Government Business and International
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Inquiry into Value-adding to Australia's Raw Materials

At the hearing on 18 October 1999, CSIRO agreed to provide further information on the wood and forest products action agenda, restructuring at the CSIRO Division of Forestry and Forest Products and CSIRO's activities in the field of rainforest plantation forestry and the potential use of biotechnology. For information, a briefing on these issues is at Attachment A.

The general issue of managing CSIRO's strategic research to ensure maximum return on government funds invested was also raised by the Committee. This issue is central to CSIRO's planning at a corporate level and at more detailed levels. CSIRO's planning and commercial decisions require judgements of likely returns to Australia, based on knowledge and best judgements at the time. The potential leakage of technology overseas is a concern but is offset by the fact that these projects are generally driven by a wish to exploit natural advantages of local resources, and addressed in the course of negotiations on intellectual property. A paper prepared by Dr Chris Mallett, CSIRO Deputy Chief Executive on the commercialisation of biotechnology is at Attachment B.

During the hearing Dr Oakeshott noted: "There is no doubt that the issues around the AWRAP, IWS and successors have had a large impact on our research funding base. From my knowledge our budget from that source declined from several million dollars in about 1990 to a few hundred thousand in our main wool serving division." As a point of clarification, Dr Oakshott was referring to the CSIRO Division of Animal Production where income from the wool industry, through The Woolmark Company has fallen from $7.7M in 1990 to $0.6M in 1999 (1998-99 dollars). The other major R&D provider in this sector is the CSIRO Division of Textile and Fibre Technology (formerly the Division of Wool Technology) where income from The Woolmark Company is expected to decline from $10.3M in 1997-98 to a maximum of $5.5M in 1998-99.

I understand the Committee proposes to consider a number of case studies as part of the Inquiry. If interested, I may be able to organise visits to the CSIRO Division of Minerals, Clayton and/or to Food Science Australia in Werribee and the Division of Textiles and Fibre Technology in Geelong, Victoria. In Canberra, a visit could be organised to CSIRO Entomology at Black Mountain, which could provide some useful insights into CSIRO's biotechnology strategies. The Melbourne based Divisions are probably more closely aligned with the type of value-adding industries that are the focus of the Inquiry.

If the Committee would like to visit to these Divisions or requires further information please contact me at the above address.

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Attachment A.

REPLY TO QUESTIONS ON NOTICE

House of Representatives' Standing Committee on Industry, Science and Resources
Inquiry into Value-Adding to Australia's Raw Materials

Issue 1: Forest and Wood Products Action Agenda

The Government is preparing a series of action agendas focused on specific industry sectors. The Forest and Wood Products Action Agenda is being coordinated by the Department of Agriculture, Forestry and Fisheries. CSIRO through the Division of Forestry and Forest Products is contributing to a number of working groups. The action agenda is expected to be completed towards the end of 1999. For further information on all action agendas please refer to: **www.isr.gov.au/agendas/index.html**

Issues 2: Restructuring at CSIRO Division of Forestry and Forest Products

Background

- CSIRO's Forestry and Forest Products is the single largest organisation in Australia conducting research into forestry, wood and paper science. It has an established international reputation as a centre of excellence in forestry and forest products research. The sector has made a positive contribution to Government policy development and its implementation in native and plantation forests, including input to the development of the Regional Forest Agreements and national codes of forest practice.

- In 1998/99 the Division's funding included:

Direct Appropriation Revenue	$17,436,300
External Revenue	$10,101,300
Total Revenue	$27,537, 600
External to Total Earnings Ratio	36.7%

- The Division is located on five sites:
  - The Forest Research Centre in Yarralumla, Canberra (117 staff);
  - The Forest Products Laboratory at Clayton in Melbourne (98 staff);
  - The Plantation Forest Research Centre at Mt Gambier in South Australia (15 staff); The Tasmanian Forest Research Centre and CRC for Sustainable Production Forestry at Hobart (22 staff); and
  - The Western Australian Forest Research Group at Floreat Park in Perth (18 staff).

  In July 1999 it had a total of 270 staff over five locations with 119 of these being research staff.

CSIRO Planning Process

CSIRO determines its research priorities and investment decisions on a triennial basis, one year prior to the start of the next funding triennium - 2000 to 2003. The assessment is done on a sectoral basis covering industries and agencies in Agribusiness, Minerals and Energy, Manufacturing, Infrastructure and Services, and Environment and Natural Resources. CSIRO

Divisions are provided with resources on the basis of their research effort for the sectors they operate in.

