SUBMISSIONS TO THE PATENT AMENDMENT (HUMAN GENES AND BIOLOGICAL MATERIALS) BILL 2010

James & Wells Intellectual Property acts for many biotechnology companies that commercialise, within Australia, technology which is derived from genes or other biological materials.

Given the significant amount of expenditure in research and development dollars that is necessary to bring these technologies into practice, often after years of study and the resultant benefits and potential benefits such technology offers to society, we strongly oppose this proposed bill in Australia.

1. Patentability of isolated biological material should not be banned, but should be controlled by normal patentability criteria such as novelty and inventiveness.

It is implied that mere isolation of a gene for example is not inventive as the act of isolating a gene is easily done with techniques that are now common-day practice for scientists.

However, those behind this proposed bill have failed to appreciate an important mainstay of patent law.

To provide an analogy, it is often not the difficulty in making a given device such as a new mouse trap using standard workshop techniques and materials. Instead, it can often be the discovery of a new concept with considerable advantages over existing mouse traps that makes it inventive; and therefore patentable.

Using the same argument for an isolated gene, it is not the ability to isolate the gene that makes it inventive and patentable. Instead, it is most often the intensive research which results in the identification of advantages and commercial uses of the isolated gene which is inventive.

Take, for example, the Myriad case in the United States regarding patents surrounding the isolated BRCA1 and BRCA2 genes, and their uses. The isolation of the genes themselves is not the inventive concept although it does require substantial human intervention and manipulation (discussed further in point 2).

It is, instead, the identification that these isolated genes, over and above all other genes in the human genome, have significant potential for therapies and diagnosis of breast cancer. Without substantial research and testing, it would not be obvious to utilise the power of these genes to treat patients, for example with gene therapy, or identify those with a pre-disposition to breast cancer to allow for preventative medicine.

We consider isolated DNA, protein, antibodies and other isolated biological molecules should be patentable subject matter only if the patentee can illustrate clear commercial value of the isolated matter through research. And, similar to all patent applications, the claimed invention should not be obvious.

Therefore, in Myriad's case in the US, we consider that the BRCA1 and BRCA1 isolated genes in their isolated form should be patentable. This is due to the extensive research needed to identify the genes' importance and mutations therein which are linked to breast cancer. Such a discovery leads to clear commercial opportunities and provides a significant benefit to society.

2. Isolated biological material is a manner of new manufacture.

An argument behind the proposed amendments is that biological materials isolated from the natural environment are not an invention as they are not man-made products.

However, all products are essentially derived from nature some way or another. The ability to isolate and/or modify such material (regardless of whether they have a biological origin in nature) can lead to useful commercial products.

Such examples include rubber from trees, or isolated components from oil. In their own right, inventors should be able to retain ownership for the isolated (and therefore man-made) invention if the isolated material is new, inventive and provide a commercially useful application.

To provide a further analogy, we submit that a berry which grows in the Amazon rainforest should not be patentable. However, an isolated free radical from the berry should be patentable if it is able to treat melanoma effectively due to its isolation and concentration. The isolated free radical which is ingested in a cancer treatment does not exist in nature by way of contrast - only the natural berry exists and that in its wholesome form does not effectively treat the cancer. Therefore, it can be seen that even minute manipulation (e.g. isolation) of a natural entity existing in nature can produce a new and useful product.

We turn now to isolated biological material from the human body. There have been patents granted in United States and other countries including Australia for over 100 years in relation to this subject matter. The first of these was extracted adrenaline in 1906, followed by insulin and Vitamin B12. Currently there are over 40,000 United States patents in relation to 2000 human genes, representing 10% of the human genome.

The basis for these granted patents is that isolated biological material from the natural setting does indeed require human manipulation, and their isolated forms have new and useful results.

For example, you would not be able to treat diabetes with a human, but you could treat diabetes with insulin isolated and purified into a concentration form away from a human. The ability to purify it into a concentrated pure sample allows for the new use. This, by definition, makes it a man-made product as it does not exist in nature in that isolated, purified and concentrated form.

To reiterate, an isolated version of a DNA molecule, for example, **DOES** require human manipulation for it to exist outside the body, and on this basis alone it does represent a product of mankind. Thus, an isolated DNA molecule is a manner of new manufacture and is patentable subject matter. Clearly, any isolated biological material that has undergone further manipulation beyond isolation is also a manner of new manufacture and is also patentable.

As discussed previously, the subject matter of a patent claim (e.g. an isolated gene) must still be both novel and inventive, according to standard patentability requirements for any invention.

Furthermore, any method of genetic testing/diagnosis should be patentable if it satisfies the general test in each jurisdiction for determining patentability of method claims.

In the United States, this is the "machine or transformation test" as outlined in the recent Bilski v. Kappos case.

In Australia, an inventive method/process qualifies as a manner of new manufacture if it satisfies "Morton's rules" as outlined in GEC's Application (1943) 60 RPC 1, and later confirmed in *National Research Development Corp* v Commissioner of Patents (1959). In more recent case law (*Grant v Commissioner of Patents* (2006), the Federal Court of Australia held that a method will only be patentable if it has a "physical aspect, being a concrete, tangible, physical, or observable effect or phenomenon".

Regardless, as long as method claims using isolated biological matter meet the specific requirements in each jurisdiction as exemplified above, such testing/diagnostic method claims should remain patentable.

As always, such claims will also need to ensure they satisfy standard novelty and inventiveness tests as well.

3. The flow-on effect to innovation will be severely compromised if the bill is passed.

The purpose of this bill is stated as "*to advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological materials, however made, that are identical or substantially identical to such materials as they exist in nature."*

As discussed above already, the isolated forms of biological material do not exist in nature.

Regardless, we are also of the opinion that the decision on gene patentability should reflect a balance of convenience for both the general public and the biotechnology industry.

The decision should allow companies to protect the valuable outcomes of their research and development investments where real innovation prevails. Indeed, a specific isolated DNA molecule of

interest can represent a valuable tool for applications not only for therapeutics (e.g. gene therapy), but also in a laboratory setting (e.g. PCR probes).

Without this level of protection, innovation in biotechnology will suffer. This will affect the development of new therapeutics, treatment methods and diagnostics available to us all including those used by doctors, clinicians and so forth. Patent protection for such innovation is in the best interest to both the public and the companies that develop new products.

Also, if patents are not available for such isolated genes for example, many new genetic innovations may be kept as trade secrets, and not become public information for use after the patent term expiry.

In the case of Myriad's genetic test, the details of the diagnostic test for breast cancer could have been kept secret for decades, much longer than the life of the ensuing patent. This would prevent others from gaining access to the testing method after the term of the patent.

A significant "pay-off" to the public regarding patent protection has always been that that a patent holder must fully disclose the invention and how it is performed. As such, after the patent expires, everyone can freely use the information at their disposal.

This is the corner-stone of the patent system. Without such a system in place, innovation will dwindle, and new innovation will, more often than not, be kept trade secrets – ultimately to the detriment of the public.

Conclusion:

The proposed bill should be fully rejected at least for the reasons outlined above.