1. Introduction

The Federation of Australian Scientific and Technological Societies (FASTS) is the peak representative body for 60,000 scientists and technologists.

FASTS was established in 1985 and has approximately 65 member organisations. FASTS is well known in Parliamentary circles as the initiator and co-ordinator of the highly successful 'Science Meets Parliament' and the President of FASTS is a member of the Prime Minister's Science, Engineering and Innovation Council (PMSEIC).

FASTS do not have a formal position on whether Australia should ratify the draft Aus-US Free Trade Agreement.

There are, however, a number of implications for science that we would like to draw to the attention of the committee.

2. Investment – Chapter 11

2.1 Introduction

FASTS are concerned that provisions of the draft FTA liberalizing US investment in Australia may diminish Australia's capacity to maximize benefits from publicly funded R&D.

It is well recognized that R&D intensive SMEs in science and technology are crucial for economic growth and success in the global economy. However, the national benefits generated by R&D intensive SMEs are at risk if the Australian Government does not exercise oversight of foreign takeovers, specifically foreign takeovers that may result in production, jobs and export opportunities being taken offshore.

It is manifestly not in Australia's national interest if we simply allow multinational firms to cherry-pick Australia's most promising and innovative technology SMEs with no constraints or oversight.

FASTS believes the investment provisions in the draft FTA are not consistent with a key policy objective of **Backing Australia's Ability** to strengthen the capacity of Australian inventions being commercialized by Australian firms and exported into the global market.

FASTS recommends;

- the Committee consider striking out provisions relating to technology transfer and domestic content in 11.9 (Performance requirements);
- the Committee request the Government review terms and conditions of publicly funded research with a view to
    - developing relevant and transparent 'national benefits' tests for commercialization of publicly funded research; including
    - conditions requiring Government approval of grant recipients to locate operations and/or production offshore.

2.2 Benefits of Investment provisions

A long-standing constraint on developing and commercializing Australian R&D has been the lack of venture capital throughout the R&D process. Thus it is plausible that measures in the draft FTA which encourage US investment in Australia may provide;

- additional investment;
- reductions in the cost of capital; and
- enhanced technology transfer between Australian and US firms.

2.3 Risks of Investment provisions

FASTS believes a combination of factors, including;

- Changes in global R&D practices towards large firms purchasing technology and intellectual property through mergers and acquisition of R&D intensive SMEs;

- Shift in Government R&D policy towards public funding of commercialization;

- Inadequate coverage of 'national benefits' conditions on recipients of public funding of R&D;

- Liberalising capacity for US takeovers of Australian firms in the draft FTA; and

- constraints on the scope of terms and conditions of Government grants and subsidies for R&D in the draft FTA;

may result in Australia losing the benefits of publicly-funded R&D through takeovers of R&D intensive SMEs and subsequent transfer of IP, know-how, jobs and export opportunities offshore.

By way of contrast, the US, through the Bayh-Dole Act and conditions on publicly funded R&D grants, maintains strict controls and barriers on foreign takeovers and offshore relocation of US firms derived from licencing of publicly-funded R&D.

2.4 Change in international business R&D practices

Since the mid-1990s it has become apparent that there are significant changes in how business R&D (BERD) is performed, notably in OECD countries.

With some exceptions, including Australia, Italy and the UK, business investment in R&D grew considerably in real terms and as a percentage of GDP in the 1990s. Two important characteristics of that growth are;

a) substantial increase in R&D alliances, mergers and acquisitions, and
b) significant increase of SMEs' share of BERD.

The growing reliance on externally developed IP by large firms is particularly notable in the growth of mergers and acquisitions of small, R&D intensive SMEs by multinational high technology firms.[1]

2.5 Focus on Commercialization in Government Policy

An important theme in innovation and R&D public policy debates is the need for Australia to maximize the benefits of publicly funded research and Australian innovation through successful commercialization of Australian ideas and inventions.

This is explicitly taken up in the recently announced **Backing Australia's Ability: Building Our Future Through Science and Innovation** program notably in the $1 billion *Commercial Ready* suite of programs which are designed to "strengthen the capacity of Australian small and medium-sized businesses to take competitive ideas to market."[2]

Informally, this policy intent is often described as 'we need more Cochlears and ResMeds'.