Sector Advisory Committees which comprise representatives of relevant industries and government guide the research portfolio for CSIRO's effort for each sector.

A process for determining the priorities for the next funding triennium has just been completed.

The process has involved:

- a mid-term review of the current Sector plans to reflect on what has been achieved and to see where improvements, refocusing and re-directions are required in the next triennium;

- preparation of Sector Outlooks to provide the context and drivers for the new Plans; and

- preparation of Sector Investment Portfolios against three budget scenarios - steady and +/- 20% - to draw out views on priorities and provide options upon which the Executive can make decisions.

The decisions signal some substantial changes to CSIRO's research portfolio overall. There has been expansion in real terms for:

- Exploration and Mining to implement new detection methods for finding "elephant" orebodies;

- Marine to initiate an integrated approach to marine management for the North West Shelf which will act as a model for other marine precincts; and

- Petroleum to enhance skills in petroleum exploration.

This has been balanced by reductions in the Meat, Dairy and Aquaculture, Forestry, Wood and Paper Industries, and Textiles, Clothing and Footwear sectors in response to insufficient adoption of research by industry. Resources have also been reduced in the Biodiversity Sector but with the opportunity for the Sector to refocus its projects to increase its attractiveness to commercial and government land managers, as well as environmentally aware members of the community.

This must not be taken to imply that the work in these sectors was unimportant or of poor quality; rather that with poor industry involvement the take-up by industry was likely to be poor and therefore the benefit to the taxpayer less than in other areas.

Impact on CSIRO Forestry and Forest Products

- As a result of the recent sector priorities process, CSIRO Forestry and Forest Products will lose $1.4 million per year from July 2000, a total of $4 million over the next triennium. The funding cuts will be made to the value adding research activities within the Forest Products Laboratory, Clayton, Victoria. These cuts, together with the unsuccessful bid for the CRC for Fibre and Paper, mean that the Division has had to reassess research priorities, cut operating costs and shed 24 positions. Achieving this staff reduction has required a redundancy program.

- Of the 24 staff who are potentially excess to requirements,two have been found positions elsewhere in the Organisation and 11 others had left CSIRO by 29 October 1999. Six other staff were retrenched in July 1999. In addition CSIRO will not reappoint seven term staff when their contracts expire. Four of the contract staff were employed in the CRC for Hardwood Fibre and Paper Science which closed on 30 September 1999. The winding up of this CRC is unrelated to the reduced funding allocation for Forestry and Forest Products.

- The Program/Project structure in CSIRO Forestry and Forest Products has been reorganised to focus on the highest priorities in line with the available budget. The Division will close or significantly downgrade work in long term studies of timber durability (biodeterioration), wood science and adhesives and pulp and paper processing. The Division will complete or renegotiate existing contracts to meet its commitments.
- CSIRO Forestry and Forest Products' work on four other sites round Australia will continue.

Issue 3: Trial program into rainforest tree plantations and use of biotechnology to enhance tree growth for export markets

- Trials to establish the technical and economic viability of growing rainforest species (typically tropical or sub tropical species) have been established at various sites in northern Australia over the last two decades by several organisations. Rainforest species would normally be grown for solid wood or veneer products (ie higher value decorative, furniture or other appearance products rather than wood fibre for commodity products) but it has not yet been established that any native Australian species offers major potential. While some may grow relatively rapidly in plantations it is yet to be demonstrated that they will have the wood characteristics found in older, slower grown trees in natural forests. One species of particular interest has been the Australian red cedar *Toona australis*. CSIRO is contributing to studies of floral biology, genetic variation and insect resistance for this species. Tree form and growth rate has been consistently reduced under plantation conditions by the cedar tip moth (an indigenous pest). Unless cedar resistant to tip moth can be produced then it is unlikely this would be a commercially viable species. *Paulownia* species have often been promoted as fast growing species suitable for a range of environments but fast grown *Paulownia* is typically of low density and suitable only for a limited range of uses. The high return market for *Paulownia* in Asia (particularly Japan) requires slower grown trees with smaller growth rings and more colour than likely in fast grown plantation trees.

- CSIRO is also involved in the assessment and genetic improvement of tropical acacias which have some potential in Australia and a small number of exotic rainforest species are also under trial in Australia via various cooperative arrangements.

