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(...)

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Ms Julie Dennett
Committee Secretary
Senate Legal and Constitutional Committees
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Dear Ms Dennett,

Inquiry into the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*

I have read the various submissions to the Committee inquiring into the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*, along with the transcripts of the hearings held on 28 and 29 April 2011, and the subsequent responses to questions on notice. I also made an earlier submission myself (identified as no. 83), and have written about the ongoing process a number of time on my blog, *Patentology* (e.g. Senate Submissions Overwhelmingly Oppose 'Gene Patent' Ban[1], 'Late' Submissions to Senate Inquiry on 'Gene Patent' Ban[2], Why IP Professionals Must Take 'Gene Patent' Opponents Seriously[3] and Update on the Australian Senate Gene Patent Inquiry[4]).

I am writing in a personal capacity to highlight an issue which, as far as I can ascertain from the records, has not been considered by the Inquiry, namely the lack of any commencement or transitional provisions in the Bill.

It is clear that the Bill's proponents, including its primary author Dr Luigi Palombi, believe that it serves to clarify, rather than to change, the existing law. Dr Palombi, in particular, has been highly critical of the practice adopted by IP Australia since 1988 in relation to the granting of patent claims directed to isolated genetic materials, contending that this practice is contrary to the existing law, but that legislative clarification is necessary because it is neither practical nor desirable to await an opportunity for the High Court to rule on the issue.

Various opponents of the Bill – including IP Australia – contend that it will bring about a change in the law, such that certain claims which have been patentable in the past will henceforth be excluded from patentability.

The Committee may be of the opinion that it is not necessary to resolve this fundamental difference of views. However it appears to me that if anything is to be achieved through this process, then nothing could be further from the truth.

Those who believe that the Bill serves to clarify existing law would no doubt argue that it therefore does not require any specific commencement date or transitional provisions, because nothing will be changed by its passage. However, it is clear that there are many who disagree with this view, and who may therefore believe that, in the absence of express commencement and transitional provisions, the Bill may retroactively invalidate many granted patents.

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[1] http://blog.patentology.com.au/2011/03/senate-submissions-overwhelmingly.html
[2] http://blog.patentology.com.au/2011/03/late-submissions-to-senate-inquiry-on html
[3] http://blog.patentology.com.au/2011/05/why-ip-professionals-must-take-gene.html
[4] http://blog.patentology.com.au/2011/07/update-on-australian-senate-gene-patent.html

Conversely, if the Bill includes commencement and transitional provisions, its supporters may feel that this implicitly confirms the validity of claims granted prior to commencement. In any event, it will not resolve the existing dispute regarding the validity of such claims.

Either way, the status of patents already granted which include claims to isolated genetic materials – many of which may remain in force until well beyond 2020 – will be no more resolved by passage of the Bill than is presently the case. Ultimately, unless and until the High Court rules on the validity of such claims (or possibly on the legality and constitutionality of any alleged retroactive effect that the legislation may have), we will be no better off than we are at present.

As Mrs Beattie made clear in her testimony before the Committee, a greater part of the problem perceived by the Bill's proponents lies in the past than in the future, because the state of the art has moved on and broad patents claiming genetic materials *per se* are more difficult to obtain on grounds of lack of novelty or inventive step. It is not at all clear that the Bill does – or can do – anything to alter the past, nor that the technology-specific amendments it proposes will serve any substantial useful purpose in the future.

In this regard, I commend to the Committee the submissions and testimony of Professor Andrew Christie, and his support for a more general and flexible approach that is able to adapt to future debates, in other fields of endeavour, around the proper limits of patentability. Recommendations 8, 9 and 10 of the ACIP Review of Patentable Subject Matter set out one possible framework for such an approach:

- provision of an exclusion, as permitted by the TRIPS Agreement, to protect '*ordre public* or morality';
- this should 'exclude from patentability an invention the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public'; and
- the Commissioner of Patents should be provided with 'an explicit power to seek advice, from any person the Commissioner considers appropriate, to assist the Commissioner in applying this exclusion.'

I thank the Committee for the good work in which it is engaged, and for its extensive and thoughtful consultation on the relevant issues.

Yours faithfully,

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Dr Mark A Summerfield