Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2012-2013, 30 & 31 May and 1 June 2012

Question: E12-011

OUTCOME 2: Access to Pharmaceutical Services

Topic: Pharmaceutical Benefits Scheme

Type of Question: Written Question on Notice

Number of pages: 1

Senator: Senator Heffernan

Question:

In 2011, IP Australia granted a drug company an extension of time in which to apply for a patent term extension – the applicable extension of time was approximately 10 years.

At the time of the delegate's decision, the patent which is the subject of a patent term extension, which effectively increases the period of a patent monopoly in the case of pharmaceutical substances by up to 5 years giving pharmaceutical patents a potential maximum period of patent protection of 25 years, had been the subject of patent litigation which went all the way to the High Court of Australia. The end result of that litigation was that although the patent's validity was mostly upheld, the patent term extension which had been granted by IP Australia, was held to be invalid. Subsequently, the patent expired and so generic pharmaceutical companies began, as they are perfectly entitled once the patent monopoly is no longer operative, to market generic versions of the previously patented medicine. However, the day before the patent expired the patentee applied for a 10 year extension so as to be able to apply for a second patent term extension (the first being invalidated) taking the period of patent protection to December 2012. In effect, the time within which the patentee could apply for a patent term extension expired 10 years earlier.

The decision in question was made in 2011 and it means, in effect, that the generic companies that began marketing a generic version of the patented drug now face a potential claim for damages and or an account of profits in regard to the sales of their products to December this year. I understand that IP Australia's decision is now the subject of a review before the Administrative Appeals tribunal (AAT).

It needs to be pointed out that the patented drug which had been the subject of an earlier patent and which ran its full 20 year term was essentially the same medicine protected by the later patent which was upheld as valid.

a) In other words, IP Australia granted two patents over the same kind of medicine. Is PBS aware of these issues? If so, what policies does PBS have in relation to these matters?
b) Does PBS liaise with IP Australia to discuss such matters?
c) What was the financial cost to the PBS of each and every patent term extension?

Answer:

a) The Department of Health and Ageing is aware of, and is monitoring these issues as they are progressed. However, The Department has no responsibility for patent policy, legislation or litigation. The Department monitors these matters as the outcome may be relevant to the Pharmaceutical Benefits Scheme (PBS) and price the Commonwealth pays for the medicine.

b) The Department liaises with IP Australia in relation to monitoring patent litigation which may be relevant to the administration of the PBS. However, it is the responsibility of IP Australia to administer patent law.

c) The Department does not cost every patent term extension as all patents are valid until challenged and a court rules otherwise.