- Biotechnology (in the sense of marker aided selection and genetic engineering (gene transfer)) offers important opportunities for the forest sector in the longer term. The greatest opportunities for progress lie in combining conventional breeding, marker aided selection and genetic engineering to improve productivity, adaptability to differing site conditions and the properties of the wood for specific end use. CSIRO has active research programs in these areas for commercially important pine and eucalypt species. Genetic improvement is a key tool in increasing productivity and gains of 10-20% in key characteristics are possible per breeding generation. Vegetative propagation is an important tool in cpaturing gains possible through genetic selection and breeding. Maximising gains from tree breeding, however, also

requires site selection, silviculture and stand management also be optimised and hence improvements in productivity require a package of measures to be in place.

- Australia has a trade deficit in forest products of about $1.5 billion per annum. The Plantation 2020 Vision to treble Australia's area of planted forest by 2020 (from 1 million to 3 million ha) could make Australia a significant net exporter of forest products as well as providing a range of other social economic and environmental benefits. Australia needs to enhance its technological input to forest production systems to ensure optimal growth rates, quality and international competitiveness.

Attachment B.

CSIRO'S EXPERIENCE IN COMMERCIALIZING BIOTECHNOLOGY IN AGRIBUSINESS

EXECUTIVE SUMMARY

Introduction

After our last meeting of the working party, I was asked to prepare a paper outlining our experience of commercializing biotechnology in agribusiness. The paper is attached, and, because of the complexity in this area, is thorough but large; *I list below our major conclusions.* Because of the nature of the paper, it either does not cover, or covers only in passing, the following issues:

- New applications such as functional foods (eg vitamin enhanced fruit) and bioremediation;
- Regulation and public safety implications;
- Consumer acceptance, especially important for animal gene biotechnology;
- The wider implications of a biotechnology-driven change in global agribusiness where the terms of trade are controlled more by multinational companies rather than local farmers as the culture changes from a production-based commodity culture to a global end-user demand-driven differentiation;
- The similarities in commercialization with other sectors with strong intellectual property protection such as pharmaceuticals, specialty chemicals and software.

Conclusions

- Under the Science and Industry Act, CSIRO works for the benefit of Australia;
- CSIRO's commercialization activities are governed by its *Commercial Practice Manual* which sets out guidelines on how that benefit should be achieved;
- Biotechnology activity is global, and requires very large sustained investment for success, and consequently has a number of large multinational players linking intellectual property from many sources;
- Within CSIRO, several strategies have been adopted to ensure successful market adoption, based on cooperating with relevant parties to incorporate Australian-owned IP into a complete, commercializable package, while returning benefit to Australia;
- The conclusion from the case studies over the last decade is that there is no single route to success. Rather, each strategy is dependent on the intellectual property, the product, the crop, the market and the companies in that market, and should be incorporated at the outset into project planning.

PREAMBLE

Australian agribusiness is dependent on export and international trade in plant and animal-based commodities and foods. Australia cannot afford to be marginalized from new biotechnologies and so relegated to a dependent player if it is to maintain its international competitiveness. Thus CSIRO has long been active in biotechnological research that will help indigenous industry enhance the quality, yield and profitability of their produce be they plants (cotton, soyabeans, maize, potatoes, tomatoes, peas) or animals (prawns, beef cattle, sheep).

This paper describes CSIRO's experience and approach to commercialization in the agribusiness and related industries of intellectual property generated through research in biotechnology. It explains why we invest in this research, how the global environment disciplines our commercialization, gives some case studies, and concludes with some comments on different market models.

SCIENCE AND INDUSTRY RESEARCH ACT (THE CSIRO ACT) 1949

CSIRO's raison d'etre and its operations are governed by the *Science and Industry Research Act of 1949* (amended in 1986), particularly Section 9(1) which describes our primary functions as:

> *(a) to carry out scientific research for any of the following purposes:*
>
> *(i) assisting Australian industry;*
> *(ii) furthering the interests of the Australian community;*
> *(iii) contributing to the achievement of Australian national objectives or the performance of national and international responsibilities of the Commonwealth;*
> *(iv) plus any other purpose determined by the Minister*
>
> *(b) to encourage or facilitate the application or utilization of the results of such research.*

It is important to emphasize that CSIRO exists not to make profit for itself but to create wealth for the nation and that nowhere in the Act is there a requirement for CSIRO to earn money from its research, other than a Federal Government requirement of raising 30% of our revenue externally.

In conformance with the requirement to "*encourage or facilitate the application or utilisation of the results of such research*", we have to maximise the likelihood of technology uptake. Our experience to date (see below) is that success is determined largely by working with companies with the appropriate capabilities and track record, be they local ones, large or small, or multinational corporations.

