

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2011-2012, 15 February 2012

Question: E12-238

OUTCOME 2: Access to Pharmaceutical Services

Topic: PATENTS

Written Question on Notice

Senator Heffernan asked:

Can the Department enlighten me on what steps it took to ensure IP Australia intervened in those proceedings so as to protect Australian taxpayers from overpaying Sanofi Aventis?

Answer:

The Department of Health and Ageing has no responsibility for ensuring that IP Australia intervenes in patent litigation. IP Australia administers patent law and will take action independently to revoke a patent where the court decides it is invalid and orders its revocation.

Under certification and notification provisions of the *Therapeutic Goods Act 1989* which implement Australia's obligations under the Australia United States Free Trade Agreement, a patent holder that intends to commence patent infringement proceedings is required to certify to the Secretary of the Department of Health and Ageing (and to the generic company) that the proceedings will be 'commenced in good faith, have reasonable prospects of success and will be conducted without unreasonable delay'. The Department of Health and Ageing has no responsibility to further disseminate this advice, only to monitor and remain a party to proceedings if necessary. Penalties do apply, however, where the patent holder's certificate is found to be false or misleading.