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<u>Submissio</u>	1 9 APR 2005 HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON SCIENCE & INNOVATION To the Standing Comm.	Submission No

Dear Committee members,

Although I realise you are after specific examples of successful innovations (to find out why they are successful where others fail), I have some general comments with regards to projects/ideas originating from Publicly-Funded Research Institutions (PFRI) and the general barriers they encounter on the road to commercialisation of research.

From the terms of reference

• Pathways to commercialisation

While some wonderful innovations are commercialised by private enterprise, the birthplace of such ideas is often the PFRIs, such as CSIRO, public hospitals, and universities.

The main challenge faced by these PFRIs to successfully commercialise inventions is the limited resources available for the protection of intellectual property (IP) rights, and the inability to successfully "develop" the IP to a significant "value-added" stage,

This means that in real terms the pathways to commercialisation are in fact limited to either out-right sale, licensing, or spin off from venture capital (VC) investment on the IP. Because, most of the time, projects/ideas from such institutions are at an early stage of development, the risk is high and the proposition not greatly appealing to potential business partners. If lucky enough to license or sell a piece of IP at this early/high risk stage, it does not generate significant revenue for the institution and its inventors.

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In the case of a spin-off from VC investment, the early stage proposition greatly dilutes ownership and diminishes the stake of the parent institution and its inventors. There is also a problem that, in some of the PFRIs (e.g. hospitals in the various Health Area Services), the institution is not allowed to hold shares in spin-off companies (the usual proposition in a spin off funded by VC investment), thereby further limiting the commercialisation pathway.

• Intellectual property and patents

The only way to have a valuable invention is through broad patent protection. Obtaining comprehensive patent protection around the world is very expensive. PFRIs can file provisional patent applications and, in some instances, go the International application (or Patent Co-operation Treaty - PCT) stage. At 30 months from the date of the original provisional application, if the patent is to progress, it must enter national phase applications in the various countries around the world where protection is sought. PFRIs usually do not have the funds to enter into national phase applications, therefore the IP does not progress, lapses, and the

innovation is lost without the commercial worth of the technology ever having a chance to be realised.

In Belgium, for example, the government has set up programs which assist inventors with patenting costs. Such programs would be extremely useful if implemented on a competitive basis here in Australia, where proposals could be submitted to an expert review panel who would assess the commercial potential of the invention and recommend funding of patenting costs in the nominated countries.

In terms of population, Australia is a small country. However, most PFRIs have their own Business Development/Business Liaison/Technology Transfer/ Commercialisation office. A lot of the work carried out by these offices is standard, e.g. preparation of various agreements (licenses, collaborative research, contract research, materials transfer, etc), researching markets, businesses, and competing products and/or inventions. Each of these offices often deals with their own attorneys and patent firms which charge premium rates for legal fees to prepare the various agreements.

It would be significantly more cost effective for the various PFRIs (and the government) to have access to a centralised resource, funded by the government, staffed with experience lawyers and people with the necessary legal/technology transfer skills to provide assistance in the preparation and review of such documents, at no cost to the PFRIs. The savings would be substantial.

• Skills and business knowledge

Working in IP commercialisation in PFRIs, it is my experience that the researchers that become inventors (hold patents) or entrepreneurs (involved in commercial ventures), communicate more easily with people who they see as their peer (someone who understands the pressures and constraints of a research environment). Therefore, it is advantageous for business development/technology transfer/commercialisation officers to have scientific qualifications. However, because these people possess scientific or technical qualifications, they are often not well prepared in business skills.

Specific business skills such as negotiation, structuring of technology deals, setting up commercial licenses, assessment of the most appropriate commercialisation pathway, valuation of IP, and dealing with VCs, although crucial to a successful business development/technology transfer/commercialisation office, are not readily available to its commercialisation specialists either due to a lack of exposure or a lack of opportunity to develop such skills.