INNOVATION AND COMMERCIALIZATION IN CSIRO

Since 1994, CSIRO's commercialisation activities have been governed by our *Commercial Practice Manual*, whose currency is overseen by our Commercial Committee chaired by a Deputy Chief Executive. There are policies that cover all aspects of the commercialization process, including staff training, contracts and contract management, intellectual property, costing and pricing, technology transfer, confidentiality and performance measures.

It is mandatory that all Divisions of CSIRO treat their intellectual property portfolio in accordance with CSIRO's *Commercial Practice Manual*. It is worth making the point that CSIRO's treatment of genetic technologies is no different from the way in which it attempts to commercialize its other intellectual property.

Innovation and the Context of Technology

> *In business, innovation is something that is new or improved done by an enterprise to create significantly added value either directly for the enterprise or indirectly for its customers*
>
> *(Managing the innovating enterprise, Business Council of Australia, 1993)*

Thus, the generation of new knowledge *per se* will not necessarily lead to commercially successful products and processes, and innovation that relies on "technology push" is less reliable and less predictable than innovation that relies on "market pull" as very few innovations that are driven by technology are systemic.

The Need for Customer Partnerships in Successful Commercialization

One of our underpinning principles of successful commercialization, derived from our years of experience in all the industries where we are active, is that we work with the customer for our research at the outset and try to incorporate our R&D into their business strategy, rather than finalize the research in isolation and then try and find a buyer for it. Acceptance of this principle means that projects are often funded, at least in part, by the eventual customer, even at early strategic stages.

The reason we apply this principle in commercialization is the need to consider complementary assets of commercialization partners. The innovations arising from CSIRO are usually technical knowledge about how to do things better than the existing state-of-the-art. In order for something new to deliver value to the consumer, it must be sold or used in the market in conjunction with other systems or assets complementary to the technical knowledge. These complementarities include both product aspects (for instance, new genes need to be incorporated into seeds farmers can buy) and supply chain features (such as compatibility with customer's manufacturing, marketing and distribution facilities). Thus, within this context, CSIRO's *modus operandi* does not and should not extend to determining the marketing strategies for products containing CSIRO technology. Whilst most companies that deal with CSIRO are happy to share, for example, a business plan or a marketing strategy for a product that contains CSIRO technology, they are not prepared to share information on their whole portfolio relevant to that market segment.

Equally, they will never allow us to determine the price structure for the technology in various territories as this is essentially a business decision independent of technology.

However, in negotiating commercial arrangements with such companies, it is practical to ensure that owing to the input of Australian technology, the products or outcomes are available here at least as favourably, and preferably more favourably, than in other countries.

THE GLOBAL ENVIRONMENT

"*The ability to clone genes, to put them into plant cells and to regenerate plants from these cells has brought technology to a stage where all our major food groups are being genetically engineered for traits such as pest resistance and particular commercial qualities".*

"Major investment, particularly on behalf of chemical companies, is being made to develop and improve biotechnology applications for crop plants. Areas that are under development include genetically modified crops with in-built disease resistance and to the creation of plants that exhibit particular traits i.e. tomatoes with a high solids content. Engineered fresh tomatoes are on sale on the US and tomato paste from engineered tomatoes is on sale in the UK".

(Reference "Developing Long-term Strategies for Science and Technology in Australia, October, 1996".)

The Development Cycle of the Industry

From a commercial standpoint, the application of biotechnology is in its infancy. Genetically engineered products will go through evolutionary development based on new and enhanced technologies. The technology base is at the Model T Ford stage. There is a long way to go to producing a Ferrari.

(Technology: The Catalyst for Revolutionary Change in Agriculture, Sano M. Shimoda, Bioscience Securities Inc., 1997.)

Biotechnology, and in particular gene technologies, have made major contributions to plant science in the last decade and the advances are now beginning to reach into commercial agriculture. Transgenic crops are being grown in the United States (1995, first crops) and Australia (1996, first crop). There will be a rapidly increasing number of commercial transgenics and they will be grown widely throughout the world. At present in some countries, for example in Europe, there is still public antagonism being voiced which has extended the discussion about the entry of transgenic crops into field production. However, these countries are already accepting the harvested commodities and processed food products derived from transgenic crops. This is true, too, of Japan.

