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December 6, 2000

The Hon Dr Michael Wooldridge MP
Biotechnology Ministerial Council
Parliament House, Canberra ACT 2600

Dear Dr Wooldridge,

In my letter of 16 November, 2000 and attached submissions, I pointed out the strategic importance to both the Virtuous Cycle and to the Australian economy of allowing successful grant applicants to own their NHMRC derived IP rights.

In response, and on your behalf, I received yesterday a letter from the NHMRC Council stating that "With regard to IP ownership, NHMRC . . . is not in a position to assign IP ownership to the IP creators" (attached).

This statement is incorrect. I refer you to: McKeough J and Stewart A(1997) Intellectual Property in Australia. Butterworth 2nd Ed Chapter 13 "Ownership and Exploitation of Patent Rights." and the following points:

1. The researcher has the legal rights to the IP (unless he or she assigns those ownership rights away): "The general assumption made by the patents legislation is plainly that it is the inventor, the person responsible for supplying the spark of creativity, who 'owns' an invention in the sense of being prima facie entitled to patent it." pg 312 McKeough and Stewart (1997).

2. In contract law, and irrespective of what the research institution may claim about it being the "employer", it is NHMRC that enters into an employment contract with the researcher for the purpose of undertaking the NHMRC funded research proposal, at least in regard to IP rights:

- It is the NHMRC (on behalf of the Government), not the research institution, that invites the researchers (not research institutions) to write and submit research proposals.

- It is the NHMRC (not the research institution), that intends to use outcomes from the successful research proposal (to provide benefits to Australia) and this is illustrated by the NHMRC, not the research institution, defining the criteria for acceptance of the offer.

- The specific offer (research proposal) is the creation of the researcher, not the research institution, and the researcher, not the research institution, that writes this specific offer to address the specific criteria defined by NHMRC.

- It is the NHMRC (on behalf of the Government), not the research institution, that deliberates whether or not to accept the specific offer (the research proposal).

- It is the NHMRC (on behalf of the Government), not the research institution, that decides whether or not to accept the offer and provides the consideration (grant funds) thereby formalising the contract.

- It is the researcher who must sign the contract accepting the conditions of award and it is the researcher who is responsible for undertaking the research project as described in the offer document (research proposal).

The administering institution is just that - it administers the contract between the NHMRC and researchers on behalf of the researchers (and NHMRC).

3. As the "employer" of the researcher's services in a contractual sense, the NHMRC is entitled to become the legal owner of the research project's IP rights (unless they have been assigned away):

"In the absence of an express contractual provision dealing with the subject of ownership of inventions, the matter falls to be determined according to the terms implied by law into a contract of employment. . . . Thus, an employee who is hired 'to design or draft' can normally expect that anything they produce in the ordinary course of their work will be taken to be their employer's." pg 313 McKeough and Stewart (1997).

4. It follows, that the NHMRC (on behalf of the Government) **IS** in the position to assign the IP rights generated by the NHMRC grant. Accordingly, the Government has three primary options:

A. It can accept legal ownership of the researchers IP rights (and responsibility for IP management) and then transfer those rights (and IP management responsibility) to the institution administering the NHMRC grant funds. This is what the draft Guidelines formally commits the Government to do.

B. It can transfer those IP rights back to the inventors by first accepting then assigning those rights back to the inventor; or,

C. The NHMRC can formally renounce any rights to claim legal ownership of the IP rights generated by the researchers by including such a statement in the acceptance contract.

The argument for the Government enabling the researchers to own NHMRC derived IP rights is compelling and has been described in considerable detail in previous submissions.

The research institutions, on the other hand, have a strategic interest in supporting the NHMRC's draft Guidelines because it formally requires the researchers to "voluntarily" assign their NHMRC derived IP rights to the administering institution. This neutralises the risk that an entrepreneurial scientist may challenge in the courts their claim to be the "employer" in regard to NHMRC funded research projects.

For good strategic reasons, the Government should be wary about accepting the draft Guidelines in its current form. These reasons include:

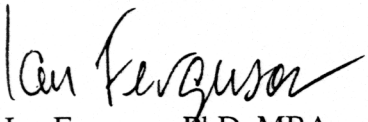
Firstly, a reasonable person will take the Guidelines not as guidelines but as Government policy. Consider the scenario where a legally aware entrepreneurial researcher has cautiously not assigned to the research institution his or her IP rights to an enabling technology that, for example, enables an effective treatment for Alzheimer's disease to be developed. An NHMRC grant is used to finance an aspect of its development and the entrepreneurial researcher independently files a patent and locates deep pocket investors to finance clinical trials and commercialisation. The multibillion dollar potential provides an incentive for the research institution to use the draft Guidelines to construct a legal argument that it is the research institution , not the entrepreneurial researcher and investor backers that are the legal owners of the patent. Thus, by condoning the shuttling of IP rights from inventor to research institution, the

draft Guidelines have the potential to involve the Government in an expensive and long drawn out battle in the courts.

Second, the draft Guidelines assumes that the administering institution is able to continue in its current role as owner and the manager of the NHMRC derived IP rights for at least the term of the NHMRC grant period. That in turn, is critically dependent on the research institution's ability to use employment contracts to capture and own IP rights from its "employees". This, in turn, is dependent on the researchers remaining ignorant about their rights and the true situation. Currently, most researchers naively assign away their IP rights to the research institution believing they have no other option. In exchange, however, many research institutions do not provide long term security of employment for researchers and so require a new employment contract with researcher to be negotiated and signed each year. The use of one year employment contracts to maintain control over IP rights is strategy that is weakly tenable at best: In less than a year, the fundamental nature of the IP relationships between researchers, research institutions and NHMRC can be transformed radically where researchers become aware of their true position and IP rights and cautiously refuse to assign away their NHMRC derived IP rights.

In conclusion, the NHMRC **is legally in a position to assign IP ownership to the IP creators**. The Government should note that the information in this letter and previous letters and submissions constitutes evidence that the Government was fully informed and aware of the possible legal and other consequences if it decides to accept the NHMRC draft Guidelines. The very fact that a reasonable legal argument can be constructed to challenge the conventional belief that it is the administering institution that is entitled to claim legal ownership of NHMRC derived IP rights raises the question: Might there be some real risks associated with accepting the NHMRC's draft Guidelines that require acquisition and transfer an inventor's IP rights? Will the Government create significant legal and political risk for itself or will it seize the opportunity to stimulate the "Virtuous Cycle"?

Yours sincerely,



Ian Ferguson PhD, MBA

cc. The Prime Minister, Mr John Howard
Professor E. McLachlan, Acting Chief Operating Officer, NHMRC Council

The Hon Dr Michael Wooldridge
Minister for Health and Aged Care

Dr I. Ferguson PhD, MBA
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Dear Dr Ferguson

Thank you for your letter of 6 December 2000 concerning intellectual property rights and National Health and Medical Research Council (NHMRC) research grants.

The award of NHMRC research grants is governed by the NHMRC Conditions of Award, details of which are available on the NHMRC web site. The Conditions of Award for all NHMRC research grants clearly state that a successful grant applicant is not employed by the NHMRC but by the administering institution nominated by the applicant. The concept that an administering institution and not the NHMRC is the employer of a successful grant applicant has been a cornerstone of the NHMRC research grants policy for several decades. It is the Commonwealth's contention that there is no contract whatsoever between the NHMRC and individual researchers who have been awarded an NHMRC research grant.

