

## SUBMISSION TO ACIP ON 'PATENTS AND EXPERIMENTAL USE - OPTIONS PAPER' - 20 February, 2005.

This submission is made from the point of view that “ optimising the patent system to promote innovation and economic growth” are the primary aims of any amendments to the patent legislation relating to experimental use. Innovation will be inhibited where scientists and researchers can not get ready and immediate access to state of the art inventions and technology which they need to test new ideas and advance their knowledge.

Economic growth from innovation stems from out competing. Any delay in accessing new technology is anti-competitive. Having to find other methods or to skirt around an existing patent or restrictive licences are all anti-innovative and anti-competitive.

As I submitted previously (submission 36) my preference would be a registration or statutory licensing scheme that allowed uninhibited use of patented and patent applied for inventions with a clear proviso that if any commercial product or process resulted then the original patent owner could recover some sort of down stream royalties. Failing that type of approach I will comment on the four ACIP preferred options.

### Research Tools

The statement of page 6 of the Options Paper that patented research tools are excluded is a concern. My interpretation of "research tools" is that the term has a broad meaning and includes any substantial thing (including product or process) that is used for experimentation or research but is not intended to include things such as kits, software and the like which are available in the market (say from laboratory suppliers for example).

I note that other submissions also refer to and include research tools (see those on pp.21, 24 for example) as if they are a relevant part of this review process..

That statement needs to be substantially clarified because its effect might be to exclude any patented invention used for research or experimentation and then impliedly also exclude those that could be the subject of a patent application. I think that substantially reduces the subject matter of this review (on that definition to virtually nothing).

### The ACIP Preferred Options

#### Option B. No change.

The arguments supporting this status quo approach are, I think, flawed. ACIP has taken the view, based on a perceived lack of “significant objective/empirical evidence of a current significant market failure”, and that consequently the current provisions have therefore not stifled innovation. That is like saying there is no glass in the window because you or anybody else cannot see it. The nature of science, invention and discovery

is such that people are not able to say, in most cases, what they have not discovered or whether or not a different approach would have been more innovation or have led to a new invention. How do you know what new drug might have been isolated by a new method if that process is not available for use?

The real, if anecdotal, example of my own experience that I gave previously is a case in point. The aim was to isolate the sheep blowfly gene for a cuticle protein as a possible insecticide target. The approach adopted was to synthesise primers based on conserved sequences of similar proteins from other species, obtained from databases. DNA sequences were also obtained from other scientists but licensing agreements may have prevented commercialisation. The project was funded by grants and by a chemical company and had a clear commercial objective.

The best approach and the one most likely to have succeeded, would have been to obtain the DNA from other laboratories for other species of diptera (flies) or two synthesise DNA probes from *Drosophila* published sequences. The genome of that fly has been mapped and, I think, sequenced and is the subject of patent protection.

The outcome in the end was that after twelve months of work and after the money had run out, a gene had been isolated but it was not the one sought. The primers had worked well but were homologous to this other gene as well. Whether or not either of the two preferred approaches would have been successful can only be speculated on but it is very likely. Here the advancement of the project was restricted because of possible patent infringement and licensing concerns.

To do nothing assumes that Australian innovation is as good as it once was and is competitive. These things can be assessed empirically even using IP Australia databases. For example, are the numbers of patents granted (possibly even patent applications) for biotechnology inventions per year increasing at the same rates as in the United States or Japan or the European Union? The body of evidence that innovation is restricted by the current patent system, or could be improved by easier access to patented inventions for experimental use, should not be dismissed so readily. For example, the linking of NIH grants to research tool availability in the US is based on real anti-innovation claims and perceptions.

It is delays associated with seeking licences or trying to skirt around existing patents or by using other, less appropriate approaches, that are, in my opinion, significantly hampering competitive innovation. The idea of the experimental use exception is to create an environment where researchers can use whatever they can find to test ideas. Any restriction, whether perceived or real, is affecting innovation whether or not empirical evidence of that can be seen. I suspect that different questions need to be asked to obtain the evidence.

Most of the approaches suggested by AC IP appear to take the view that uncertainty in drafting legislation is all right because the courts can then interpret it. Surely that is

wrong. The idea is to get the legislation as clear and unambiguous as possible given the status of the area of law at the time, and then the courts interpret the unforeseen and new developments. Otherwise why not simply get rid of legislation drafters and rely on the judges entirely. How can lawyers and patent attorneys properly keep up with the law and effectively advise clients in that sort of uncertain environment?

### Options C7 and C8

These options do very little to assist innovation. They simply support the current patent system and use the distinction between experimenting "with" or "on" an invention to restrict its use to simply testing it. To stimulate innovation, which means to do new things not yet tried or even contemplated, the invention must be available for unrestricted experimentation. Remember Fleming and penicillin and the concept of thinking outside the square. All that is being done with these options is to allow experimentation in the very limited sense of testing for infringement and utility (i.e. testing the value and extent of the patent). There is nothing innovative about doing that because the invention already exists. For example, it would be all right to experiment on a disc drive to establish if it can be made to work at a higher rate but not to use it as the basis of a rotating flying device (flying saucer), without infringing. Where is the innovation in that?

Using the term "include" does not help as it is still restricted by statutory interpretation rules and inherent judicial conservatism. That is not what is required here to stimulate innovation. Innovation is contra to and opposed to uncertain legislative drafting and judicial conservatism.

These two options may assist the incrementalists and those who take cautious and tiny steps but do not assist the true innovators (I think you refer to "secondary inventions" in this context) who attempt to advance by giant leaps and who need to be permitted more latitude in experimentation, to use inventions for purposes they were not designed for. Biotechnology giant leaps abound in its methodology and include things like PCR, Southern blot, DNA sequencing and the like.

### Option C1

As a consequence of the aforesaid, of the four options preferred by ACIP I favour Option C1 but suggest some aids to interpretation are required to minimise uncertainty. Since the majority of submissions appear to support the idea that the current law includes such an experimental use exception anyway this option removes residual uncertainty and makes it clear to patent applicants and owners that their monopoly is subject to this limitation. However, in my view even more uncertainty could easily be removed by giving some guidance by attempting to define "experimentation" or "experimental use".

The dictionary meaning for "experimentation" should remain the basis but the definition might state that it, "(1) includes any use which is solely or mainly to test a new or novel

idea, procedure, process or product with the purpose of advancing the knowledge in the area, and (2) does not include any use made under this provision solely or mainly for the purpose of avoiding infringement of the original patent.

In my view any reference to commercial purpose should be avoided in this option because the only reason for having this discussion is the potential commercialisation of biotechnology innovation.

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