We can expect that regulations and legislation will be in place such that transgenic produce will be a regular component of international trade. There may be a period when regulations pertaining to transgenics will be used as artificial trade barriers in some countries but this is likely to be transient.

The incursion of transgenic plants into commercial agricultural practice will be accepted because the technology offers, along with conventional plant breeding, higher quality products with greater efficiencies in production. Many of the quality traits that will be adjusted by gene technology will be of considerable significance for human health and will increase the market

opportunities for plant-based agriculture. Expectations, too, are that there will be significant yield increases because the new technologies are enabling scientists to break through existing yield barriers and at the same time are providing the opportunities for sustainable agricultural practice. For example, the "insect-proof" cotton (Bt-cotton) now being grown in Australia offers, for the first time, a key component technology for extensive integrated pest management; its positive environmental features are already being appreciated by the public of Australia.

Crop yield increases, along with greater surety of supply, will be of consequence to the great demand for food production over the next several decades. World population growth is such that the present food supply will have to double by 2030. Gene technologies, with their simple delivery package where the genetic code for improved traits is built into the embryonic cells of the seed, will enable subsistence agriculture in developing countries to profit in time, as well as the extensive agriculture of developed countries.

The principal focus of this paper is on plant-based biotechnology; because of worldwide community concerns about biotechnology and animal welfare, exemplified by Dolly the cloned sheep, animal gene technology has been slow to develop. Once these concerns are allayed, and an appropriate regulatory regime is in place, this status could change. Those companies with the appropriate asset base, expertise to understand and use the technology, and capital to acquire it could rapidly disseminate gene technology, especially if vertical integration occurs.

The Role of Multinationals

Large multinational companies, previously based in the agrichemicals business, have increasingly oriented their business systems to gene technologies through internally restructuring to consolidate these high-risk – high-return activities into a single business unit. They have also made strategic mergers, particularly in the last 12-18 months; for example AgrEvo is a merger of Hoechst and Schering, and Novartis is a merger of Ciba-Geigy and Sandoz. Probably the largest player at the moment is Monsanto. These multinationals are not only acquiring specialist gene technology companies that have been successful over the past decade, but also seed companies. They have changed their strategy from being technology purveyors to developing a vertically integrated system, where they can maximise their profits from gene technologies through the direct sale of seed to large-scale agriculture at a global level. It is possible that in the future their vertical changes will continue to cover major food processing companies or even extend to marketing fresh produce but as yet this has not happened to any significant degree.

There is a second run of quite powerful players, such as Zeneca, Rhone-Poulenc and Du Pont. Du Pont is likely to form a close operating alliance with Pioneer, one of the major seed companies of the world. Rhone-Poulenc is forming alliances with Groupe Limagrain, the fourth largest seed company, and another important alliance is Dow Elanco and Mycogen.

These relatively few players, through their intellectual property holdings and their vertical paths into agricultural production, are becoming increasingly important in international markets and they are beginning to influence the Australian scene. The initial focus of these companies has been the major crops - maize, cotton, soybean,
canola - and in their second array, they are now setting up their business systems in potatoes, wheat, rice and barley.

Impact on Australia

The strength of the large multinational companies in plant gene technologies is beginning to affect Australian agriculture. Outside the USA, Australia is the first country to commit to large-scale commercial planting of transgenic crops and this trend is expected to accelerate rapidly. However, it is the intellectual property holdings of these companies that are beginning to limit the operation of the Australian research providers for Australian agriculture. Because these companies were early, large investors in plant gene technology research they were able, in many instances, to gain powerful intellectual property positions in some of the key enabling technologies. In other cases they have acquired those key enabling technologies from public research institutions or small companies through licensing and acquisition. The consequence, now becoming evident, is that in many cases, these large companies are not willing to grant licences for their enabling technologies. In some cases this is because of litigation concerns, particularly in crops that may be small on a world scale but still of considerable consequence to Australia, and in other cases because they are still in the process of building their global business system strategies. Apart from the delay, it is unlikely that Australia will be able to feature as a significant player in most of these crops unless we invest in research programs that target complementary or competitive traits.

Australian plant gene technology research is of high international standard and in some areas leads the field. Even though over the past few years the leading Australian laboratories have become aware of the need to protect the outcomes of their research and have been enhancing their expertise in the protection, registration and acquisition of intellectual property, there are two factors of overriding importance. Firstly, although we have excellent plant gene technology research, we are only 2% of the world scientific activity and there are a number of other laboratories around the world of equal excellence. We have good international research linkages and this is still a strength to Australia. Nevertheless, we have to be aware that there are a lot of discoveries being made elsewhere that are becoming protected by intellectual property tools with regard to their availability for commercial agriculture, even though we still have ready access at the research level.