The NHMRC, like other funding bodies in Australia, such as the Australian Research Council, recognise the Common Law rights of administering institutions and universities as employers to the IP generated by their employees from grant funded research. Researchers and their administering institutions should have clear agreement in relation to IP rights prior to the commencement of research projects. The NHMRC views its role as a public research funder providing research funding to administering institutions, and expects the administering institutions to have IP policies in place.

In your response to the draft document, you have raised a number of legal issues and your concerns will be relayed to the appropriate bodies for further consideration.

I would like to thank you for your interest and input into this matter.

Yours sincerely

Dr Michael Wooldridge

06 FEB 2001

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Big science, little money

AUSTRALIAN SCIENCE IS WORLD-RENOWNED, SO WHY HAS IT PRODUCED SO FEW COMMERCIAL SUCCESSES? BY BETH QUINLIVAN

Although there have been a handful of successes, the commercialisation of university-developed technology in Australia has been a sorry tale. The biggest successes recently have been ResMed and Radiata Communications. ResMed, now capitalised at $2.5 billion and listed on stockmarkets in the United States and Australia, manufactures and sells sleep therapy products around the world. The first of these products was invented by Professor Colin Sullivan at Sydney University. And when the US computer networking giant Cisco Systems recently purchased Radiata in a $570-million deal, it was buying wireless technology developed by scientists David Skellern and Neil Weste at Macquarie University in Sydney.

There are also several emerging success stories, including Entigen (previously called eBioinformatics), an online scientific research system that has been developed by Professor Tim Littlejohn of Sydney University. The latest round of fund-raising, in December last year, brought in a Silicon Valley partner and valued the company at $75 million.

The telecommunications company Astracon, which recently raised $45 million and whose shareholders include Cisco and the US network management company Telcordia, evolved from the computer science faculty at the University of Queensland.

The Sydney company Proteome Systems, one of the international leaders in the field of protein studies, is commercialising work that was started by its scientists while they were employed at Macquarie University. Its fund raising in September last year valued the company at $170 million.

Some of the emerging success stories are found in the photonics industry (which includes laser, fibre optic and electro-optical technology). The Australian Photonics CRC (co-operative research centre), which is

PAUL ONE

based in Sydney, has already spun off 10 companies, all of them using different applications of the technology. The combined capital raisings of the spin-off companies have been more than $200 million and have attracted some big names in the telecommunications sector.

The Adelaide companies Bresagen (with a market capitalisation of $63 million) and GroPep (capitalised at $113 million) were developed from research carried out at the University of Adelaide — BresaGen with its work on stem cells and GroPep with its work on proteins that promote cell growth. Metabolic Pharmaceuticals, capitalised at $81 million, is developing compounds for treating obesity and diabetes, using research done at Monash University.

Melbourne IT was a well-publicised university commercialisation, but it cannot be called a success. It was floated last year by the commercial arm of the University of Melbourne, MEI International. MEI pocketed $79 million from the sale of 85% of the company in the float (it still holds 15%). Melbourne IT investors have watched the company's shares rise from an issue price of $2.20 to $17 in March last year before falling to about $1.10.

There are other commercial successes stemming from university research, but as a total picture, it is slim pickings — and local successes look modest when compared with the hundreds of health and technology companies that emerged from big US universities in the past decade.

The head of the PricewaterhouseCoopers emerging technologies practice in Australia, Andrew Sneddon, says: "There is some brilliant technology in universities and in the CRCs. There are lots more Radiatas out there — probably hundreds of technology opportunities — that haven't been commercialised.

"Australia's scientific calibre is recognised as being of a very high level. When you look around, there is some brilliant work being done. The photo voltaic [solar] cells are also brilliant science, although at this stage the commercial results aren't there. At the CRC that is doing the eye R&D, they are achieving amazing results with their new contact lenses, but again the commercial returns haven't yet come through.

"Commercially, the whole sector could do better. Science deserves more success through commercialisation than is happening at the moment."

MARK BRADLEY: Freeing research staff to chase backers is an interesting change in approach

Among its other achievements, the Co-operative Research Centre for Eye Research and Technology — known as the eye CRC — has developed a contact lens that people can leave in for extended periods, even while they sleep. It has also done substantial work on surgical projects, including implantable lenses that will last between five and 10 years, and a new synthetic polymer lens that would eliminate the need for reading glasses.

The head of the Rothschild Australia venture capital bioscience fund, Geoff Brooke, says: "Traditionally, university research was always licensed out to big companies, with the universities getting returns from royalties. In general, universities have made very little out of royalty income and almost none has been made in Australia.

"What happened in the United States, however, is that a number of the universities have made significant money by spinning their technology into small companies, taking an equity position. Some of those companies have become enormous, and universities including Stanford, MIT, Wharton and Pennsylvania have made millions of dollars."

There are success stories in the field of commercialising university research, but as a total picture, it is slim pickings.

The limited success of Australian universities in making money from their technology is a big loss for the universities and their staff. Under financial pressure after years of government funding cuts, they are missing out on millions of dollars of potential revenue.

But the failure to better integrate research and commerce has broader consequences: much of the critical work that will prevent Australia from drifting towards scientific and technological irrelevance is being done in universities and research institutes. Unless this work is nurtured and developed, there will be a hard-to-fill hole in Australia's future technological, scientific and financial base.

But why have more commercial successes not emerged from Australian universities over the past decade? Why is it, for example, that the largest medical school in the country — Melbourne University — has not produced a series of biotechnology and health-related commercial ventures? Prana Biotechnology, a $12-million company researching Alzheimer's disease, is the only listed biotechnology company to have come from Melbourne University in the past couple of years.

Many explanations have been offered for the small number of successful university commercialisations, including the lack of very early stage investment capital and the lack of government support in the form of tax incentives. Other reasons include a lack of expertise in the management of emerging businesses, and the stretched resources in universities, which results in frustrated scientists moving overseas or into other fields.

But the universities also have to carry a substantial share of the responsibility for the relatively small number of commercial successes that have been born in their laboratories. Most financiers and investors who have tried to commercialise university research — even small projects — have stories about deals that have fallen apart or have been difficult to consummate because of a lack of experience, lack of reasonable decision processes, extensive delays, ineptitude or plain greed on the part of the universities.

One example of such a failure was the development of a rapid diagnostic test for the all-pervasive golden staph bacterium, which is a big problem for hospitals and their patients. A university scientist was working on a project that she believed could predict the development of golden staph. A preliminary patent was granted, and although the university agreed to help promote the project, it was aiming for investors who were not prepared to take the high risk of early-stage research. After a frustrating period trying to gain some support, the scientist took another job and the patent eventually lapsed.

Brooke believes that universities in Australia have become better at developing their technology. "They tend not to be quite as suspicious or nervous about doing deals with people from the financial side," he says. "Still, it all takes a long time — reassuring them, explaining, for example, why they should not have two board seats, and so on."

The Rothschild fund was an early investor in Entigen. Brooke says: "At Sydney University, getting the original approval for eBioinformatics was a difficult process but

WHO SHARES THE KNOWLEDGE?

