

SUMMARY : The Burnet Institute's Submission to the Senate Standing Committee on Legal and Constitutional Affairs - Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (*Bill*)

- The Burnet Institute is an independent, not-for-profit public good organisation and its mission is to improve the health of disadvantaged and marginalised communities in Australia and overseas. This is achieved by uniquely merging innovative and translational medical research with epidemiology and surveillance roles, and with practical public health action.
- The Burnet feels that the effect of the Bill if passed would be extremely broad, and will have some serious consequences for our Institution's continued research and development and for medical research in general. The Burnet has a number of Australian patent applications relating to biological materials for the detection, prevention and treatment of diseases such as HIV, hepatitis, malaria and cancer. The Institute strongly believes that the ability to patent such technologies is an essential element in enabling medical technologies to move from the bench to the bedside providing practical solutions to many public health issues.
- The Burnet Institute's capability for research translation relies strongly on the ability to attract funding and partner with commercial investors or biopharmaceutical companies. Without patent protection these investors will choose not to fund the development of Australian medical research technologies. This will not only impact on those conducting medical research, but will also impact Australian patients who will potentially miss out on early access to such technologies
- The key driver behind this debate surrounds a solution that protects patient's rights which will not hinder medical research and the ability of the Industry to develop new technologies to benefit these patients in the future. The Burnet suggests that this Bill will not achieve such a solution and in fact, will potentially prevent the further development of new medical advances that would benefit Australian patients due to the inability to attract commercial funding and biopharma partnerships.
- For the above reasons the Burnet Institute urges the committee to reject the private members Bill and as an alternative take on board the recommendations made from the Australian Law Reform Commission's report on gene patenting and human health in 2004. Many of these recommendations have also been captured by the committee. The Burnet specifically endorses recommendations 11, 12 and 13.



Burnet Institute
Medical Research. Practical Action.

Ms Julie Dennett
Committee Secretary
Senate Standing Committee on Legal and Constitutional Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

20th February 2011

Dear Ms Dennett,

Submission to Senate Standing Committee on Legal and Constitutional Affairs - Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (*Bill*)

We wish to provide this submission to the Senate Standing Committee on Legal and Constitutional Affairs (***Committee***) in its inquiry on the Bill.

We ask the Committee to consider our submission in the context of the effects that the Bill (if passed in its current form) would have on our research and the ability to take potentially lifesaving diagnostics, vaccines and therapies from the bench to the bedside.

The Burnet Institute's mission is to improve the health of disadvantaged, marginalised communities in Australia and overseas. This is achieved by uniquely merging innovative and high-technology medical research with epidemiology and surveillance roles, and with practical public health action. Burnet also has a special emphasis and proud tradition of research translation, clinical trials, capacity-building and influencing public health policy. The Burnet Institute has special expertise in virology (especially HIV, hepatitis viruses and influenza) and in other infectious diseases such as tuberculosis and malaria. Burnet also has substantial programs in immunology and vaccine development in areas such as cancer and auto immune diseases. A major strategic focus of the Institute is the **translation of research into tangible and practical benefits** for the global community.

POTENTIAL EFFECT THE BILL WILL HAVE ON THE ABILITY OF THE BURNET INSTITUTE TO FULFIL ITS MISSION

DIRECTOR
Professor Brendan Crabb

CHAIR
Mr Alastair Lucas

PATRONS
CHIEF PATRON
Professor David de Kretser AC
Professor Gordon Ada AO
Hon Steve Bracks
Mr Nobby Clark AO
Dr John Connell AM
Mr Bryce Courtenay AM
Rt Hon Sir Zelman Cowen AK
Professor Allan Fels AO
Rt Hon Malcolm Fraser AC
Professor David Ho
Hon Michael Kirby AC
Professor Sir Peter Morris AC
Mr John So

AFFILIATES
Alfred Medical Research and Education Precinct (AMREP)
University of Melbourne
Monash University

Head Office

85 Commercial Road, Melbourne, Victoria, Australia 3004
GPO Box 2284, Melbourne, Victoria, Australia 3001

Tel +61 3 9282 2111 Fax +61 3 9282 2100 Email info@burnet.edu.au www.burnet.edu.au

The Bill proposes to exclude the patenting of the following under Australian law:

'biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to, such materials as they exist in nature.'

In our view, the effects of this ban on the patenting of biological materials would be extremely broad, and will have some serious consequences for our Institution's continued research and development and for medical research in general. In particular, the current wording captures biological material as diverse as proteins, monoclonal antibodies (mAbs), natural chemical compounds, viral and cancer epitopes for the development of vaccines. The Burnet has a number of Australian patent applications relating to these biological materials for the detection, prevention and treatment of diseases such as HIV, hepatitis, malaria and cancer. The Institute strongly believes that the ability to patent such technologies is an essential element in enabling medical technologies to move from the bench to the bedside providing practical solutions to many public health issues.

One of the main outcomes of medical research is the development of new technologies that address key unmet medical needs and provide patients and the population in general with improved health outcomes. The Burnet Institute's capability for research translation relies strongly on the ability to attract funding and partner with commercial investors or biopharmaceutical companies. Over the years, the Burnet has spun out four companies and has been successful in attracting over \$3M in funding in the past three years from mid-stage investors and companies on the strength of its research and patent position. One of these technologies is in phase II clinical trials for the treatment of cancer and two others are less than two years away from first clinical studies. It is important to note that these new technologies will not only benefit the Australian public through improved health outcomes, but also have a positive impact on the Australian economy by creating and maintaining jobs in medical research, clinical trials and other related contract research organisations.