The other factor of importance is that the public research institutions in Australia, although skilled in research and increasingly in the protection of the research results, are not resourced to the level needed for the management and protection of intellectual property on a world scale. In our own experience, in the Gene Shears company, the association of CSIRO with Johnson & Johnson, a major international pharmaceutical company, and to a lesser extent with Groupe Limagrain, a significant seed company, has been absolutely critical for the management of the intellectual property portfolio, without which Gene Shears would have no future.

The participation of a major, experienced company like Johnson & Johnson provides direct expertise and advice but also, by virtue of its size and global positioning, protects Gene Shears from some intellectual property attacks.

THE ISSUES AND CASE STUDIES

The major issue is, bearing in mind the current development cycle and market dominance of exclusively foreign-owned multinational companies, how best can Australia capitalize on its publicly funded biotechnology ?

Before answering this question from the CSIRO perspective, it is instructive to look at our experience in commercialising biotechnology, which has been mixed and can be categorised in the following ways:

1. No Customer - slow commercialization
2. No regulatory regime or consumer acceptance – no commercialization
3. Early days - uncertainty with little benefit to Australia
4. Scientific excellence and effective networks – substantial benefit to Australia

Examples of case studies relevant to each of the above categories are given below.

1. No Customer - Slow Commercialization

Case Study – CSIRO Prawn Project

Within four generations we've got 20-25% improved growth simply by selecting on external characteristics alone.…..CSIRO is trying to……free itself from vagaries of public funding cuts. This research has already happened so the intellectual property is owned wholly by CSIRO.

(Interview with Dr. Nigel Preston, CSIRO Division of Fisheries; "Superprawns Challenge Aussie Curse", Simon Grose, THE CANBERRA TIMES, Saturday January 11, 1997.)

Although not a gene technology, our experience with improved prawn breeding is instructive. For many years the CSIRO Division of Marine Research has worked on the selective breeding of Kuruma prawns (*Pinaeus japonicus*) at the Brisbane Laboratories. This research was fully funded by CSIRO.

The collective know-how of the research team developed 20-25% improved growth by selecting on external characteristics alone i.e. by choosing the biggest prawns as parents.

The researchers became frustrated in their attempts to attract investors and for a period of time there was danger that the technology would be licensed to an overseas company, so threatening Australia's competitive edge in prawn farming. The CSIRO researchers were faced with all the ingredients of the old Australian paradigm:

- The need for a quality primary product
- The need for the best technology in the world
- Small companies who want the technology but don't have the resources or incentives to support the introduction of the technology for the market
- Large companies, conservative by nature, uninterested in taking risks in a new area
- Public funding sources whose conditions on grants are difficult to satisfy.

CSIRO attempted to exploit this technology through the establishment of a consortium; however, this route failed because the potential members could not come to a mutually acceptable agreed position. This case study is an example of CSIRO adopting a technology-push approach without first investigating the potential acceptance of the technology in the market place.

The Lesson: Having a suitable customer (with finance and appropriate capabilities) working with the research team at the outset of a project greatly increases the likelihood of successful commercialization.

2. No Regulatory Regime or Consumer Acceptance – No Commercialization

Case Study – Bresagen / Bunge

This pig costs $12M and as yet we are not permitted to bring it to the market.

(Reference: Interview with Dr. John Smeaton, published in DER SPIEGEL, May 12, 1997.)

Despite posing no risk to human health, Bresagen has been unable to sell surplus transgenic animals for human consumption because of a lack of Government policies in this area.

(Flight Regulations for Pigs: Dr. John Smeaton, paper presented at the LES ANZ Annual Conference – Perth, 1997)

Bresagen produced a line of commercially viable pigs with enhanced growth hormone production with the advantage that the pigs grew faster for a given amount of food, putting on more muscle and less fat. Because there was no regulatory agency prepared to approve the use of these animals for human consumption and declare the technology safe, Bunge has slaughtered all the pigs and the germplasm is in existence as semen (and perhaps ova) stored in liquid nitrogen. It is highly likely that this technology will go overseas. It is not the inability of the Australian company that produced the pigs to commercialise them but the lack of a regulatory pathway that has caused the problem.

The Lesson: Without public and regulatory acceptance, the commercialization of excellent technology will fail.