Universities' commercial divisions and intellectual-property policies

UNIVERSITY	OWNERSHIP OF UNIVERSITY-FUNDED RESEARCH	ROYALTIES: DISTRIBUTION OF NET PROCEEDS	COMMERCIAL DIVISION	CONTACT
Adelaide	University	Inventor 33.3%, university 33.3%, Luminis 33.3%	Luminis	www.luminis.com.au
Australian National (Canberra)	University	More than $100,000: inventor 35%, Anutech 15%, uni department 30%, university 20%	Anutech	www.anutech.com.au
Macquarie (Sydney)	University	Inventor 50%, university 25%, faculty 10%, Macquarie Research 15%	Macquarie Research	www.mq.edu.au
Melbourne	Academic staff	More than $50,000: inventor and commercial partner 95%, university 5% More than $1 million: inventor and commercial partner 85%, university 15%	MEI International	www.mei.unimelb.edu.au
Monash (Melbourne)	University	Inventor 33.3%, university 33.3%, faculty 33.3%	Montech	www.montech.com.au
New South Wales	University	Inventor 33.3%, university 33.3%, Unisearch 33.3%	Unisearch	www.unisearch.com.au
Sydney	University	Inventor 33.3%, university 66.6%	No separate company	www.usyd.com.au

SOURCE: BRW

But it isn't just the money. There is not really such a shortage of investment funds. Finding the right people to put the deals together and run the companies is a more difficult proposition than raising the money.

LES FALLICK

now it is a good relationship and the university has done well out of it. They sold the rights to the technology in return for 40% equity in the company; after recent fund-raisings, that is down to about 10%. But the current capitalisation of Entigen is $75 million, so the university is sitting on a $8-million equity position, which could be substantially more in an IPO [initial public offering]."

Negotiating licensing arrangements with universities is a notoriously long process. Mark Bradley runs a biotechnology incubator business called Xcelerator. It is funded privately, and in return for equity in small biotechnology ventures, it provides scientists with laboratory space, advice and support.

One of the companies it has invested in is BTF. The two BTF scientists previously worked at Macquarie University, where they developed a series of tests to accurately measure giardia and cryptosporidium levels in water. Having found a market for their products during Sydney's water crises three years ago, they decided to leave the university and develop a business. Bradley says it was nearly a year before they could settle the licensing and royalty arrangements with Macquarie University.

Sneddon says that to commercialise something effectively, it is essential to get the intellectual property out of a CRC or university and into a legal vehicle. "But universities can make it difficult to get the intellectual property into a company; a significant number have been very reluctant to take an equity position for reasons of risk management. They prefer to hold on to the intellectual property and receive a royalty stream."

When universities have taken equity in a company that evolved from their research, they have often done well financially. Montech, the commercial operation of Monash University, has a 25% share in Metabolic Pharmaceuticals, which is worth $21 million. Luminis, the commercial arm of the University of Adelaide, owns 18% of GroPep, which is worth $21 million. The 22% stake in Bresagen that Luminis owns is worth $13.4 million.

But success is not assured. ANU has a 2% stake in one of last year's biotech floats, Pi2. This company was looking at treatments for venous leg ulcers, but the results of recent clinical trials have not been encouraging. Its share price is about 10¢, compared with 50¢ in the float.

The question of intellectual property is under review. All universities have a policy on intellectual property, and in almost every case, the university holds the intellectual property. If research or an invention that has been developed by academic staff at the university is commercialised, the university will take a share of the royalties or, increasingly, it will take equity in the resultant business.

Last year, Melbourne University took a radical step with its intellectual property. University staff are now able to have full ownership of intellectual property, but the university gets royalties if the commercial process is successful. Bradley says: "They are basically saying 'Get on with it yourself'. If you can find some financial backers for the project, then go and do it, and the university will get royalties later. It is an interesting change in approach."

ResMed inventor Colin Sullivan, who remains head of the sleep-disorders unit at Sydney University, believes that Melbourne University has the right approach. "What they are saying to their staff is that if they can do something, they can have a go, but then if it works out, give something back to the university at a later date," he says. "Patents mean a lot but sometimes they don't mean as much as people think they do. The biggest part of the intellectual property is in the intellectual know-how and expertise of the people. Where institutions want to tie up all the potential from a venture, they can end up destroying it."

ResMed is a success, but it was anything

A SHARE OF THE ACTION

How universities are backing their research to market

UNIVERSITY	COMPANIES	CURRENT COMPANY VALUE ($m)	UNIVERSITY'S SHAREHOLDING (%)
Adelaide	GroPep	113.6	18
	Bresagen	63.3	22
Australian National	Biotron	12.1	7
	Pi2	4.3	2
	Praxis	3.1	2
Macquarie	Radiata	570*	Licence income
Melbourne	Melbourne IT	49.5	15
	Prana Biotech	12.5	15
Monash	Metabolic	81.4	25
Sydney	Entigen	75	8
	ResMed	2,500	Licence income

* Sale price

SOURCE: BRW

but an overnight sensation. Sullivan believes that attitudes in universities have changed in the past decade. Twenty years ago, when he was looking for support for the production of his pressurised sleep devices, people at Sydney University thought it was a joke. "Active disinterest was the general approach, but universities now are more active in assisting the process," he says. "The universities are going through a learning phase. People understand the importance of commercial results, but at the moment they are still looking for the best ways of making the system work." Sullivan believes that a lack of investment money for developing research being done in universities is still a big problem.

One of the issues in the debate on commercialisation is the effectiveness of the commercial divisions that Australian universities have set up during the past 10 years. All universities have some form of commercial and consulting division, which usually oversees specialist consulting services undertaken by staff and in many cases controls initial commercialisation of research undertaken in the university.

The commercial operations of the universities will be under the microscope over the next few months as a Senate inquiry into higher education begins (submissions are due by the end of March). The inquiry was forced on the Howard Government by the Australian Labor Party and the Australian Democrats, following the New South Wales auditor-general's report last year on university commercial operations.

The report revealed big losses by some universities on their commercial forays, and it showed that substantial amounts of money had been siphoned from university funds to cover the losses. For example, last year Anutech, the commercial arm of Australian National University, received an allocation of $4.7 million to help cover a $6-million loss incurred on its commercial activities.

Most universities have set up limited liability companies. In some cases, an invention or research developed in the university must be offered first to these

PAUL JONES

ANDREW SNEDDON: "There is some brilliant technology in universities and in the CRCs"

companies. For example, the Unisearch arm of the University of NSW gets first bite at any commercialisation of the university's research. Macquarie University must offer first option on any commercial venture to Macquarie Research.

However, the University of Melbourne, as part of its new approach to commercialisation, does not require staff to give MEI first option on the commercial development of research. The chief executive of MEI, David Lloyd, says MEI previously insisted on owning 35% of everything developed by the university. "We ended up with lots of 35% stakes in companies not worth very much. It is now a free market here, which is much better."

The head of private equity at the Gresham investment group, Les Fallick, believes that universities have made some basic mistakes in attempting to commercialise research. Often the staff of the universities' commercial divisions do not come from the corporate sector and do not have the necessary experience in financing or management that would help the developing venture get off the ground.

