Australian Institute for Innovation

Ms Julie Dennett
Committee Secretary
Legal and Constitutional Affairs Legislation Committee
Parliament House
CANBERRA ACT 2600

Dear Ms Dennett,

Re: Inquiry into Patent Amendment (Human Genes and Biological Materials) Bill 2010

The Australian Institute for Innovation welcomes the opportunity to comment on the proposed Bill and on the claims made for and against it. Like many others involved in this discussion, our guiding principle is that the community receives the benefits that can flow from new medical therapeutics, diagnostics and devices. Our conclusion on the impact of the Bill, being informed by a wide commercial experience in the translation of research to real products and services, is that the legislation would materially and adversely constrain the delivery of health improvements to the Australian community.

We provide a commentary below on the salient reasons supporting our conclusion. At the outset, we table our full endorsement of the Open Letter lodged by ***AusBiotech and Medicines Australia*** jointly and by the submission of the ***Walter and Eliza Hall Institute*** **of Medical Research (the "WEHI").**

1. As a prologue, we draw attention to the level of capital investment and risk involved in the development of new medical therapeutics, diagnostics and devices.

   As a community, we want continued access to safe and effective medical products. Each new medical product requires a substantial commercial investment to support the pre-clinical activity, clinical trials, the regulatory interactions, the establishment of manufacturing and distribution facilities and the other costs associated with bringing the product to market. Moreover, these risks are not absolute but relative, with the added significant commercial risk that another product will prove superior. To think that biologic based therapeutics and diagnostics can be developed without commercial investment is fanciful. All considerations of this legislation need to be mindful of this context.

2. The foundation of our conclusion is that patent protection is essential if we are to translate research discovery and knowledge to products and services of value, and that constraints on patent availability will constrain the flow of such products.

   The translation of research discovery into effective and safe diagnostics and therapeutics requires commercial investment. Substantial risk-taking capital is required.

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capable of adjudicating the allocations of such risk capital, even it were able and willing to fund. Without patent protection, investment in the commercialisation of research outcomes will not occur. It is simply the fact that tenants do not undertake capital improvements, owners do.

3. The proponents of the legislation suggest that investment activity will continue, because "processes or methods involved in their isolation, purification and synthesis are and so long as they also meet the other patentability criteria of novelty, inventive step and have a practical application can be patented". This argument misunderstands the basis on which such developments in process and methods occur.

   Investment in the development of processes and methods to refine biological compounds, which is crucial to increase effectiveness and safety, occurs because of the existence of the base patent either on the biological compound or on the biological receptors. It is not that such developments are impossible, but the absence of base patents adds a layer of risk that will discourage investment. All patents are subject to defeat by work-around but methods and processes are particularly weak in this regard, and by themselves are often judged an insufficient foundation for commercial investment. The practical fact is that any discussion with the biotech/pharmaceutical industry regarding the commercialisation of a new therapeutic starts with the question of whether a composition of matter patent exists.

   We challenge the proponents of the legislation to demonstrate the validity of their claim by cataloguing the number and application areas of medical therapeutics that are supported only by methods and process patents relative to those founded on biologic patents.

4. Restriction on the scope of patents is also likely to lead to higher a higher cost of new products.

   What is often unseen in the dynamic of this investment activity is that most of the commercial investment in this sector is part of a portfolio of such investments. In these portfolios, successful investment must first compensate for the many failures that inevitably occur. If constraints are imposed on the investment opportunity set, a response will occur, either in the form of a withdrawal of investment capital generally or a requirement for higher returns on the remaining opportunity set. Neither of these outcomes will serve the community's interest.

5. Contrary to the forecast that research will be empowered by the change, the legislation is more likely to have a significant long-term adverse impact on the research community in Australia.

   The absence of patent protection on biologics will be a disincentive for commercial firms to enter into research collaborations, or provide materials under MTAs with Australian researchers. Further, if there is little likelihood of achieving a translation

outcome from biologics research, why would the Australian taxpayers continue to support such research?

6. The limitations proposed on the patenting of biological materials close off a significant proportion of potential new therapeutics and diagnostics.

   The submissions endorsed above clearly draw attention to those many biologic therapeutics on the market today, saving and improving lives. The argument that patents should be restricted so researchers are unrestricted does not weigh in well when the counterpoint is that the cost of the researchers' freedom is the loss of community's freedom to access new biologic therapeutics.

7. The concerns and emotions raised over the impact of current patents on genetic testing and diagnostics is understandable as we take the first steps towards a new world of personalised medicine, but substantial commercial investment will still be required for such tests to be safe and effective.

   On this point, we first believe that the furore over the gene patents is out of proportion t the reality of what has actually happened. This point is well addressed in other submission and so the facts are not repeated here.

   We agree with Associate Professor Judy Kirk's view that: "Genetic tests will be an increasingly integral component of health care in the future. It is important that individuals have equitable access to high quality, appropriate and affordable genetic testing." However, it is not clear the legislation would deliver this result. Even diagnostics require substantial clinical evidence to warrant their use, and this again requires commercial investment. Inadequately tested diagnostics are as much a safety risk to the community as untested drugs.

8. Finally, we observe that some other submissions appear to attack the submissions of the pharmaceutical/biotech industry based on its "vested interests" and in particular, that because it is profit motivated, it cannot speak to the public interest. In our opinion, this is misplaced rhetoric.

   The fact that some of the parties are profit-based organisations does not invalidate the content of their contributions to the debate. It is not their motivations that concern us, but their investment behaviour. And our concern about investment behaviour extends beyond the immediate biotech industry. The fact is that there is today almost no investment support for Australian innovation from our superannuation system. The changes to the investment risk profile that will occur under this Act will be a further disincentive to local capital market support for innovation.

We agree it is timely to undertake a critical analysis of the issues related to genetic science and the patent system, but we see no evidence that this discussion has yet occurred. Our analysis, and that of the endorsed submissions, conclude that an exclusion zone around the patenting of new Intellectual Property based on biologics, their derivates and analogues

will raise increase investment risk and consequently adversely impact commercial investment and collaborative research activities.

Our recommendation is that two broad analyses take place as a central part of the consideration of the legislation, these being:

- an examination of the current portfolio of therapeutics available to the community to compare those whose IP is based on biological composition of matter patents, non-biological composition of matter patents and process and methods patents; and
- an examination of the costs of the development of genetic diagnostics and the clinical proof of their efficacy and safety, and the expected source of funding such development in the absence of commercial investment.

In summary, we believe that the proponents of the legislation need to table evidence, not opinion, that the legislation will have its purported effect of improving outcomes for the community. For our part, we see no such evidence.

Yours faithfully

Paul M Cheever
Director

24 February 2010

About the Australian Institute for Innovation

Founded in August 2010, the Australian Institute for Innovation is an independent, not-for-profit organisation whose purpose is to advance innovation practice and to inform innovation policy for the benefit of Australia. As a "think tank", the Institute does not undertake commercial activities. Its operations are supported by sponsorship funding from governments and innovative organisations.