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

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We would like to thank the Committee for giving us the opportunity to make a further submission with regard to the inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (the Bill). We note that we were asked to respond to two issues:

1. whether the amendment to the Bill, tabled by Senator Heffernan on 28 April 2011 remedies the sorts of problems raised by us in our earlier submission; and
2. whether all diagnostic processes are really the application of discoveries rather than inventions, as intimated by Dr Graeme Suthers on behalf of the Royal College of Pathologists in testimony before the Committee prior to our testimony on 28 April 2011.

1. The amendment to the Bill

One of the issues that we raised in our original submission was our concern about the lack of clarity in some of the language used in the Bill. We were particularly concerned about words such as: 'components', 'derivatives, 'biological material' and 'substantially identical' as well as the title to the Bill and other matters.

We note that the amendment removes the word 'derivative' from the Bill. The words 'substantially identical' also have disappeared, but it is unclear whether the intention is to strike them out, or if they have been deleted accidentally – the marked up copy does not show their removal. The word 'component' has been moved down to the definition of 'biological materials', which in our view will have a minor effect at best. Otherwise the definition of 'biological materials' remains unchanged. There is also a new definition of 'identical'.

We welcome removal of the word 'derivative' from the Bill, because of uncertainty as to its scope. However, we believe that there is still such a level of uncertainty and ambiguity in the Bill that we would be unwilling to endorse it based on the argument that the lack of clarity problem that we raised in our initial submission has been addressed.

Another central feature of our original submission was that the Bill in its original form was too broad. Our concern on this point has not been fully addressed in the amendment to the Bill. Admittedly, an attempt has been made to narrow the ambit of the biological materials exclusion by the new definition of 'identical'. We have pondered for quite some time on the likely impact of the Bill in its

amended form, should it be passed by Parliament, but we have been unable to come to a firm conclusion.

The Committee will doubtless appreciate that we, and others, spent a considerable amount of time engaged in detailed analysis of the Bill as introduced into Parliament in 2010 during the course of preparing our submissions. We have not been able to undertake the same level of analysis of the tabled amendment, given the obvious time constraints. It is of some concern to us that other individuals who also engaged in detailed analysis of the original Bill have not been given the same opportunity as us to scrutinize and make submissions on the amendment to assist the Committee in evaluating the possible consequences of passing the Bill as amended.

The requirement for biological material to be structurally and functionally identical to such materials as they exist in nature appears to make the newly amended exclusion quite narrow. Nevertheless, we believe that depending on how the amendment is interpreted it still has the capacity to have unintended consequences if it results in excluding materials that would otherwise be patentable. As such, we would be unwilling to support the Bill based on the argument that the breadth problem raised in our initial submission has been addressed.

On an alternative narrower interpretation, the Bill could have such an insignificant impact on the perceived problems resulting from patenting of biological materials that its sole value is symbolic. In our respectful view, we submit that Parliament should not be involved in symbolic law making, particularly in areas such as this, which are urgently in need of more practical reforms.

In our view, the other concerns that were raised in our initial submission have not been addressed by the amendment.

2. Diagnostic processes as applications of inventions or discoveries

We note that many diagnostic processes have been patented in Australia and in other jurisdictions. We noted in our earlier submission that empirical research in Europe indicates that these diagnostic patents could have a more significant impact on access to genetic testing than gene patents per se.

In the testimony by Dr Suthers on 28 April he expressed the view that diagnostic processes were simply the applications of discoveries. We must first note that we have great respect for Dr Suthers, and for the effort that he puts in to reform of patent law. Without trying to put words into his mouth, we believe that this statement is based on his strong belief that gene sequences are not patentable subject matter because they are not inventions.

We submit that the manner of manufacture requirement is currently interpreted by IP Australia to include isolated and synthetically manufactured gene sequences. Until there is a change in the law through legislative amendment or

judicial authority, it is difficult to accept the proposition that diagnostic processes are the applications of discoveries, not inventions (with the rider that the gene sequences must have been isolated and synthetically manufactured, and must fulfil the other patent requirements).

Should the law change with regard to the designation of isolated and synthetically manufactured gene sequences as discoveries rather than inventions, this will not necessarily prevent the patenting of diagnostic processes. There are many examples of process patents that have been granted for inventive processes that are the applications of known products. To illustrate this point, we refer to the decision of the US Court of Appeals for the Federal Circuit in *Prometheus Laboratories, Inc v Mayo Collaborative Services* handed down in December 2010. This case involved a patent claiming methods for determining the optimal dosage of known thiopurine drugs used to treat gastrointestinal and non-gastrointestinal autoimmune diseases. This case is not directly on point, since the issue here was whether methods of using known drugs satisfy the subject matter requirement in 35 USC 101. However, the case provides important guidance on the essential issue of whether methods of using products of nature are patentable. In coming to their decision, the Federal Circuit referred to the recent decision of the Supreme Court in *Bilski v Kappos*, 130 S. Ct (2010) on the patentability of business methods, which confirmed that a law of nature, natural phenomenon, or abstract idea cannot be patented. However, the Supreme Court added that 'an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.' *Bilski v Kappos*, 130 S. Ct. at 3230 (quoting the earlier decision in *Diamond v Diehr*, 450 U.S. at 188). On this basis, the Federal Circuit in *Prometheus* held that the claimed methods satisfied the subject matter requirement in that jurisdiction. This suggests more broadly that claims to methods of using products of nature can also satisfy the subject matter requirement, at least in the US.

As such we do not believe that the argument that diagnostic processes are the application of discoveries will provide a great deal of assistance in dealing with potential detrimental effects of patents claiming such subject matter on the delivery of genetic testing services in Australia.

An argument could be made that, even under current Australian law, a claim for evaluating whether a person has an increased chance of developing a disease based simply on comparing their gene sequence against another reference gene sequence is not a manner of manufacture. The basis for this argument is that such a comparison does not have a 'concrete, tangible, physical or observable effect' as required in *Grant v Commissioner of Patents* (2006) 67 IPR 1. This requirement is commonly known as a physicality requirement. It could be argued that a claim to a simple comparison of sequences that may indicate an increased chance of developing a disease, lacks the necessary physicality because there is no clear physical outcome. However, such an argument remain highly speculative, and seems to be somewhat at odds with US decisions like *Bilski* and *Prometheus*.