"But it isn't just the money," Fallick says. "There is not really such a shortage of investment funds. Finding the right people to put the deals together and run the companies is a more difficult proposition than raising the money."

As part of its recent innovation statement, the Howard Government announced two new funds to help take projects to a stage at which they could attract venture capital. According to the statement, the pre-seed fund will provide $78.7 million over five years, starting in 2001-02. It will be specifically aimed at universities and public sector research agencies. No further details were provided. The Government has also added $20 million to the biotechnology innovation fund, to provide early-stage research funds.

Several universities have also increased the funds available for investment in home-grown technology. Unisearch now has a $10-million pool, and the universities of Melbourne and Queensland have recently contributed $10 million each to a seed-capital fund, Uniseed, which will also provide early-stage funds.

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June 7, 2000

Professor Ron Johnston
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Dear Prof Johnston,

I am writing in response to the request for submissions from researchers which have an interest in commercialising research (email from Dr P Carron - May 31).

Please find attached an analysis which identifies a number of impediments to development of Australia's knowledge based industries. The analysis concludes with an adminstratively simple strategy to both stimulate commercialisation of NHMRC funded biomedical research and facilitate emergence of globally competitive biomedical industries for Australia.

The analysis was sent, in confidence, to the NHMRC Executive Council in September. An unmodified copy of that document is attached.

Yours sincerely,

Ian Ferguson PhD MBA

cc. Dr Mark Matthews, Policy Intellegence Pty Ltd
PO Box 3725, Manuka, ACT 2603

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September 10, 1999

Professor Richard Larkins
Chairman
Executive Council, NHMRC

Dear Prof Larkins,

Re: Facilitating the growth of knowledge based biomedical industries

I am writing directly to you, in confidence, because the attached information may be regarded as politically sensitive.

The Federal Government has signalled serious interest in developing a national intellectual property strategy which might be used to underpin the development of Australia's own globally competitive knowledge based industries. This interest has been signalled by requests for submissions to the Innovation Summit, Intellectual Property & Competition Review, as well as feedback regarding proposed changes to the NHMRC.

Attached is an analysis which identifies a number of impediments to development of Australia's knowledge based industries. A key finding of this analysis is that: the educational/health and the commercial industry sectors of the economy are in active competition for the same intellectual capital and intellectual property but the playing field is not level. This competition is a result of convergence in the activities undertaken within the universities and research institutes and that undertaken within the commercial industry sector.

This analysis concludes with a suggested strategy which is administratively simple to implement, but transformational in effect. This strategy aims to enable Australia to leverage off its strength in biomedical research and create globally competitive biomedical industries without any increase in Federal Government spending.

Key to this suggested strategy is a different policy regarding the allocation of intellectual property rights associated with federal government grants. As any redistribution will result in winners and losers, and the losers may be politically formidable, the NHMRC and Federal Government may consider it to be politically wise to internally investigate the suggested strategy in confidence, before it is publicly disclosed.

This analysis might be forwarded to the Innovation Summit and Intellectual Property and Competition Review in response to their requests for submissions. If you have alternative suggestions, please contact me.

I trust that this analysis and suggested strategy may be of use to the NHMRC and Federal Government in ensuring that Australia develops its own globally competitive national intellectual property strategy and knowledge based industries.