The focus on commercialization is evident in other Government R&D programs notably the change in selection criteria of CRCs announced in December 2003.

2.6 Existing constraints on transferring ownership

Despite the Government's policy intent to maximize the benefits for Australia of commercializing Australian inventions and innovations, there are few constraints in the existing framework to prevent foreign takeover of Australian firms, and subsequent relocation of production offshore, derived from publicly-funded R&D.

The Industry Research & Development Board (IR&DB), which administers a number of Commonwealth industry R&D programs, are required to consider 'National Benefits' when assessing applications for various programs including R&D Start and COMET.

The 'National Benefits' test includes consideration of an application's capacity to contribute to national productivity and economic growth, diffusion of knowledge and skills and societal, community and ecological benefits. [3]

The potential benefits or necessity of overseas commercialization are explicitly allowed for and in these circumstances the IR&DB considers applicants' level of commitment to retaining or enhancing the firm's R&D facilities in Australia and technology transfer arrangements from overseas to Australia.[4]

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[1] OECD, *Changing Business Strategies For R&D And Their Implications For Science And Technology Policy*: OECD Background and Issues Paper, 2001, www.oecd.org/dataoecd/35/17/2347279.pdf

[2] *Backing Australia's Ability: Building Our Future Through Science and Innovation*, Commonwealth of Australia, 2004, p. 23

[3] AusIndustry, Policy No. 1: National Benefits, http://www.ausindustry.gov.au/content/content.cfm?ObjectID=B6AC2D62-38FC-465B-86419B6956541313

[4] *ibid*, 2(a) and 2(b)

A condition of R&D Start and COMET contracts is grant recipients cannot vary the grant conditions, including ownership, without the permission within 10 years of commencement of the grant. In the event of a proposed takeover or variation to contract, the IR&DB may consider elements of the 'national benefits' test including technology transfer arrangements.

If an application to allow overseas commercialization fails the 'national benefits' test, the IR&DB may terminate the project agreement and require repayment of relevant grants or loans.

FASTS believes the scope of the 'national benefits' test will be constrained by the performance requirements provisions (11.9) of the draft FTA, notably in respect of technology transfer (see below).

There are no commensurate provisions to the 'national benefits' test of the IR&DB in other publicly funded R&D initiatives including Australian Research Council (ARC) or National Health and Medical Research Council (NHMRC). Moreover, should a future Government seek to develop 'national benefits' criteria the draft FTA will constrain the scope of such a test.

2.7 Liberalization of investment in Draft FTA

The draft FTA requires that each party accord to investors of the other party national treatment (11.3) or Most-Favoured-Nation (MFN) (11.4) treatment for the 'establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments'.

Various non-conforming measures, notably for media, property, Telstra and Qantas are listed in Annex 1 and Annex II.

A key measure in Annex I lifts the threshold by which foreign investment in Australian firms needs to be notified to the Australian Government's Foreign Investment Review Board (FIRB) from $50m to $800m for most industries, including manufacturing and agriculture (Annex 11-I Australia-5 (c)).

FASTS notes the 'ratchet' provisions of 11.13.(c) that cover Annex I means a future Government could further liberalise this threshold but could not make it more restrictive if it became apparent that lack of oversight and analysis of investment proposals was having a detrimental effect including takeovers of our most promising R&D intensive firms.

2.8 Constraints On Terms and Conditions of Government Grants And Subsidies for Publicly-funded R&D

Chapter 10 – Cross Border Trade In Services and *Chapter 11 – Investment* – provide exemptions from other liberalizing provisions in the draft FTA for Government subsidies and grants, including subsidies and grants for R&D.

In the case of trade in services; subsidies, grants, Government-supported loans, guarantees and insurance are exempt from all other provisions in Chapter 10 (10.4.(d)).

However, the scope of exemptions for goods is much narrower than for services.

Government provision of subsidies and grants for goods is not required to comply with provisions affecting national treatment (11.3), most-favoured-nation (11.4) and senior management and boards of directors (11.10).

However, provisions preventing the imposition on investors of a comprehensive range of performance requirements (11.9) including technology transfer (11.9.1.(f)) and domestic content requirements (11.9.2(a)) do apply to grants and subsidies.

