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Ref:

The Executive Director
Australian Law Reform Commission
GPO Box 3708
SYDNEY NSW 2001

Dear Executive Director,

Re: Issues Paper 27 - Gene Patenting and Human Health

My interest in this ALRC issues paper (IP27) stems from a background of 20 years as a medical and biotechnology research scientist prior to becoming a lawyer. I have returned to science for short projects periodically and last year spent some months assisting a Monash University academic with her book on "research tools".

Consequently I have seen first hand the changes in how scientific research is conducted in Australian Universities, as it has progressed from mainly academic pursuits in the 1970's to mainly commercial ventures in the 2000's.

Observation suggests that most scientists see patents and IP generally as a necessary evil that they wish would simply go away because of the work involved and costs of administration, associated with licensing for example. All of which interferes with their actual job of doing science.

To my mind the proposed New Defences referred to in Chapter 14, if instigated with clarity and certainty, would be a workable means to overcome most of the difficulties addressed in IP27.

A major difficulty of the present system for research scientists is that a lot of basic science is simply trying new things to see if they work. So if a scientist hears/reads about a new gene fragment with an interesting function he may wish to try it in his cell line or expression system etc. just to see what happens, without necessarily any preconceived notion of the likely outcome. That approach is wholly scuttled when a licence has to be obtained and other formalities complied with. In the distant past he would simply obtain a small amount of the DNA from a colleague who had obtained it from someone else for a different purpose who had got it as a gift from the originator. Alternatively he would synthesize some from the published sequence. Nowadays infringement proceedings might follow such actions.

In my view a suitable “research defence” would allow the scientist to do the quick and dirty experiment before wasting time with licences etc.

It is all very well to talk about implied research exceptions to infringement but who will be the first to test it in court? It will generally only be when someone has achieved a valuable product resulting from their research that the original gene patent owner will be seeking to enforce his rights to share in the profits. Arguments supporting the suggested existing implied defence are not strong on my reading of it. Most significantly a judge is more likely to require a clear express provision where the need for research must have been in the minds of the legislature to the extent that they would have expressly stated such a obvious and important exception if it had been their intention.

“Use”, on any dictionary meaning, by a salaried research scientist whilst at work for an institution in the business of making money must surely be within the concept of exploit even if the aim were peer review and professional advancement.

No one is likely to want to test this implied exception. The proposed express defences would provide the certainty necessary for scientists (if not lawyers) who want to get on with doing science.

There are two issues that occur to me in this area. The first is whether the proposed defences could be very much strengthened to gain support of commercial partners by having within them provision for “see through” licensing in the event use of the patented gene product or research tool leads to a commercial product down the track.

It must be simple and easily administered to gain acceptance. One possibility is for departments and institutions to maintain annual registers of such research tools and patents used, possibly to be lodged with IP Australia or some other authority. Then, if a commercial product or patentable product is achieved at a future time the owner of the original gene product patent (or research tool) could still gain some benefit from their efforts without having to commence infringement proceedings.

So, for discussion purposes, my proposal would be a register of gene products and research tools used. If it is properly registered then the defence applies; if not then infringement proceedings are available. Where a commercial product results a royalty will be paid to the original patent owner. The amount of the royalty should be set by legislation (possibly pursuant to some sort of scale). Alternatively it could be determined by an independent body based on written submissions. Obviously some products would involve a greater “use” of the patented gene or research tool than others resulting in a greater royalty. The system would allow for use of more than one gene patent/tool.

In my view this or a similar type of scheme could achieve what is required with minimum administration. Failure to register simply returns to the present situation with infringement proceedings open, while registration allows unfettered use in research and some benefit to the originator upon success in commercialising the research.

An alternative to this type of scheme might be some sort of collecting society similar to those involved in copyright but that involves setting up an entirely new administration and I would not favour it over the first proposal.

The second and major issue requiring thought is that most research tools and gene patents used by Australian scientists originate from labs or institutes and companies from overseas (especially the USA). Also any commercial products developed will be aimed at overseas markets. Consequently some discussion of how defences in the Australian Patent Act could apply to these overseas gene patents and tools and whether the registration/royalty scheme outlined supra could apply to them.

These proposals should be extended to the other defences in Chapter 14.

Compulsory licence provisions do not seem to assist in these areas because, I think, of the legalities in pursuing them.

Yours sincerely,

I F Turnbull.