Yours sincerely,

Ian Ferguson PhD MBA

cc. Prof W Anderson, Chairman of Research Committee
Mr Bob Well, Secretary

IN-CONFIDENCE

FACILITATING THE GROWTH OF AUSTRALIAN KNOWLEDGE BASED BIOMEDICAL INDUSTRIES: IMPEDIMENTS TO GROWTH & SUGGESTED CHANGES

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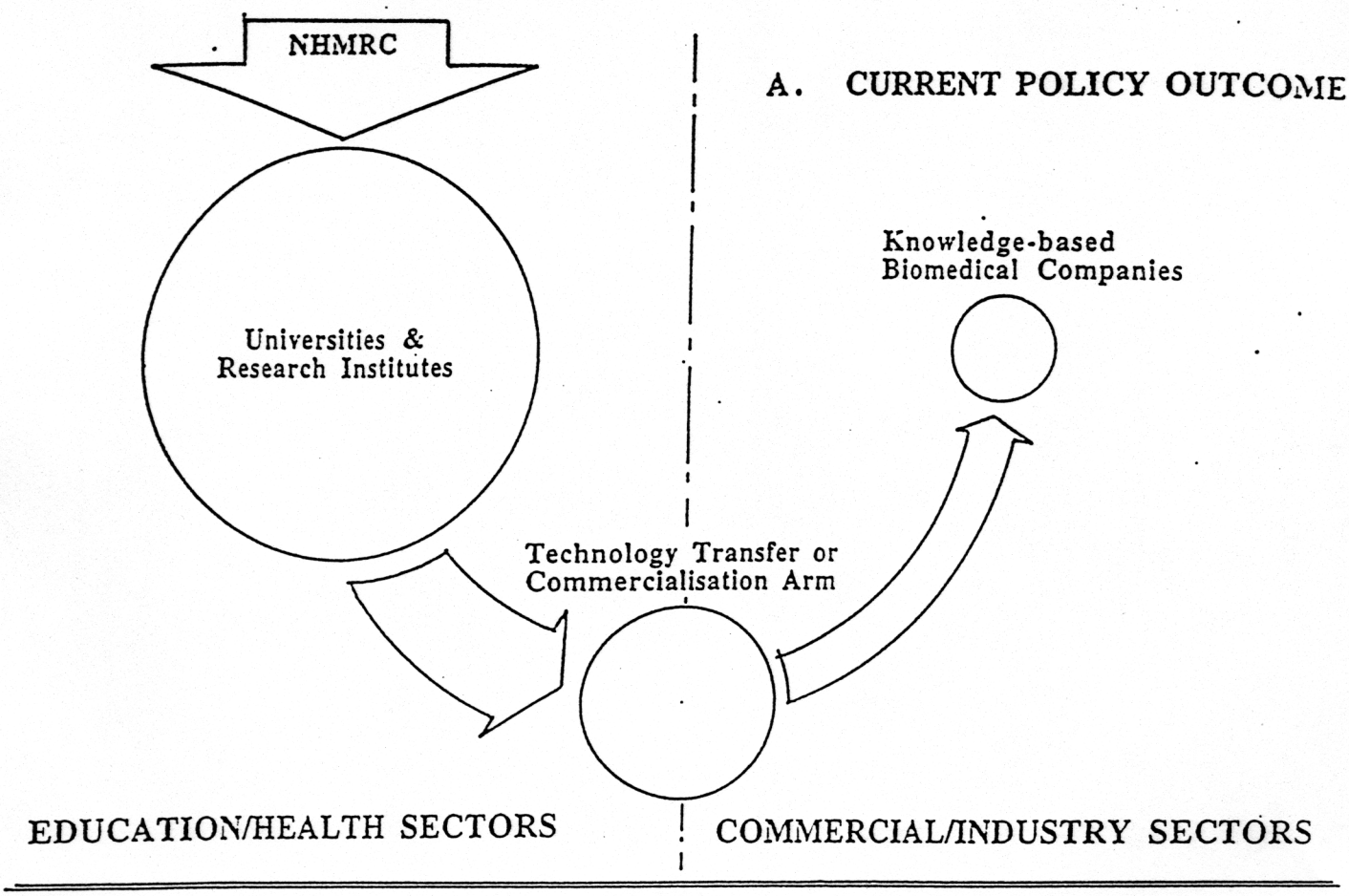
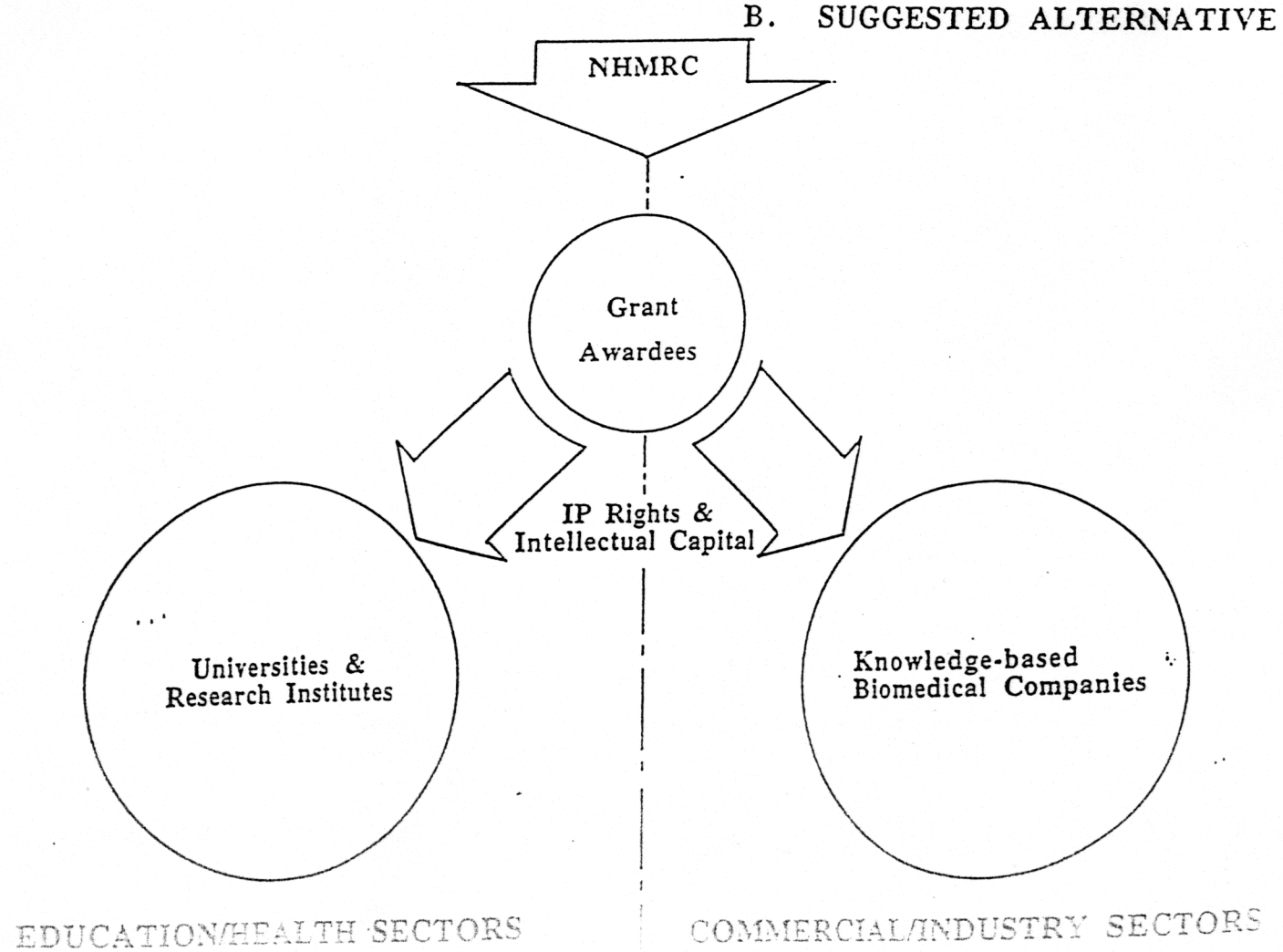
FLOW OF MAJOR ECONOMIC BENEFITS FROM THE NHMRC





EXECUTIVE SUMMARY

Australia has a strong and globally competitive biomedical research sector but has not levered this strength into a similarly robust biomedical industry. This analysis identifies a number of possible contributing factors. These include:

o Australia's education/health sectors and industry sectors are in active competition for the same intellectual resources. This is the result of continued convergence in the innovation focused activities of researchers in universities and research institutions and that required for growth of local knowledge based industries.

o The playing field is not level in this competition. For example, the tax payer subsidises the direct cost of activities of researchers in universities and research institutions by providing them with grants from bodies such as the NHMRC. The level of subsidy available, for example, to local biopharmaceutical industry in the form of START and similar industry support grants, is only half that amount and dependent on availability of risk capital.

o The current structure rewards universities and research institutions for retaining ownership and control over the key intellectual resources needed to seed new ventures. To provide security for investors, transfer of intellectual property and intellectual capital from the education/health sectors into the commercial industry sectors is required to attract risk capital.

o Under the current system, NHMRC funds are used by universities and research institutions to finance their position in the economy as employers of Australia's intellectual capital in the biomedical area and are rewarded with assignment of intellectual property rights. This rewards the administering institution, rather than the scientist, for generating commercially valuable intellectual property. Consequently, scientists do not receive the salary signals needed to encourage research aimed as generating commercially valuable intellectual property for Australia.

o The doubling of the NHMRC budget under the current system will preferentially benefit institutions in the education/health sector of the economy. This will amplify the competitive advantage of this sector of the economy at the expense of the industry sector. That is, it will be more difficult, rather than easier, for new biomedical focused industries to emerge.

This analysis concludes with two suggestions which are administratively simple for the NHMRC to implement:

I. Assign intellectual property rights associated with the NHMRC grant to the grant awardee rather than the administering institution on the condition that these IP rights remain within Australia.

II. Award NHMRC grants to successful applicants rather that the administrative body and ask applicants to nominate the entity who will administer the grant on behalf of the successful applicant.

These changes are tacit recognition that it is the knowledge worker, not the administering institution, who controls the process for generating commercially valuable intellectual property for Australia. Together, the suggested changes: (i) empower these knowledge workers to catalyse a metamorphosis of Australia's current strength in biomedical research into vibrant and dynamic globally competitive industries; and, (ii) removes current impediments to the emergence of these biomedical industries by leveling the competitive playing field, stimulating mobility of intellectual capital and transfer of IP and compensating scientists who work towards developing new biomedical industries for Australia.

CONTENTS

INTRODUCTION

Statements issued by Treasury and the Federal Government signal that it expects the doubling of the NHMRC budget to lead to parallel growth in Australia's biomedically focused knowledge based industries. This requires growth in the amount of intellectual property (IP) and intellectual capital in the commercial industry sector.

NHMRC funds are being used increasingly to finance biomedical research projects with potential to generate IP and commercial outcomes which, under the current system, vest to the education/health sector. For the Federal Government to realise its expectation, growth of biomedically focused knowledge based industries will be dependent on unencumbered movement of IP and intellectual capital from the educational/health sectors into the commercial sector.