This may have a direct impact on the existing terms and conditions of R&D Start and COMET and may adversely constrain the capacity of the Government to implement 'national benefits' criteria to other publicly-funded R&D programs such as the ARC, Universities and NHMRC.

As discussed below, the US currently requires that firms with a licence for IP derived from federally funded research are required to substantially manufacture in the US. This performance requirement is, at face value, inconsistent with the provision that requires domestic content requirements cannot apply to Government grants and subsidies. It is not clear whether the US intends to change its law to ensure consistency with the FTA, nor is there anything in the US annexes that go to this.

2.9 Bayh-Dole Act (US)

The policy intent of the *Patent and Trademark Amendment Act (1980*) - commonly called the Bayh-Dole Act - is to maximize the economic benefits of federally funded R&D for the US by ensuring inventions from federally funded research are made available to the US public for the US public's benefit (35 U.S.C. s.200).

Essentially, the Act requires inventors/researchers to maximize the opportunities to commercialise inventions that emerge from federally funded R&D.

Inventors/researchers may elect to own and exercise IP rights of their inventions (s. 202(a)), providing they take out a patent (s.202(c)). However, the US Government can claim ownership if an inventor does not exercise this right, take out a patent or commercialization is not reasonably pursued (use-it or lose-it) (s. 202(c), s.203). Where inventors do not take out title or fail to meet their obligations, the US Government licences the IP to US firms.

In addition, the National Institutes of Health (NIH) maintains rights to *all* NIH federally funded inventions including a non-exclusive, non-transferable paid-up licence to practice or have practiced for, or on behalf of, the US any invention anywhere in the world.

The Act also requires that licenses of IP created from federal funds can only be awarded to firms who will substantially manufacture in the US and imposes significant constraints on foreign takeovers or attempts to take manufacturing offshore (s.204).

Under Bayh-Dole, the US Government retains the right to approve or not approve any decision of a relevant firm with a licence to relocate production offshore. The only

circumstances that the US Government permits inventions derived from federally funded R&D offshore are when it is not commercially feasible to manufacture in the US or the grantee has not been successful in their attempts to licence the patent to domestic US industry.

Federal funding agencies including the NIH stipulate in their terms and conditions of grants that grantees/contractors are required to comply with all provisions of Bayh-Dole.

Foreign recipients of NIH funding - Australia is second to Canada in success of foreign NIH grantees - are also bound by Bayh-Dole provisions.

In 2002, the NIH proposed a further policy change whereby foreign recipients of grants could only exercise IP rights in their country while the NIH would hold all rights for the rest of the world. [5] This policy is not yet in effect but highlights the asymmetry between the NIH and the NHMRC.

2.10 Foreign Investment Review Board (FIRB)

It could be argued that lifting the threshold for notification to FIRB for US investment in manufacturing from $50 m to $800 m will make little difference in practice as the Government, through FIRB, have only rejected 4 out of 2285 investment proposals from all countries in the past 5 years.[6]

This success rate reflects current Government policy. However, should Government policy change in the future as a response, for example, to cherry-picking by multinational firms of Australia's most promising companies, the increased threshold will preclude examination of a considerable proportion of Australian firms including all science and technology R&D intensive SMEs.

FASTS understands FIRB do not collect data on the ownership or origin of intellectual property in investment proposals. Thus its current operating practices mean it is not in a position to identify firms developed around IP generated from publicly-funded R&D.

2.11 Firms in receipt of publicly funded support of R&D

Thousands of Australian firms have received public funding for R&D and innovation including;

- 560 R&D Start grants and loans to the value of $552 million since 1 July 2000.[7] (Cochlear received R&D Start grants in its developmental stage)

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[5] NIH, *Planned modification of rights to subject inventions made through funding agreements to foreign entities* http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-039.html

[6] Centre for International Economics, *Economic Analysis of AUSFTA*, CIE: Canberra and Sydney, 2004 p. 32

[7] DITR, Business Expenditure on R&D Fact Sheet, http://www.industry.gov.au/content/itrinternet/cmscontent.cfm?objectid=D1B8B525-15D4-4033-8C8C99E155319140&indexPages=/content/itrinternet/allprogramsandservices.cfm?indexType=crossindustry,/content/itrinternet/cmsindexpage.cfm?objectid=48A520BD-20E0-68D8-ED2DD21B7BC06B4B,/content/itrinternet/cmsindexpage.cfm?objectid=48A5DFEA-20E0-68D8-EDB550B8BD2CB714

