

Research Matters

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<http://researchaustralia.org/research-matters/summer-2010/#test6>

Gene Patent Legislation Update

AusBiotech has produced an excellent overview of the issues in relation to the recent Private Members bill around patenting genes.

While the campaign to ban gene patents has been for running many years, the debate has escalated recently with parliamentarians advancing bills in both houses.

The Bill introduced to the Senate last week proposes a legislative amendment, which would exclude from patentability "biological materials which are identical or substantially identical to such materials as they exist in nature, however made." If progressed in its current form it would have far-reaching and unintended consequences across the industry. The Bill has been referred to the Legal and Constitutional Affairs Legislation Committee for inquiry and report is due by 16 June 2011. The Senate Community Affairs Committee reported on Friday afternoon, after a two-year inquiry.

Research Australia and AusBiotech are collaborating with key organisations - and working to ensure that people have complete information.

Key happenings & background

- The Australian Law Reform Commission (ALRC) report of 2004.
 - Many reasonable recommendations including around research use exemptions on gene patents; to date none of these reforms have been instigated.
- In 2008 there was the threatened withdrawal of a key gene-based diagnostic for breast cancer.
- In response to significant public outcry, the Senate Inquiry (2008) was established to investigate the impact of gene patents on the cost and provision of health care in Australia and on the research community.
 - 78 submissions and multiple face-to-face consultations.
 - AusBiotech's submission called for no or minimal amendment to current legislation, lest there be significant unintended negative consequences on biotechnological innovation.
 - Major objections to patenting of genes submitted by the Cancer Council of Australia with support from high profile.
 - Complex issues led Senate to delay report several times and report on 26 November 2010 (see below).
- New York court invalidated Myriad gene patent claims.
 - Myriad has appealed and an outcome is not expected before end 1Q 2011.
 - In November 2010, the US Department of Justice submitted an Amicus Brief indicating support for a ban on the patenting of naturally occurring genes, but recommending that modified genes, eg

cDNA, be retained as patentable subject matter.

- Federal High Court case against Myriad/GTG brought by Cancer Voices and an individual from Queensland with pro bono legal support.
 - Myriad offers to surrender patent in Australia but parties remain in discussion about scope of court proceedings.
- Melissa Parke advanced a Private Member's Bill on 18 October 2010 to "ensure that patents cannot be granted over any biological materials which are identical or substantially identical to what exists in nature," which received bi-partisan support on first reading.
- Coalition parliamentarians (including Peter Dutton) introduced a similar Bill into the Senate on 24 November, which was referred (26 November) to the Legal and Constitutional Affairs Legislation Committee for inquiry and report is due by 16 June 2011. Submissions are invited by 25 February 2011.
- Senate's inquiry into gene patents by the Senate Community Affairs Committee reported on 26 November 2010. The report made 16 recommendations and said in its executive summary that: "A number of considerations persuaded the committee that it would not, at this point in time, recommend that the act be amended to expressly prohibit the patenting of genes."

Research Australia would welcome your feedback in relation to this Bill by 15 February 2011.

If you would like to provide feedback so that Research Australia can augment the AusBiotech view, please contact Gabby Fennessy by email at gabby.fennessy@researchaustralia.org