A strategic analysis is required to identify the major impediments to the transfer of IP and capital from the education/health sectors into an emerging and rapidly growing biomedical industry. This paper identifies some of these impediments for internal discussion by the NHMRC.

Convergence as a Driving Force

Convergence in the activities of scientists in the educational/health sectors and the commercial sectors is being driven by their use of common technologies (e.g., molecular biology based technologies). Where the outcomes of these activities may be patented (e.g., discovery of new genes, therapeutic products or methods of treatment), IP and commercial value can be created without regard to whether this activity occurred in a commercial setting or within a research institution or university.

As a result of convergence, the educational/health sector is entering into competition with the commercial sector in the area of creation and commercial exploitation of IP. Pending increases in the flow of NHMRC derived funds into the educational/health sector can be expected to exacerbate this situation.

Australia's intellectual capital in the biomedical area

Historically, the relative absence of alternative employment opportunities in Australian industry has resulted in the vast bulk of Australia's biomedically focused intellectual capital being locked in the educational/health sector. Employing institutions are rewarded for developing policies and practices which are designed to attract and retain this intellectual capital by, for example, being able to extract on-costs from the NHMRC grants paid to their employees.

Convergence in the innovation focused activities of researchers in universities and research institutions and scientists in local knowledge based industries means that Australia's education/health and industry sectors are in active competition for the same intellectual capital as a source of IP. Emergence and growth of Australia's biomedically focused innovation based industries will be require a net transfer intellectual capital and IP from the education/health sector into the industry sector. Factors which act to impede this movement need to be identified.

Factors influencing growth of biomedical focused innovation based industry

Growth of a biomedically focused innovation industry is absolutely dependent on intellectual resources being present in the industry sector. Key factors which will influence the relative growth rates of the biomedically focused innovation based industries compared with that of educational/health sector include:

1. Innovative activity: The relative level of government derived subsidies paid to entities in the education/health sector vs those paid in the commercial sector of the economy for the purpose of undertaking innovation focused projects.

2. Commercialisation of Innovations: The relative level of government derived subsidies paid to entities in the education/health sector vs those paid in the commercial sector of the economy for the purpose of commercialising innovations.

3. Management of the Innovation Process: the relative level of investment made by entities in the education/health sector vs those paid in the commercial sector of the economy for the purpose of managing the innovation process to maximise potential commercial return.

4. Transfer of IP: Impediments to the transfer of IP from the education/health sector into the commercial sector to seed new ventures.

5. IP Creation Process: Impediments to process for creating commercially valuable IP in the education/health sector for subsequent transfer into the commercial sector.

6. Movement of Intellectual Capital: Impediments to the movement of intellectual capital from the education/health sectors into the commercial sector.

7. Career Opportunities: Relative availability of opportunities for knowledge workers to be retained in the education/heath sectors or in the commercial industry sectors to pursue careers.

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STRATEGIC ANALYSIS OF FACTORS INFLUENCING INDUSTRY GROWTH

1. <u>Innovative activity:</u> The relative level of government derived subsidies paid to entities in the education/health sector vs those paid in the commercial sector of the economy for the purpose of undertaking innovation focused projects.

The tax payer provides subsidies in the form of grants to employing institutions to accumulate knowledge workers.

Employers in the education/health receive subsidies for employing biomedical researchers. These subsidies take the form of project on-costs associated with grants from bodies such as the NHMRC. To attract this subsidy, the university or research institution has to: (i) retain ownership and control over the knowledge workers who are able to successfully secure these grants; and, (ii) bear the costs associated with infrastructural support. These grants cover the full cost of undertaking the high risk research project.

Employers of knowledge workers in the commercial industry sector receive their subsidies in the form of matching grants from bodies such as the IR&D board. The amount of tax-payer funds available to subsidise similar activities by researchers in industry is approximately half the amount available to employers in the education/health sector.

Analysis

The costs of: (i) retaining ownership and control over the knowledge workers who are able to successfully secure these grants; and, (ii) bearing the costs associated with infrastructural support are essentially the same for both the commercial entity and the university or research institution. However, to attract the tax-payer funded subsidy in the form of, for example, matching START and similar industry support grants, the commercial entity has the additional hurdle of having to also locate investors who are willing to place their cash at high risk to finance the R&D project.

Employers in the health/education sector receive double the tax-payer funded subsidies to support the activities of the knowledge workers.

2. <u>Commercialisation of Innovations:</u> The relative level of government derived subsidies paid to entities in the education/health sector vs those paid in the commercial sector of the economy for the purpose of commercialising innovations.

The NHMRC assigns all the IP rights to the university or research institution administering the grants. By so doing, tax payer funds are being used to subsidise the commercial actitivies of the education/health sector; these commercial benefits subsidise the technology transfer and commercialisation arms attached to the universities and research institutions.

Analysis

Local innovation focused commercial enterprises are at a competitive disadvantage to the technology transfer and commercialisation arms of universities and research institutions. Unlike the local innovation focused commercial enterprises, the commercialisation arms of universities and research institutions do not have to invest their own funds in high risk innovative activities to obtain IP rights to commercialise.

3. <u>Management of the Innovation Process:</u> The relative level of investment made by entities in the education/health sector vs those paid in the commercial sector of the economy for the purpose of managing the innovation process to maximise potential commercial return.

The commercialisation arm owns a monopoly on the IP outcomes of the scientists in that research institution or university and consequently does not have to invest management time and resources in the innovation process to generate windfall profits. In contrast with their counterparts in industry, the commercialisation arms of universities and research institutions typically are not involved actively in assisting individual researchers in either: (i) strategically selecting research projects to maximise potential to generate commercially valuable IP; or, (ii) efficiently design and managing the research project to minimise the risks associated with generating commercially valuable IP.

Analysis

In essence, the commercialisation arm of the research institution or university is built upon a model which assumes that commercially valuable IP will be generated as a natural outcome of investment in basic research. Subsidies in the form of assignment of IP rights to the administering institution means that commercialisation arms of universities/research institutions need not invest in improving the efficiency of the innovation process to exploit its intellectual capital monopoly.

This model contrasts with the industry proven model which assumes that investment in basic research generates only opportunities to create commercially valuable IP. Accordingly, industry bears the cost of employing commercially focused managers or scientists to identify, develop and exploit these opportunities.

4. <u>Transfer of IP:</u> Impediments to the transfer of IP from the education/health sector into the commercial sector to seed new ventures.

The commercialisation arms of universities/research institutions have a commercial responsibility to maximise the return they can generate from selling or licensing the IP generated by the scientists employed by the university/research institution.

Even where local industry has first right of refusal to access IP generated locally, the impost of a commercialisation arm between the innovator and local industry adds significantly to the cost of local industry gaining access to commercially valuable IP within the educational/health sector.

Analysis

Parallel growth of investment in biomedically focused knowledge based industries is dependent on at least parallel growth in the value of IP assets owned by industry. This is because investors will not provide risk capital investment unless those funds can be secured against ownership of IP of at least equivalent value.