The reality is that bringing a vaccine or therapeutic through the clinic and to patients, costs between \$500-800 M with an average timeframe of between 12-15 years. Commercial investors and biopharmaceutical companies rely on patent protection to enable them a limited time to earn a return on investment free from competing identical products. Without this protection these investors will choose not to fund the development of Australian

medical research technologies. This will not only impact on those conducting medical research, who will likely choose to re-locate and conduct their research, development and clinical studies overseas, or re-consider their employment opportunities, but will also impact Australian patients who will potentially miss out on early access to such technologies. International companies will be less likely to target the relatively small Australian market for early release of new technologies without patent protection, and local “copycat” products will rarely be available due to the high cost of clinical trials and product registration, which could rarely be recouped from the Australian market alone.

The peril of moving away from a country of novel biopharmaceuticals to a country of generics will result in Australia losing its reputation as a knowledge economy drifting from developed economies such as the US and Europe towards those of the developing world. Additionally, the regulatory hurdles required for bringing generics to the market in Australia will likely be similar to those for novel therapeutics as the Therapeutic Goods Administration is unlikely to accept data on the basis of foreign clinical trials. The issue of greatest concern is “who will pay for the cost of development?” Without patent protection, investors will not be attracted to fund the highly cost intensive phases of research and clinical development and the government is not in the business of investing in drug development.

THIS BILL DOES NOT ADDRESS KEY AREAS OF REFORM THAT WOULD PROTECT BOTH RESEARCHERS AND END USERS

The main arguments used in support of the Bill revolve around protecting the end user (patients) so as to prevent another Genetic Technologies BRCA1/2 incident as well as to enable unimpeded medical research. The key driver behind this debate surrounds a solution that protects patient’s rights which will not hinder medical research and the ability of the Industry to develop new technologies to benefit these patients in the future. The Burnet suggests that this Bill will not achieve such a solution and in fact, will potentially prevent the further development of new medical advances that would benefit Australian patients due to the inability to attract commercial funding and biopharma partnerships, thus stifling the innovation of new medical advances. For these reasons we strongly urge the Committee to reject the proposed Bill.

The Burnet Institute believes that there are areas for reform that will protect all stakeholders. These are captured in the recommendations from the Australian Law Reform Commission’s report on gene patenting and human

health in 2004. These are also mirrored in many of the recommendations made by the Senate Committee in 2010.

Recommendation 13 made by the Committee is of particular relevance to the Burnet Institute as it proposes that the *Patent Act 1990* be amended to provide a broad research exemption. While Burnet has not been restricted in conducting research due to the presence of patents on genes and biological materials, there is a certain degree of confusion as to whether researchers are protected by law to be enabled to do so. The Burnet suggests that clarification of research exemption will provide comfort that medical research could not be hindered by the presence of patent rights.

Burnet Institute strongly believes in the public health principles that new medical advances be made available to all and agree that further safeguards need to be put into place to ensure that patients are not restricted access to these technologies by aggressive company tactics. The Institute, therefore supports recommendations 11 and 12 made by the committee that focuses on clarification of crown use provisions.

CONCLUSION

The Burnet Institute believes that the above recommendations go a long way to address the concerns by the public to ensure access to new technologies that are subject of gene and biological material patents. Additionally, the recommendations provide clarity for researchers in being able to conduct research unimpeded by the presence of patent rights.

We believe the proposed Bill will in fact prevent the Burnet from attracting further commercial funding and biopharma partnerships for many of its technologies. Consequently if passed, the Bill will impede the development of new medical advances in Australia. This will inevitably lead to a reduction in employment opportunities, a reduction in biotech capacity, a significant brain drain of our world-class scientists, and a loss of reputation in Australia being a leading knowledge nation. In addition, Australian patients will be the ones to suffer by not have priority access to new diagnostics, vaccines and treatments.

For the above reasons the Burnet Institute urges the committee to reject the private members Bill and as an alternative take on board the recommendations made from the Australian Law Reform Commission's report on gene patenting and human health in 2004. Many of these

recommendations have also been captured by the committee; the following are endorsed by the Burnet:

- **Recommendation 11**

The Committee recommends that the *Patents Act 1990* be amended to clarify the circumstances in which the Crown use provisions may be employed; and that the Government develop clear policies for the use of the Crown use provisions. The Committee recommends that the Government adopt the Australian Law Reform Commission's recommendations on this issue from its 2004 report, *Genes and ingenuity* (Recommendations 26-1 to 26-3).

- **Recommendation 12**

The Committee recommends that the Government amend the *Patents Act 1990* to clarify the scope of the 'reasonable requirements of the public' test, taking into account the recommendation of the Australian Law Reform Commission on this issue in its 2004 report, *Genes and ingenuity* (Recommendation 27-1); the Committee recommends that the Government review the operation of the competition based test for the grant of a compulsory licence, with particular reference to its interaction with the *Trade Practices Act 1974*.

- **Recommendation 13**

The Committee recommends that the *Patents Act 1990* be amended to include a broad research exemption.

The Burnet thanks the committee for the opportunity to present a submission and would welcome a further discussion by interview should the committee deem necessary.

Yours sincerely,

Professor Brendan Crabb
Director and CEO