Dear Ms Moore,

Re Submission – Pharmaceutical Patents Review

My submission addresses the information requirements associated with the applications for extensions of time in the current *Patents Act 1990* (Cth). The key submissions are:

(a) The evidence justifying patent extensions for any subject matter beyond the standard patent term calculated from the application date (priority date) is not available. This has been recognised by the Industrial Property Advisory Committee (1984) expressly calling for no patent term extensions and the Intellectual Property and Competition Review Committee (2000) remaining silent on the matter.

(b) To address this lack of evidence justifying patent term extensions there were amendments in the *Intellectual Property Laws Amendment Act 1998* (Cth) that introduced a (further) pharmaceutical specific extension and required applicants submit various forms of information (*Patents Act 1990* (Cth) s 76A). While this information is collected it is not made publicly available despite a commitment from the Department of Health and Ageing that ‘collective information would be publicly available’.

(c) The information collected according to the *Patents Act 1990* (Cth) s 76A should be subjected to an analysis to determine whether it is useful in guiding policy about patent term extensions (and other areas of patent policy). As appropriate that provision should be reviewed and removed if unnecessary (because the provided information is of no benefit or use), modified if better and more relevant information might be collected, or retained if the information is relevant but not yet sufficient.

(d) While the *Intellectual Property Laws Amendment Act 1998* (Cth) was prepared according to the pro-competition requirements of improving legislation in the *Competition Principles Agreement*, patent term extensions were an election commitment that had not been properly tested. The patent term extension should be assessed according to the *Competition Principles Agreement* methodology requiring evidence demonstrating that the benefits patent term extensions to the community as a whole outweigh the costs and that the objectives of extensions can only be achieved by restricting competition.

A background policy analysis of the *Patents Act 1990* (Cth) s 76A is attached.
If you have any queries or require further information please do not hesitate to contact me.

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**Information provision in the *Patents Act 1990* (Cth) s 76A**

At the time the current patent term extension was being introduced in the *Intellectual Property Laws Amendment Act 1998* (Cth) there was unanimous support for the provisions in the Senate¹ and House of Representatives.² A key amendment introduced in the Senate was to attempt to address in the longer term the justification for patent term extensions, balancing incentives to invest in research and development, and the increased price consequences of further exclusivity.³ The mover stated:

>This amendment requires that those who are applying for the additional patent time provide some information to the government. The aim of this is to basically assess whether what the government is trying to do is actually working and whether the money that we are spending – as I said before, we are looking at over $800 million in a period of 10 years – is being put to best use. I think the wording is self-explanatory: the total amount spent on each type of research and development, including pre-clinical research and clinical trials, in respect of the drug which was the subject of the application.⁴

The amendment requires that after a patent extension has been granted the patent holder submit information to the ‘Secretary of the Department’ before the end of each following ‘financial year’ being:

(a) details of the amount and origin of any Commonwealth funds spent in the research and development of the drug which was the subject of the application; and

(b) the name of any body:
   (i) with which the applicant has a contractual agreement; and
   (ii) which is in receipt of Commonwealth funds; and

(c) the total amount spent on each type of research and development, including pre-clinical research and clinical trials, in respect of the drug which was the subject of the application.⁵

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¹ See Commonwealth, *Parliamentary Debates*, Senate, 26 March 1998, 1375 (Ian Campbell, Senator for Western Australia), 9 July 1998, 5322 (Kate Lundy, Senator for the ACT), 5323 (Meg Lees, Senator for South Australia), 5324 (Bob Brown, Senator for Tasmania).

² See Commonwealth, *Parliamentary Debates*, House of Representatives, 26 November 1997, 11274 (Warren Truss, Minister for Customs and Consumer Affairs), 11 March 1998, 1049 (Stephen Martin, Member for Cunningham), 1051 (Jackie Kelly, Member for Lindsay), 1053 (Martyn Evans, Member for Bonython), 1058 (Allan Rocher, Member for Curtin).


⁵ *Patents Act 1990* (Cth) s 76A.
This provision has been implemented through a process that requires the information be lodged with the Secretary of Health and Family Services:

As at 18 December 1998, [the] Deptartment of Health have advised their requirements as:

- the details of the amount and origin of any Commonwealth funds spent in the research and development of the drug which the subject of the application (sec 76A(a)) and the names of any body with which the applicant has a contractual agreement and which is in receipt of Commonwealth funds (sec 76A(b) as well as the total amount spent on each type of research and development (s 76A(c)) relate to activities occurring in Australia concerning the specific drug registered on the [Australian Register of Therapeutic Goods], on which the application for extension of term is based.
- the total amount spent on the drug (s 76A(c)) needs to cover the period from initial research up until the granting of the extension of term. The Health Department would then require a supplementary return which provides the amount of research and development funds spent on the particular drug for the period from granting the extension of term up until the expiry of the patent.
- access to the information in the notification would be governed by the [Freedom of Information Act 1982 (Cth)]. However, collective information would be publicly available.6

This information is provided to and maintained by the Pricing Section, Pharmaceutical Evaluation Branch of the Department of Health and Ageing.7 Despite the commitment that ‘collective information would be publicly available’ this information is not presently publicly available.

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