A centralised resource providing these skills (and training in them) would be extremely useful.

## Capital and risk investment

The VC scene is very small in Australia. Although most of the VC firms say that there are no good projects for investment, the reality is that VCs in Australia are very risk-averse. Most research coming out of PFRIs is project-based, not product-based. That means that the research is early-stage and in need of significant development. While the VCs provide breathing room for a small number of fortunate commercial "ventures", they do not support the larger base of project IP - often centered on a

single project with limited scope of IP protection. This situation is unlikely to change. More support should be given to single projects with great commercial potential (a project that address an untapped market need without it turning into the formation of a company).

As an example, once some IP protection is sought (maybe at the level of an International or PCT application), biotech projects from PFRIs fall into a "development support gap" where most have exhausted the common funding sources (NH&MRC, ARC, BIF, etc...) and where modest amounts of R&D funds (maybe \$300-\$500K) would allow progression to that next stage of development where its value would be significantly increased while minimising some of the risk, and therefore, becoming a much more attractive proposition for licensing to a small biotech company who can progress it to the next stage. It is at this level of the small (yet financially secure) biotech company that support is necessary. Australia needs more small, dynamic, successful, and financially sound "product development" or "proof-of-concept", "preclinical/phase I and II clinical trial companies" that are willing to take on the risk and to significantly increase the value of research projects origination from PFRIs.

## • Research and market linkages

It is all about size. Regardless of the brilliance of the science behind a particular invention, small research groups without strategic market linkages will not be successful in the long term. The shortage of resources will impact the institution's ability to attract and maintain key staff. Creating both research and market linkages is paramount in the success of a project. Access to grants, laboratory facilities, assistance with the design, setup, and progression of trials (for example in health, clinical trials, etc) or proof of concept work (in engineering), expert business advice, etc, optimises the research effort, providing the inventors with scientific background the ability to access large "networks" which can support the commercialisation effort. The freedom of staff to move within these networks is also important. Programs which provide continued support structures to develop and maintain these linkages are necessary.

• Factors determining success

Although it is impossible to identify a given set of factors that assure the success of a given project/invention (if it were, all VC projects would succeed), it is not so difficult to identify the reasons for the failure of projects/inventions:

1-inability to access adequate resources to conduct product development,

2-inability to attract and maintain key staff,

3-reluctance to "let go" and transfer control to expert business advice by professionally-qualified people who have "been there, done that".

Successful ventures are innovative, flexible, and continually monitor performance.

• Strategies in other countries that may be of instruction to Australia

1- Concentration instead of dilution or duplication of resources (i.e. Medicon Valley in Scandinavia)

2- Mechanisms to significantly increase R&D investment as % of GDP (e.g. introduction of legislation enacting a percentage of profits from North Sea oil to be invested in R&D in Norway).

3- Financial support programs to cover IP protection (as in Belgium).

4- Changes in IP policy in PFRIs transferring IP rights to the inventors in the first instance. It is the current view that PFRIs which employ and provide facilities for research and development, own all of the IP of its employees. Most inventions arising from PFRIs often originate from a small group of inventors who have been with the organisation a long time and have well established and supported laboratories with no shortfall of post-graduate students, etc

Although possible, it is unlikely that a researcher who has been in a given organisation for a number of years and has developed and grown his/her own laboratories over those years would come up with an invention that they claim was developed on their own time and, therefore, that the IP belongs solely to the inventor.

By transferring the IP rights to the individual, it promotes innovation (as people feel they "own" their inventions). This is the model used in some of the most successful universities in the US (e.g. Stanford University).

The inventor will always require the use of the facilities and personnel in their own institutions (their labs, their students, etc) to develop the idea. The institution has the funds to protect the IP, while the individual doesn't. The "ownership" of the IP by the individual means little if they cannot exploit it. As well, there is a sense of loyalty to the institution and inventors will in most cases be happy to share the spoils of the invention.

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