3rd May 2013

Re: SUBMISSION TO THE PHARMACEUTICAL PATENTS REVIEW

Dear Mr Harris,

We read with interest the recent Pharmaceutical Patents Review Draft Report April 2013. The Baker IDI Heart and Diabetes Research Institute is dedicated to reducing death and disability from cardiovascular disease, diabetes and related disorders. The Institute has established an international reputation for translation of medical research. We believe that the monopoly protection provided by patent law is necessary for the translation of some medical discoveries from research into the market in order that the discovery will provide a benefit to the patient. We also recognise that the resources to pay for health care are finite. We understand that the Pharmaceutical Patents Review was established in order to address whether this monopoly, provided by a combination of patent and regulatory controls, is suitably balanced so as to serve all parties equally.

The Institute is not expert in these matters, but our core business is the delivery of best practise medical care to patients and in satisfying unmet clinical need through discovery and development. We would make the following observations in regard to the recently issued Draft Report, and the call for submissions which preceded it.

With regard to the Pharmaceutical Patents Review Background and Suggested Issues paper November 2012, our views are reflected by the submission made by the Walter and Eliza Hall Institute (January 28 2013). In brief, we concur on the following points:

- The period of patent exclusivity for a pharmaceutical product should be at least equivalent to that provided by US and European countries, of the order of 15 years from marketing approval
- Patent laws in Australia have now been strengthened and more closely aligned with US and European countries. These laws do not readily provide the opportunity for inappropriate extension to patent life, as implied by the imprecise term “evergreening”
- The period for data exclusivity provided by Australian regulations should be aligned with US and European countries since this is an integral part of the monopoly.
With regard to the Pharmaceutical Patents Review Draft Report 2013, we would make the following observations in regard to the draft recommendations.

“Draft Recommendation 6.1 The Government should maintain the current approach that allows extensions for drugs and formulations but not for methods of use and manufacture, which will continue to provide an incentive for the development and supply of active pharmaceutical ingredients and new formulations, without adding to the existing cost of medicines in Australia.”

First, it is important for the Review to acknowledge that there is considerable difference between “method of use” patents and “manufacture” patents. Neither of these types of claims would prevent a generic from entering the market of the innovator once their original patent monopoly had expired.

A method of use claim provides the means to commercially exploit the discovery that an existing drug may provide benefit to a new patient population. To establish the utility of an existing drug as a useful treatment for a new disease indication, it is still necessary to demonstrate through clinical trials that the drug is effective. The monopoly provided by the method of use claim provides a means for these costs to be recovered.

A new method of manufacture claim may provide improved cost of goods or product quality, and so has the potential to enhance the value of the innovator’s product. Consider that this benefit is derived from investment in research and development. The manufacturer of a generic can use the method of manufacture used by the innovator to first bring the product to market, and so this new “method of manufacture” does not extend the original monopoly.

In closing, we encourage the Patent Review, when issuing its final report, to provide clear and transparent argument in support of any recommendations that change the monopoly provided by patents and regulations significantly from those provided by the major markets of US and Europe. It is our view that it will be the harmonisation of such systems that has the potential to provide patients in Australia with the most equitable access to the best of medical care.

Professor Garry Jennings AM
Director
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