Peter MacCallum Cancer Centre
St Andrews Place
East Melbourne Victoria
Locked Bag 1 A'Beckett Street
Victoria 8006 Australia
Phone +61 3 9656 1111
Fax +61 3 9656 1400
ABN 42 100 504 883

www.petermac.org

Locations
East Melbourne
Box Hill
Bendigo
Moorabbin
Richmond [privat
Sunshine

Compulsory Licensing of Patents Inquiry
Productivity Commission
Locked Bag 2, Collins St East
Melbourne Vic 8003

28th September 2012

Dear Commissioner McClelland,

Re: Submission re Compulsory Licensing of Patents for the Peter MacCallum Cancer Centre

The Peter MacCallum Cancer Centre is a Public Health Service created pursuant to the Health Services Act (1988) (Vic) ("Peter Mac"). Peter Mac has previously provided responses to Senate Committee hearings with respect to "gene patent" inquiries. Our initial concerns in this area stemmed from a negative interaction in regard to licenses in relation to BRCA gene assays. The terms of that case have been widely reported and will not be reiterated here, and the final outcome did not require Peter Mac to consider any action by way of access to the compulsory license or crown use provisions of the Patent Act due to a change in company policy by the patent licensee in Australia.

Peter Mac's experience overall has been that the existing patent system does not act to hinder our activities in provision of healthcare or in performing research. The single example of a case that was problematic to us was solved as a result of public pressure towards the company involved. As a whole, the existing system functions well and provides incentive for further development in the field of medical research, for which extremely high development costs would be otherwise prohibitive. There remains however a public perception, and indeed a possibility, that there may be isolated occasions where patent holders may seek to attempt to enforce their rights unreasonably and either not supply patented materials in the Australian market or apply unreasonable licensing provisions to their use.

The carving out of certain subject matter (namely the so-called "gene-patents") from the definition of patentable materials has been proposed as a method of solving this potential problem. It is apparent however that this would not be effective (for example in the Myriad case, removal of gene patent claims would not remove claims to the assay itself) and provides an additional risk that companies will either fail to invest in medical research in fields that are non-patentable, or simply not provide the products within Australia. In addition this is likely to be an ongoing process of modification to keep pace with the rapid rate of new discoveries in the medical research field.

It is important however that the balance between commercial incentive for the patent holder and the access to patented technologies as a matter of public good is well balanced. For this reason, the Patent Act already includes provisions that allow for the rare circumstance where a patent holder may unreasonably attempt to enforce their rights; the compulsory licensing and crown use provisions. These provisions have been rarely used, an indicator that the existing patent system on the whole works well. In the case of Peter Mac, there have been no cases where we have considered resorting to these provisions. However it remains a possibility that Peter Mac, as a state health care service, would wish to access the crown use provisions to

pursue access to health care that was otherwise not able to be accessed by our patients at a reasonable cost. It is important to state that such access to the crown use or compulsory license provisions would be of no value to Peter Mac whatsoever if they could not be accessed in a cost and time-effective manner.

As an effective deterrent to unreasonable enforcement of patents, the process for accessing compulsory licensing and crown use provisions must be clearly elucidated and readily accessible. The process for assessment of these applications must be easily understood and transparent, with guidelines to assess how a “reasonable” licensing fee would be calculated. A better understanding of the review process would allow most disputes to be settled before reaching the application phase and provide a better means of assessing risk if such measures are to be undertaken. Instigation of extended legal cases should be avoided wherever possible.

In summary, the current patent system works well in meeting the needs of Peter Mac for access to health care and for conduct of research. While the need for protective provisions such as compulsory licensing and crown use is recognised, they are of little value unless they are readily accessible, affordable and well defined.

Yours sincerely,

Shari Lofthouse

Manager, Intellectual Property and Development
Acting Director of Commercialisation