- 138 Biotechnology Innovation Fund grants since inception in 2000[8]
- 800 grants approved in COMET since 1999[9]
- 275 start-up companies have been accepted into the incubators program of Building Information Technology Strengths (BITS)[10]
- 4707 companies had registered for the R&D tax concession by August 2003 for FY 2001-02. Nearly 600 SMEs registered for the 125% R&D tax offset for 2001-02 and nearly 500 firms registered for the 175% R&D Tax premium in the same year.[11]
- 61 companies have received Innovation Investment Fund (IIF) funding since inception[12]

In addition, the ARC awarded 921 Discovery grants for the 2003 round and 586 new linkage grants in the two rounds October 2002 and May 2003 and in 2003 the NHMRC approved 911 new grants.[13]

The outcomes of many of these grants – and research in public sector research agencies such as CSIRO, AIMS and ANSTO - will produce new IP, which will provide commercial opportunities for existing Australian firms or drive new spin-off companies.

2.12 Recommendations

While acknowledging possible benefits from US investment in Australian firms, FASTS believes the Committee must consider the possible negative impacts of the draft FTA in terms of maximizing public benefits of commercializing Australian R&D.

FASTS recommends;

- the Committee consider striking out provisions relating to technology transfer and domestic content in 11.9 (Performance requirements);
- the Committee request the Government review terms and conditions of publicly funded research with a view to developing
    - relevant and transparent 'national benefits' tests for commercialization of publicly funded research; including
    - conditions requiring Government approval of grant recipients to locate operations and/or production offshore.

[8] *Real Results Real Jobs, Backing Australia's Ability: The Australian Government's Innovation Report 2003-04*, Canberra 2004, p. 71
[9] *ibid*, p. 68
[10] *ibid*, p. 72
[11] *ibid*, p. 61
[12] ibid, p. 66
[13] ibid, pp. 29,30, 35

FASTS notes however, that IP arrangements and issues around commercialization of publicly-funded research are highly complex, particularly when it involves multiple sources of funding and investment.

FASTS believes the key public policy intent of the Bayh-Dole Act to maximize public benefits from publicly funded research is highly commendable. We do not, however, recommend that Australia simply adopt Bayh-Dole provisions.

The need for examination of these issues is urgent and any changes to current arrangements will require careful consideration and detailed consultation with universities, CSIRO, ARC, NHMRC, industry, IPA and others in the research and intellectual property sectors.

3. Sanitary and Phytosanitary measures – Ch. 7

3.1 Background

FASTS believes that good science is a necessary condition of robust policy, import risk assessment and regulation of sanitary measures.

Invasive species and introduced diseases have had major impacts on the environment and commercial agriculture and aquaculture (eg cane toads and phylloxera). To date, conservative quarantine practices have played an important role in Australia avoiding or minimizing exposure to diseases and pests that have seriously damaged agricultural production in other countries (eg fire blight). Indeed, Australia's reputation for being comparatively clean and low in disease, has given Australian agricultural exporters competitive advantages in many markets.

However, a number of factors are increasing the risk to Australia's environment, human, plant and animal health and commercial agriculture, including

- increasing flows of people, goods and services;
- climate change;
- reduced investment in relevant education and research disciplines such as parasitology; and
- growing resistance of diseases and parasites to chemical controls; and
- apparent changes in regulatory practices.[14]

In short, the importance of good science informing policy and risk assessment is **increasing**.

Assumptions about risk that may be robust today could well be invalid in the future as a consequence of climate change. Australia exposes itself to great risk if we become complacent, fail to support relevant research and monitoring or allow trade considerations to undermine proper scientific analysis.

FASTS Recommends;

- The Committee urge the Government initiate reform of Biosecurity Australia's objectives and operations.

[14] On this refer *An Investment in Human and Animal Health: Parasitology in Australia*, FASTS Occasional Paper, Mark Sandeman and Lesley Warner (eds), Canberra, 2002

3.2 Objectives

The DFAT *Guide To The Agreement* states:

> Nothing in the chapter undermines the right of either party to determine the level of protection it considers appropriate (p. 35).

