Response of Prof. Christie to Questions on Notice
2 October 2009

A. Time from Application to Grant

I have been asked to respond to the following questions: Could you please comment on the time intervals between patent applications and deadlines for finalisation up to 54 months later? Should this timeframe be changed in any way? Would more stringent requirements for 'utility' within patent law negate any need to reassess the timeframes for patents?

I assume that the period of 'up to 54 months later' mentioned in the question is a figure provided to the Committee as being the typical time from application to grant for a gene patent. I have no knowledge of how accurate is this figure, but it strikes me as likely to be correct because it is in the typical timeframe of 3-5 years for determination of a patent application generally.

As the Committee has no doubt been informed, a number matters of affect the length of time it takes to determine the outcome of a patent application, including: backlog at the Patent Office; contentiousness of application (i.e. how much back-and-forth arguing about the application occurs between the patent examiner and the applicant); and desire of the applicant to have the matter determined either quickly or slowly (any particular patent applicant may have a reason to desire one or the other).

All other things being equal, as a matter of general principle it is in the public interest to have patent applications decided more quickly rather than more slowly. This is because it is in the public interest to know whether or not a patent will be granted for the application; and, if so, to know in what form the claims of that patent will be granted. Put simply, a quicker determination of the patent application leads to 'certainty' sooner – which is considered to be a good thing from society's point of view.

It follows from the above that it would be desirable, from society's perspective, for the typical time from patent application to grant to be reduced. However, it needs to be recognised that achieving quicker examination will have costs. First, there are financial costs. This is because the Patent Office will be required to employ a greater number of patent examiners. Recruitment and retention of patent examiners has proved difficult in recent times for the Australian Patent Office. The extra costs of additional examiners will have to be borne by patent applicants, through higher fees. Secondly, reducing the time from application to grant may result in a lower quality of examination – i.e. more patents being granted with claims that are not valid. A reduction in quality might occur because there is less time for examiners to undertake a comprehensive prior art

search. It might also occur because of institutional pressure on examiners to 'dispose' of applications quickly; the easiest way to dispose of an application is to grant it.

It is very difficult to know if these costs would be outweighed by the advantages (earlier certainty) of quicker examination. It is also very difficult to know how likely it would be that quicker examination could actually be achieved. Some of the potential for delay rests with the applicant. It is difficult for the Patent Office to distinguish between meritorious and non-meritorious delay on the part of applicants – thus part of the potential for delay is largely out of the control of the Patent Office.

In summary, while in theory it would be desirable for there to be a shorter time between application and grant, the difficulties and the costs of achieving this might make it impossible or undesirable in practice.

Finally, you ask if a more stringent requirement to examine for utility would negate any need to reassess the timeframe. My view is that the timeframe will not be impacted one way or the other by a stringent examination for utility. That is to say, requiring a stringent utility examination will not add any additional time to the period (examination for utility is not a time-consuming exercise) and it will not change the advantages and the disadvantages of having a shorter examination period.

B. Gene Patent Examples

I have been sent 10 patents for genetic inventions. I have assumed, *but not verified*, that the claims in these documents are the claims in the actual granted Australian patent for the invention. I have only focused on *claim 1* in each patent.

The claims 1 in these patents fall into two basic categories:

1. a claim to a **biochemical substance**, of which there are two types:
   (a) a **nucleic acid** coding for a polypeptide (loosely, a gene): 728863; 686004; 691958; 773601; 2004200978; 624105; 714041
   (b) a **polypeptide** (loosely, a protein for which a gene encodes): 600650
2. a claim to a **medical use**, of which there are two types:
   (a) a **diagnostic test** (loosely, identifying a genetic mutation): 691331; 2004200978
   (b) a **treatment** (loosely, gene therapy): 200248844

I have undertaken a brief review of the specification of the patents where claim 1 is to a gene – i.e. patents in category 1(a). This review suggests that in each

case a specific, substantial and credible utility for the gene has been disclosed. Thus, it would seem that an enhanced (i.e. US-style) utility requirement would be satisfied in each of these cases.

For the patents in this category, the effect of claim 1 (assuming it to be valid) is that the patentee is given exclusivity in relation to *all* uses of the gene, not just the uses that are disclosed in the patent specification. This is to be contrasted with the second category of patents, where claim 1 is to a medical use. In those cases, the effect of claim 1 (assuming it to be valid) is that the patentee is given exclusivity in relation to the claimed method of diagnosis or method of treatment. That is to say, the exclusive rights of the second category of patents are narrower than the exclusive rights of the first category of patents.