

**Senate Standing Committee on Economics**  
**ANSWERS TO QUESTIONS ON NOTICE**  
Innovation, Industry, Science and Research Portfolio  
Budget Estimates Hearing 2011-12  
30 May 2011

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**AGENCY/DEPARTMENT:** IP AUSTRALIA

**TOPIC:** Amgen Patent

**REFERENCE:** Question on Notice (Hansard, 30 May 2011, E24)

**QUESTION No.:** BI-8

**Senator Heffernan** - On what basis did IP Australia decide to extend Amgen's patent monopoly by one year, four months and 13 days? And the logic and the paperwork that enabled you to come to that decision-the paper trail?

**ANSWER**

Sections 70 to 79A of the *Patents Act 1990* set out the statutory basis for extension of term of patents for pharmaceutical substances (pharmaceutical patents). The provision is available for pharmaceutical patents where there are delays in the regulatory approval of the pharmaceutical substance under the *Therapeutic Goods Act 1989* which is administered by the Therapeutics Goods Administration (TGA). The extension of term of Australian Patent 600,650 was granted because all the statutory provisions of Sections 70 to 79A of the *Patents Act 1990* were satisfied.

Section 77 of the *Patents Act 1990* sets out how the length of extension of term is calculated. The length of an extension is equal to the period between the date of the patent (as defined in section 65) and the first regulatory approval date (as defined in section 70) less five years.

With respect to Australian Patent 600,650, the date of the patent is 11 December 1984. The first regulatory approval date is 24 April 1991. Therefore, the length of the extension of term was one year four months and 13 days.

The paperwork relating to the application for the extension of term and IP Australia's decision is provided at Attachment A.