The commercialisation arms of universities and research institutions have a commercial responsibility to maximise the returns they can generate from the IP rights flowing to them. The resulting limitation on the transfer of IP from the educational/health sector into the commercial sector must act as a brake on emergence and growth of knowledge based biomedical industries in Australia.

5. <u>IP Creation Process:</u> Impediments to process for creating commercially valuable IP in the education/health sector for subsequent transfer into the commercial sector.

Rapid growth of local knowledge based industries will require a dramatic increase in the amount of entrepreneurial activity leading to establishment of start-up companies. A key to establishment of an innovation focused businesses is the transfer of IP rights into the start-up company vehicle together with intellectual capital in the form of an entrepreneurial researcher. The entrepreneur is then in a position to exchange equity in the company vehicle owning the IP rights for the risk capital needed to start business operations.

This is situation in which the university or research insitution are in a position to benefit. The entrepreneurial scientist knows that the university or research institution must receive compensation (e.g., cash payment and/or equity share) for providing the research facilities used in generating the IP. As the university/research institution provides clear cost information for the use of its facilities (e.g., overhead charge as a multiple of direct project expenses), the entreprenuerial scientist is in a position to negotiate for access to the research facilities.

Currently, scientists with entrepreneurial drive and capable of generating the commercially valuable IP rights are locked in the health/education sector and know themselves to be in a Catch 22 position. They know they can use grants from funding bodies such as the NHMRC to generate the commercially valuable IP they need to seed new ventures. However, they also know that if they generate the required IP, then ownership and control of that IP will vest to the research institution or university. This substantially diminishing any incentives that the entrepreneur may have to create a spin-off company.

Entrepreneurial researchers know this to be an economic situation which is difficult to justify. If s/he were employed within a commercial organisation, it would be that commercial organisation which would be providing the R&D project funds and thus have a legal claim over the IP outcomes. However, within the research institution or university, the entrepreneurial researcher must secure their own funds in the form of grants to finance their own research project but then observe that s/he is denied a legal claim over the IP outcomes.

This contrasts to the situation faced by students undertaking innovation focused research as a part of the course of study. They have a legal claim over the IP generated as a result. Indeed, there are many examples of students graduating from Stafford University and using their personal IP in starting new Silicon Valley based ventures (e.g., Stafford University Network (SUN) Microsystems).

Analysis

Currently, tax payer derived funds in the form of NHMRC and other grants are artificially separated into a current value component (actual dollars) and a future value component (the IP rights) for award to different entities.

The NHMRC awardee is denied direct ownership of the future value component of the grant. Consequently, the NHMRC awardee is not encouraged to think entrepreneurially because s/he does not consider strongly issues such as: (i) how to identify opportunities to generate commercially valuable IP; and, (ii) how to manage activities to realise the commercial potential of the resulting IP.

6. <u>Movement of Intellectual Capital:</u> Impediments to the movement of intellectual capital from the education/health sectors into the commercial sector.

A key limiting resource in knowledge based industry is availability of intellectual capital needed for growth - (i) researchers and innovators able to generate IP with commercial potential; and, (ii) management able to realise that commercial potential and generate tangible benefits.

As the biomedical researchers are the source of the IP which will drive growth of Australia's biomedically focused industries, it is essential that they receive salary signals which will encourage development of an entrepreneurial culture. Under the current NHMRC salary system, knowledge workers are not compensated for generating commercially valuable IP. That component of their economic worth is assigned to the university/research institute administering their grant. Instead, the knowledge worker receives direct compensation appropriate for their level of technical and scientific managerial expertise.

In industry, researchers who develop commercially valuable IP receive compensation in the form of options to purchase equity in the company to which the IP is assigned. Such a system is not practical where the employer is a university or research institution. A different system is needed which compensates and hence provides incentives to researchers for developing commercially valuable IP.

7. <u>Career Opportunities:</u> Relative availability of opportunities for knowledge workers to be retained in the education/heath sectors or in the commercial industry sectors to pursue careers.

Australia has developed a strength in biomedical research in part as a result of a NHMRC supported career path. Historically, career support was available primarily to support activities in academic or basic research undertaken in university or research institution. While convergence has resulting in similar activities being undertaken in an industry setting, there remains effectively no NHMRC support for pursing a career path with an industry focus. This deprives industry of an opportunity to shape the career aspirations of emerging talent.

Availability of NHMRC career support within but not outside of educational/health sectors signals clearly to the young biomedical researcher that there are few viable career options in industry. Such perceptions coupled with limited employment opportunities in local industry can be expected to influence young biomedical researchers in major career choices such as whether to pursue a career in Australia or overseas.

Analysis

NHMRC career support provides the education/health sector with opportunities to develop intellectual capital with expertise in generating new knowledge. Provision of intellectual capital with ability to generate new knowledge adds value to universities by enhancing their core responsiblity for transfer of knowledge (education/training). Provision of intellectual capital with ability to generate new knowledge adds value to research institutes by lowering the costs of the institute developing that new knowledge itself.

By having access to NHMRC career support program, the education/health sector has a competitive advantage over the sector: The option currently does not exist for enabling NHMRC career support to directly add value to core industry activities.

8. Summary of Analysis

1. Compared with companies in the biomedical industry which can access subsidies of up to half the project expenses, e.g., in the form of START grants, employers in the education/health sector can receive subsidies of up to all the direct project expenses (excluding overheads), eg., in the form of NHMRC grants.

This results in companies in the biomedical industry sector being at a competitive disadvantage to universities and research institutions in the education/health sector. This competitive disadvantage can be expected to increase as funds from the doubling of the NHMRC budget flows preferentially into the health/education sector.

2. Compared with companies in the biomedical industry which have to bear the cost of at least half the expenses involved in generating a return from commercially valuable IP, employers in the education/health sector do not have to bear any direct cost to obtain commercially valuable IP because the IP rights are assigned directly to the entity administering the grant.

This results in the commercialisation arms of universities and research institutes having a cost structure which is subsidised by the tax payer and thus having a competitive advantage over companies in the biomedical industry. This competitive disadvantage can be expected to increase as funds from the doubling of the NHMRC budget flows preferentially into the health/education sector.

3. The commercialisation arm of the research institution or university and the commercial entity in the industry sector use different models to generate and commercially exploit IP. The university commercialisation arm does not need to invest in managing the innovation process to exploit its monopoly and generate commercialisable IP. This contrasts with the approach used in industry which involves significant investment at the levels of identification of strategic opportunities, project design and management used to manage the innovation process.

4. The assignment of IP rights to the institution administering the NHMRC grant deprives the innovator of the incentive needed to consider the commercial outcomes of the proposed research. Consequently, the innovator may be indifferent to whether or not the proposed research has clear commercial objectives.

5. The assignment of IP rights to the institution administering the NHMRC grant short-circuits the company spin-off process by removing from a position of control, the key individual needed to seed the venture - the entrepreneurially driven scientist.

6. Currently biomedical researchers receive a base salary which compensates them for technical and scientific skills but are denied a salary component which rewards performance in the area of development of commercially valuable IP. The absence of this salary signal reinforces the perception that effort made towards generating commercially valuable IP will not be rewarded.

7. Currently, NHMRC career support for biomedical researchers is used to add value to the education/health sector of the economy but not to the industry sector of the economy.

