Economics Legislation Committee
ANSWERS TO QUESTIONS ON NOTICE
Industry, Innovation and Science Portfolio
2015-16 Supplementary Budget Estimates Hearing
22 October 2015

AGENCY: IP Australia

TOPIC: Gene patents – High Court Decision

REFERENCE: Question on Notice (Hansard, 22 October 2015, page 69)

QUESTION No.: SI-18

Ms Beattie: The amendments that were made under raising-the-bar bill included increasing the bar for inventive step. It included examination for utility, which was not examined previously. It introduced, as you might appreciate, the broad research exemption. It increased the requirement for the description requirements in the claims of the specification of the patent.
Senator KIM CARR: That refreshes my memory. That is what I understood it to mean, but this patent was brought before those amendments to the IP regime here.
Ms Beattie: It was granted before those amendments, yes. In fact the patent was granted over 20 years ago and has now expired.
Senator KIM CARR: I see. Would a patent of that type have been issuable under raising-the-bar amendments?
Ms Beattie: It would be more difficult to be issued. It goes back to the time at which it was applied for. If the patent were applied for before the human genome was published and the raising-the-bar legislative provisions were in place then it would possibly have been more difficult to satisfy the inventive step requirement, because it was higher.
Senator KIM CARR: No, I am trying to get to another point. Could you have a patent of the type that the High Court has now struck down registered given our current legal framework?
Ms Beattie: It is difficult to make a general analysis without a specific claim before you in terms of understanding.
Senator KIM CARR: All I am saying is that was the subject of the High Court ruling. Could that be registered in today's legal framework?
Ms Beattie: I will have to take that on notice.
Senator KIM CARR: Could you take it on notice? When I watched the media reports I thought that these matters had already been attended to with the package of measures that have been described as raising the bar. Can you confirm that that is the case or otherwise?
Ms Beattie: The High Court considered what was patent-eligible—
Senator KIM CARR: at that time.
Ms Beattie: Even today. The raising-the-bar bill did not change the provisions of the manner of the manufacture test—the patent eligibility component. There was nothing in the raising-the-bar bill that addressed that, and the High Court was focused on that particular element of the legislation.
Senator KIM CARR: I presume there is no proposal to change the legislation to strike down or neutralise the High Court decision.
Mr Kelly: The High Court decision is fairly recent. At the moment, we have sought no authority for legislative change.
Senator KIM CARR: Yes, I understand that. My point is: is there intention to amend IP legislation to take into account the High Court decision one way or the other?
Mr Kelly: At present there is no intention.

ANSWER

The substantive changes to Australian patent law brought about by the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* apply to patents and applications where the request for examination was filed on or after 15 April 2013.

Myriad's patent 686004 was applied for and granted under the former provisions of the *Patents Act 1990*. The High Court did not revoke the patent. Rather, it was asked to consider and revoke three claims that were directed to isolated nucleic acid. The remaining 27 claims were not challenged and were not revoked. However, by the time of the Court's decision the patent had expired at the end of its normal 20 year term.

The *Raising the Bar* changes will have the effect of reducing the scope for patent claims of the type revoked in the Myriad case. For example claims 1 and 3 might be challenged on the basis of not being useful across their full scope. This is because some of the isolated BRCA1 nucleic acids containing sequence variations were not demonstrated to be of diagnostic relevance.