3. Early Days and Uncertainty

Case Study – Calgene's FlavrSavr

In the early 1980's, recognizing the importance of tomatoes as a high-value, major volume crop, CSIRO began research on what vegetable markets had identified as the key challenge – why do ripe tomatoes soften when they ripen and so become difficult to transport. The work at North Ryde identified and partially sequenced the enzyme polygalacturanase (PG), which softens cell walls once the fruit is ripe.

At the time, in 1983, owing to the lack of a commercialization partner in an unstructured industry, and the call on resources required to go further, the work was stopped and the

intellectual property sold for $20, 000 to the new start-up company, Calgene, in one of the earliest transactions of its kind in the world. After tens of millions of dollars expenditure on research (to "switch-off" PG) and regulatory clearance, Calgene brought the product successfully to the USA market. However, consumers soon found that the flavour difference between FlavrSavr and "ordinary" tomatoes was not significant and did not warrant the price premium associated with FlavrSavr. The growers found that their increased costs (associated with licensing fees) were not offset by better yield (yield was less than "ordinary" tomatoes) and better sale prices.

On the other hand, in a competing technology, Zeneca's genetically modified tomato (with high solids and therefore "bulkier") was found to be cost effective and is enjoying very good sales in the UK for processed products such as tomato paste, principally because of the marketing efforts of the major retailer selling it.

Later Tomato Work

There is, however, a strong follow-up to our early experience. 1992-93 studies on alcohol dehydrogenase levels in tomatoes as they matured led to the hypothesis that an increase in alcohol dehydrogenase activity early in the ripening period of a tomato may substantially improve the flavour in fresh tomatoes such that they could still be transported while firm and yet have flavour when they reach the consumer. This idea was discussed with Zeneca who were in the process of taking commercial tomato products to market. As a result a joint project was mounted between Zeneca, the Horticulture R&D Corporation and CSIRO to take this idea to proof of concept. The project is partly completed and so far has been successful. Contract conditions, as well as obtaining direct research funding from Zeneca, also call for Zeneca to maintain the cost of Intellectual Property protection for this idea, and in return they have the first right to negotiate the commercial outcome with CSIRO should the project be successful.

Transformation of tomatoes was carried out by a CSIRO employee in the Zeneca laboratories at Jealott's Hill in the UK. The material was then returned to Australia for further analysis, and thus far experiments have been successful with double blind taste-tests showing that the chosen tomatoes do have improved flavour. The current experiments plan to use English and Australian tomato lines to confirm this proof of concept. Zeneca has already taken transgenic tomato products to market successfully and has the resources available in terms of enabling technology and market experience to take this product to market if proof of concept proves successful.

The strategy in this project has been to form an alliance between CSIRO and an international company with proven capacity to get material directly to market.

The Lesson: In most cases, Australia alone does not have the resources or market access, or often the total required intellectual property, to take successful discoveries in biotechnology to the global markets these products can command and need to recoup investment in R&D.

4. Scientific Excellence and Effective Networks - Substantial Benefit to Australia

There is an opportunity for Australia now to gain effective entry into the global agribusiness systems, with protection and advantage to Australian agriculture. Although licensing is becoming less common, the companies are interested in acquisition of new intellectual property, which could be of advantage to them in our effective linkages of research into agricultural practice. The multinationals recognise that this country has some of the most effective plant gene technology research teams in the world and that these are likely to be of consequence in the development of their own business systems. They are willing, in most cases, to consider trades with some of their intellectual property.

Importantly, since the companies have gone into vertically integrated systems, Australian public researchers can sometimes extend their bargaining chips from intellectual property to germplasm. Where Australia has something of great value in either or both of these categories, there is an opportunity for it to be used as a catalyst for the generation of a strategic alliance between a major multinational, an Australian public research institution and, where possible, an Australian company or companies.

Conditions for Alliance Formation

We are likely to be able to forge these alliances because of our excellence and achievement in plant science research and our effective linkages of research into agricultural practice.

In forming these strategic alliances it will be very important to define the perimeters of the alliance carefully because an Australian public research institution needs to be able to form alliances with more than one of the multinationals for maximum benefit to Australia. This flexibility is indeed possible and the multinationals are quite comfortable with this policy provided the perimeters are drawn respecting crops and territories.

Case Study – Cotton

CSIRO's Division of Plant Industry has built up an international recognition for its excellence in cotton breeding. Since the release of its first varieties in 1984 when 100% of cotton seed planted in Australia was of the American Deltapine varieties, now CSIRO varieties are 94% of cotton seed planted and are out-performing the Deltapine varieties.