SUGGESTED RESPONSE

Problem Restated

NHMRC funds are being used by universities and research institutions in the educational/health sector to compete with Australia's biomedical industries for intellectual capital and IP.

The NHMRC needs a mechanism for continuing to fund biomedical research in a manner which does not enhance this competition and stymie the robust growth of Australia's biomedical industries.

Suggested Solution

Suggestion I. Assign IP rights to the grant awardee rather than the administering institution.

Rationale

The ownership by students of the IP outcomes generated in the course of their study provides a model which can be used to enable the NHMRC to compensate biomedical workers for generating commercially valuable IP.

While this administrative change is simple it will have a profound and transformationary effect on biomedical research in Australia.

Expected Benefits

Positive benefits to Australia can be expected at different levels, including:

At the level of creation of IP.

Rewards for generating commercially valuable IP. Where the NHMRC assigns the IP rights to the grant awardee, rather than the administering institution, the grant awardee is in effect receiving: (i) a base salary, appropriate to their level of technical and scientific managerial expertise; and, (ii) a performance component, appropriate to the economic value of the IP created by that grant awardee.

Competition between biomedical researchers to generate commercially valuable IP. Establishment of a direct relationship between performance and reward provides the stimulus needed to encourage biomedical researchers: (i) to identify opportunities to generate commercially valuable IP; and, (ii) to manage their research project to achieve the desired commercial IP goals. An entrepreneurial culture among biomedical researchers can be predicated to evolve.

Stimulus for emergence and growth of biomedical industries. Ownership of the IP outcomes of their research can be expected to increase the number of scientists wanting to facilitate the commercial development of their IP in order to realise potential commercial rewards. Expected consequences are: (i) Increases in the rate of spin-off and start-up companies; together with, (ii) migration of commercially focused scientists from the education/health sectors into the commercial sectors.

At the level of universities/research institutions

Rewards for generating commercially valuable IP.

The technology transfer and commercialisation arms associated with universities and research institutions will lose their subsidies paid in the form of transfer of IP rights. At present this level of subsidy (i.e., covering all, not half, of the direct project costs) is not available to entities sponsoring their own innovation funded R&D in the commercial industry sector. This will level the playing field between the health/education sector and the commercial industry sector in the competition to generate commercially valuable IP.

Competition between biomedical researchers to generate commercially valuable IP.
Removal of the subsidy paid in the form of transfer of IP rights will mean that the technology transfer and commercialisation arms associated with universities and research institutions will need to earn, rather than receive as a given, the rights to commercialise IP generated from NHMRC grants. Competition between (i) technology transfer/commercialisation arm of the university/research institution; and, (ii) entities in local industry will be stimulated to earn the rights to work with the researcher where the grant awardee owns the IP rights and has the choice of working with either. To win this business, technology transfer/commercialisation arms can be expected to offer services to researchers aimed at helping them manage the innovation process in exchange for the opportunity to protect and commercialise the IP.

Stimulus for emergence and growth of biomedical industries.
Transfer of ownership and control of IP rights is key to seeding new innovation focused businesses. In the absence of existing local industry partners, biomedical researchers and their host research institute/universities will have a mutual interest in working together to attract investors and establish commercialisation partners needed to gain access to the NHMRC Development and Partnership Grant funds. For the investor, the opportunity to negotiate separate deals with: (i) the research scientists for access to IP rights; and, (ii) the university/research institute for research project and infrastructural support can be attractive, and especially so where resulting entity is positioned to commercialise the outcomes of a NHMRC Development or Partnership grant.

Expected Costs
Cost to the Federal Government
The direct cost to the Federal Government does not change. This is in harmony with the federal government's revenue neutral policy for tax reform and reform of the business sector.

Cost to the health/education sector
The assignment of IP rights to the grant awardee instead of the administering institution will be interpreted as a reduction in the level of government support to the education/health sector. To reduce the economic impact of this decision, universities and research institutions may be expected to make use of contractual (employment contract) and other means to continue this economic benefit.

Primary Risks
Reactionary Restrictions
To reduce the economic impact of the perceived reduction in the level of government support to the education/health sector, universities and research institutions may be expected to make use of contractual (employment contract) and other means to continue this economic benefit.

IP Movement
Transfer of IP rights to grant awardees rather than administering institutions introduces the risk that tax payer funded IP may exit Australia either directly where the IP rights are sold to an overseas entity or indirectly by emigration of the knowledge worker.

Suggested Risk Reduction Strategies

Suggestion II. Award NHMRC grants to the applicants rather that the administrative body; ask applicants to nominate the entity who will administer the grant on behalf of the successful applicant.

If benefits associated with administering NHMRC grants are to flow to sectors other than the education/health sector, it is important that the grant awardee is not restricted from nominating a commercial organisation as the entity which will administer the grant on behalf of the awardee. Maximum mobility of intellectual capital in the economy will be obtained

where the awardee retains the option of changing the administrator while in receipt of a grant.

Expected outcome
Where grant awardees retain the option of changing administrators, existing employers and administrators are less likely to resort to using restrictive contractual agreements to acquire IP rights (e.g., contracts which require the grant awardee to assign IP rights to the administrator). Instead, to attract and retain knowledge workers, existing employers and administrators will have to fundamentally rethink how to attract and retain knowledge workers in an information age.

An intended consequence of providing NHMRC grant awardees with freedom of choice in terms of grant administrator, is to encourage the providers of research facilities to consider provision of infrastructural and other support needed to attract and retain the best and brightest biomedical researchers. In response to this competitive pressure, different universities and research institutes can be expected to focus on building on their strengths, shedding their weaknesses with the aim of differentiating into distinct world class centres of excellence. Evolution of centres of excellence can be expected, each catering for knowledge workers in different specialty areas (e.g.. fields such as immunology, virology, neuroscience, etc or technical processes such as molecular biology, imaging technologies, pharmaceutical testing, etc).

Removing restrictions on mobility on intellectual capital within Australia will facilitate the assembly of large multi-disciplinary teams of experts to tackle the bigger challenges of strategic importance to Australia.

Suggestion III. Restrict assignment of IP rights to awardees on the condition that the IP remains within Australia.

Given that it is the Australian tax payer which is financing the NHMRC grant and which made possible the generation of IP, it is reasonable to make the assignment of such IP rights conditional that it remains within Australia. This will reduce the risk that Australia does not benefit from the IP.

NATIONAL INTELLECTUAL PROPERTY STRATEGY

Over the years, Australia has lost a significant proportion of its investment in intellectual capital to overseas countries. The combined effect of increased mobility of intellectual capital within Australia coupled with changes in the work environments can be expected to make Australia an especially dynamic and attractive area to undertake biomedical research.

Award of IP rights to scientists within Australia on the provision that the IP remains within Australia might provide conditions which not only encourages Australian scientist to stay in Australia, but may even allow Australia to attract and retain intellectual capital and investment from overseas.

Given that the Federal Government has signalled an interest in cultivating a global competitive advantage in biotechnology, the approach outlined here for the NHMRC might be extended to be applied more broadly (e.g., also to ARC grants). This might stimulate emergence of other knowledge based innovation focused industries in Australia in parallel with biomedical industries (e.g., biotechnology based agricultural industries). Such industry developments may put Australian in a strong economically position for growth as it enters the 21st century.