

# Australia: Extension of Term Provisions

FB RICE

The Australian Patents Act 1990 currently provides for the extension of term of certain patents claiming pharmaceutical substances for a period of up to five years.

## Requirements for grant of an extension of term

Extensions are available only for patents that disclose and claim a pharmaceutical substance per se or a pharmaceutical substance produced by a process that involves the use of recombinant DNA technology. Patents claiming methods for producing a pharmaceutical substance produced by a process that involves the use of recombinant DNA technology are also eligible for an extension. Extensions are not available for method treatment patents.

The other requirements for obtaining an extension of term are as follows:

- Goods containing, or consisting of, the pharmaceutical substance must be included in the Australian Register of Therapeutic Goods (ARTG);
- There must be a period of at least five years between the date of the patent and the first Australian regulatory approval; and
- The patent term must not have been previously extended.

During the term of the patent, it will not be an infringement if a person exploits the claimed pharmaceutical substance solely for purposes in connection with obtaining regulatory approval for therapeutic use in Australia or any foreign country (springboarding).

The term of the extension is calculated as the period from the date of the patent until first Australian regulatory approval reduced by five years. The maximum term of extension is five years.

The application for an extension of term of a standard patent must be made within 6 months after the latest of the following dates:

- The date the patent was granted; or
- The date of commencement of the first inclusion in the Australian Register of Therapeutic Goods of goods that contain or consist of any of the relevant pharmaceutical substance(s).

## The rights of the patentee if a term is extended

After an extension of term has been granted, during the extended period a patent will not be infringed if:

- A person exploits the claimed pharmaceutical substance for a purpose other than for a therapeutic use; or
- A person exploits any form of the invention other than a pharmaceutical substance per se.

## Multiple Pharmaceutical Substances

If the possibility exists that more than one pharmaceutical substance may be registered, we recommend that each substance be the subject of a separate application to maximise the possible extension of term for each of the respective pharmaceutical substances. This is achieved by the filing of a divisional application, the due date of which is 3 months from advertisement of acceptance.