originator applicants** will, generally, no longer need to lodge a Section 26B Certificate. However, it would seem that a Section 26B Certificate would be required where an originator seeks to register a new presentation of an existing registered product, but where the existing product is registered in the name of a different entity within the originator group. Such situations are likely to be rare.

The provisions will also have less application to **complementary medicines** as that sector does not generally rely on evidence or information submitted by others. Although applicants for registration or listing of complementary medicines are required to submit evidence or information to establish the safety or efficacy



of the goods, this evidence or information is generally bibliographic, or literature based.

The amendments will apply to applications for registration or listing made on or after the amended provisions commence. The amendments are currently before Federal Parliament and have only recently been read for the first time. Accordingly, they are unlikely to be passed into law for some time (if at all). As currently drafted the amendments are specified to commence on a date to be fixed, or not later than 6 months after receiving Royal Assent.

By narrowing the scope of persons required to lodge Section 26B Certificates, the scope of situations where a certificate under section 26D will be required will also be narrowed. Readers will recall that, before commencing proceedings to enforce a patent against a person who lodged a Section 26B Certificate, a patentee must certify under section 26D that the proceedings are to be commenced in good faith, have reasonable prospects of success and will be conducted without unreasonable delay. This amendment should be welcomed by the local biotech industry.

AUTHOR: JEFF BERGMANN



Jeff is a senior associate of the firm. His primary area of expertise is the commercialisation of intellectual property and technology including, licensing and corporate structuring. He works with technology-based companies as well as scientific and medical research organisations, advising them on capturing and exploiting their intellectual property.

To contact Jeff please phone +613 9254 2888 or email jbergmann@davies.com.au



DAVIES COLLISON CAVE

If you would like to be removed from our mailing list, please send an email to mail@davies.com.au or telephone Melissa McLennan on +61 3 9254 2777.

The contents of this information sheet are not intended to be, nor are they, a complete statement of the law on the particular subject matter and are for information purposes only. This update is not a substitute for legal advice.

Melbourne

1 Nicholson Street,
Melbourne VIC 3000
Telephone +61 3 9254 2777
Facsimile +61 3 9254 2770

Sydney

Level 10, 10 Barrack Street,
Sydney NSW 2000
Telephone +61 2 9262 2611
Facsimile +61 2 9262 1080

Brisbane

Level 3, 303 Coronation Drive,
Milton QLD 4064
Telephone +61 7 3368 2255
Facsimile +61 7 3368 2262

Canberra

Level 11, 60 Marcus Clarke St,
Canberra ACT 2601
Telephone +61 2 6248 8063
Facsimile +61 2 6248 6591

Newcastle

130 University Drive
Callaghan NSW 2308
Telephone +61 2 4960 8366
Facsimile +61 2 9262 1080