FASTS is not so confident that this is so. The objectives of Chapter 7 go explicitly to resolving trade issues 'and thereby expand trade opportunities'.

The draft agreement provides for the creation of two bi-lateral Sanitary and Phytosanitary Committees – a general committee and a Standing Technical Working Group on Animal and Plant Health Measures.

The objectives of the general committee include "protecting human, animal, or plant life" and "facilitate trade between the parties" (7.4.3).

The objectives of the technical working group are to "resolve specific bilateral animal and plant health matters with a view to facilitating trade (Annex 7-A 4(a))."

That is, there may be an intrinsic conflict in the objectives of both committees.

FASTS notes that US agribusiness interests have clearly interpreted the new arrangements as a concession by Australia to the USA.

Clearly, that is the interpretation of the American Farm Bureau Federation who state in their press release of 10 March 2004:

> AFBF's analysis of the proposed free trade agreement forecasts that annual exports of high-value U.S. food products to Australia will grow by $150 million to $200 million after that nation removes non-tariff trade barriers, particularly in the area of sanitary/phytosanitary rules. [15]

FASTS believes scientific analysis of risk must have priority over trade imperatives.

We are concerned that both the objectives of the committees and their character as bureaucratic instruments to facilitate trade may undermine the fundamental role that proper scientific analysis must have in a sound quarantine system.

Our concern is compounded by the fact that there are no provisions requiring independent scientific expertise on the membership of either committee.

If the draft FTA is ratified then confidence in the two bi-lateral committees will be highly dependent on the capacity and approach of the lead Australian agency, Biosecurity Australia.

3.3 Biosecurity Australia

FASTS is aware that the confidence of agriculture sectors and relevant scientists in Biosecurity Australia is diminishing over time due to concerns that trade considerations are inappropriately prioritized over scientific analysis of risk. Recent

[15] *http://www.fb.com/news/nr/nr2004/nr0310a.html*

debates and decisions over pineapples, Atlantic salmon, apples and pig meat have raised skepticism of Biosecurity Australia's capacity to make good judgments.

More specifically, scientists are concerned with the changing culture within Biosecurity Australia, including

- Increasing emphasis on a 'least trade restrictive' approach that has the potential to undermine the science base of IRA;
- Attempts by Biosecurity Australia representatives to 'direct' IRA teams toward facilitating trade;
- Inadequate record keeping of Import Risk Assessment (IRA) committees; and
- Scientific errors in Biosecurity Australia's modeling and data;

For some detailed evidence and discussion of such concerns FASTS draws the attention of the Committee to the three Senate Rural and Regional Affairs and Transport Committee inquiries into the Import Risk Analysis of bananas, apples and pork meat.

Evidence presented to that committee raises serious concerns over Biosecurity Australia's procedures and culture consistent with the concerns noted above.

FASTS believe the arguments for significant reform of Biosecurity Australia's processes and objectives are strong. We recommend the Government initiate reform of Biosecurity Australia with some urgency. This should be done irrespective of Parliament's determination on the draft FTA.

4. Intellectual Property – Patents (ch. 17.9)

4.1 Background

The patent system is crucial to encourage R&D innovation and FASTS are broadly supportive of changes in the Australian patent system in the past few years to lift the threshold of patentability and improve the capacity of patent holders to protect patents.

Patents can, however, be a serious constraint on research.

FASTS believe that patents should not be permissible for factual scientific information including naturally occurring genes and gene sequences.

There is considerable international concern over the issuing of gene patents. There arguments against issuing patents for genes and gene sequences include ethical arguments, constraints on bona fide research and discovery of a gene or gene sequence does not satisfy a fundamental - and internationally recognised criteria for a patent - that it should be an invention.

Such concerns have resulted in major biotechnology research initiatives including the Human Genome Project and the International Haplotype Mapping (HapMap) Project placing their research results in the public domain with no constraints or costs on access for researchers.

No jurisdiction in the world permits patenting of genes or gene sequences *per se*. Debates over what is patentable typically revolve around questions of isolable genes and gene sequences.

It is fair to say that there is a widespread belief internationally that the US Patent system – unquestionably the most powerful patent regime in the world - has not got the balance of interests right and patents have been issued for isolable genes and gene sequences that stretch the criteria of patentability beyond what many scientists, ethicists and legislators consider as acceptable. The European Union, for instance, is vigorously opposed to the USA approach.

4.2 FTA Provisions

It is not clear what implications there are for the Australian patent system in the draft FTA.

The advice FASTS have received from DFAT is that the patent provisions in the draft FTA are consistent with existing Australian law so presumably there will be no changes at all or no changes of substance.

However, there does appear to be some variance between the proposals in the draft FTA and the current *Patent Act 1990*.

For example, article 17.9.1, seems to imply a broader definition of patents by changing the definition of invention. It makes the USA and Australia provide patents for "any invention … provided … (it) … is new, involves an inventive step, and is capable of industrial application". Presumably, this will replace the current definition in Schedule 1 of the *Patents Act 1990*, which defines invention as 'a manner of new manufacture within the meaning of s.6 of the *Statute of Monopolies'*. That statute lists a number of exclusions including that a patent is "not contrary to the law, nor mischievous to the state by raising of the prices of commodities at home or hurt of trade, or generally inconvenient". The scope of this exclusions list is not, however, replicated in 17.9.2(a).

17.9.2(b) does allow for a change in Australian law. It provides that parties *may* exclude 'diagnostic, therapeutic and surgical methods for the treatment of humans and animals'. Under current Australian law exclusions relate to generating a human being (*Patent Act* (1990) s.19(2)). FASTS understand that the Federal Court has allowed that treatments are patentable.[16]

In addition, article 17.9.3 refers to 'exclusive rights' but these aren't defined elsewhere in the chapter so we are not sure exactly what this might mean.

Accordingly, FASTS are unable to really determine whether there are any substantive implications for science and R&D that are specific to the patent provisions in the draft FTA. Close examination of any legislation will be required.

We note that in some of the commentary surrounding the FTA, the Government has stated "Australians will benefit through closer harmonisation of our already strong

[16] *Bristol-Myers Aquibb Co v Faulding (2000).*

intellectual property regime with that of the largest intellectual property market in the world".[17]

It is not clear to FASTS what the scope of 'harmonisation' will mean in practice.

As the committee will be aware, law operates at a variety of levels including parliamentary legislation and regulation; judicial, including case law; and administrative and normative practices of agencies.

There is a view that the apparent expansion in the US of what is patentable in respect of genes and gene sequences seems to be driven by interpretations at the officer level in the US patents office as distinct from US legislation.

FASTS does not have the expertise to provide the Committee with the relevant legal analysis of this but if this is, in fact, the case then this may have some implications to Australian patents if 'harmonisation' is interpreted broadly and acted upon.

4.3 Australian Law Reform Commission Inquiry

The Committee will be aware that the Australia Law Reform Commission is currently reviewing gene patenting and human health. An issues paper and a discussion paper have been released and the final report is due in June 2004.[18]

FASTS considers the ALRC to be a highly credible organisation and the processes of their reviews to be genuinely consultative and comprehensive.

FASTS believes public debate over such an important set of issues as gene patents and consequences for research, human health and ethics should not be constrained or pre-empted by a trade agreement.

5. Government Procurement – Ch. 15

Fasts welcomes the liberalization of access for Australian firms to US Government procurement programs. At face value, this provides opportunities for firms in a variety of advanced technology and the service sectors to benefit. In practice, it is not clear how many Australian firms will benefit due to far to a range of distortions in the procurement process, including US State Government's interventions in support of local firms.

In addition, there will be extensive costs associated with tendering as appeals mechanisms are used extensively and aggressively. Nevertheless, these provisions are a significant improvement on current arrangements and as such are welcome.

6. Mobility

A defect in the FTA is the failure to resolve the barriers that constrain labor mobility to the US, specifically business people wishing to work in the USA for periods greater than 6 months. This impacts on Australian businesses, notably, given FASTS interests, R&D intensive technology SMEs trying to expand into the US market.

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[17] *http://www.dfat.gov.au/trade/negotiations/us_fta/outcomes/08_intellectual_property.html*
[18] *http://www.alrc.gov.au/inquiries/current/patenting/index.htm*