The cotton industry, through the Cotton R & D Corporation, gives strong support to the breeding programs and there is effective transfer and adoption of new varieties through the licensing arrangement between CSIRO and Cotton Seed Distributors, a non profit industry-based company set up to provide high quality planting seed to cotton farmers. All cotton farmers in Australia buy 100% of their planting seed each year.

In the licensing agreement with CSD, CSIRO retains full ownership of the germplasm, which is protected under Plant Breeders' Rights. CSD has been granted exclusive licence for our varieties for production and marketing of seed worldwide; it has the right to sub license only with our agreement. A royalty is paid back to CSIRO based on a percentage of the selling price and this royalty is shared on a proportional equity basis with the Cotton R&D Corporation. The relationship between CSD and CSIRO is excellent with very good communication and interaction; it is based on mutual trust built on high performance by both parties. CSD, in

addition to the revenues provided to CSIRO through the sale of seed, make substantial investments in support of the long term CSIRO research supporting the cotton industry. The interaction with CSD is critical because the late-stage large-scale trialing of elite material would be beyond our capacity to carry out and to finance. CSD accepts these responsibilities and we work in close collaboration.

Transgenic Cotton

When it became apparent that the cotton industry in Australia would be in difficulties through the developing Heliothis-resistance to available chemical insecticides, CSIRO proposed, initially to CSD, that they should initiate molecular biology research in cotton. We established that the optimum strategy for the introduction of an effective Heliothis insecticide gene would be to form a relationship with Monsanto. The basis of this decision was that there was heavy and complex intellectual property protection, with a number of players. Monsanto appeared to have a strong position and certainly had the most effective science. CSIRO negotiated a research contract with Monsanto and made provision for a commercial relationship to be formed between Monsanto and CSD. The Monsanto-CSIRO interaction was made possible because of Monsanto's recognition of the high research capability of the CSIRO group. Both CSIRO and Monsanto worked together to gain regulatory approval for the first transgenic crop in Australia. When the approval was given, CSD, under commercial agreement with Monsanto, was able to sell, under NRA regulations, the transgenic seed for the 1996-planting season. They negotiated an intellectual property licence with Monsanto.

It was important that CSIRO restrict its relationships to the research phase and not be involved in any direct commercial negotiations on business.

The relationship between Monsanto and CSIRO has been effective but was not without its difficulties at times. CSIRO found Monsanto to be slow in providing information and there was certainly a learning phase for the two parties in establishing an effective working communication. Similarly the small Australian company, CSD, had to find an appropriate way of working with the large multinational at the commercial level.

An International Business

CSIRO initiated discussion of the possibilities of sale of Australian varietal seed in other countries and consultation with the industry, through the Australian Cotton Growers' Research Association, the representational body of the industry. The international sale of Australian cotton seed was something the whole industry considered very carefully. Initially, the industry felt that the availability of our cotton seed elsewhere in the world could disadvantage the Australian industry.

Our varieties are protected by Plant Breeders Rights but this in itself makes our seed available to be used by other breeders in the development of their own cultivars so there is no direct way of protecting our germplasm beyond a certain time period and beyond certain requirements of novelty. The industry recognised this and also recognised that our breeding program needed to provide a continual flow of increasingly improved varieties. They saw that if we were offering what were basically outmoded Australian varieties at the international level, we ought to be able to further benefit the Australian industry through the profits of international seed sales and yet in no way reduce our competitive position in the international market. It was agreed that this would

not harm and in fact would be likely to benefit the Australian cotton industry, an attitude paralleled in the wine industry.

CSD carried out international trials in a number of countries and set up a new company, Cotton Seed International (CSI), with responsibilities for running an international business. CSIRO agreed to a sub licensing to CSI. Subsequently, CSI formed a joint venture (CSE) with LGI, itself a joint venture between, Groupe Limagrain and Rhone-Poulenc. CSE has begun a cotton seed selling business in Turkey, Spain, Greece and Brazil. Once again CSIRO received royalties and maintains ownership of the original germplasm.

Transgenic Cotton in the International Market

Competition from CSI brings an unheralded player to the table. Adding to the competitive pressures on Delta and Pine Land in 1998 and beyond will be the addition of CSI to the competitive picture. CSI is the international subsidiary of CSD, the Australian cottonseed cooperative…..Additionally, CSD has exclusive access to the biotechnology of CSIRO, the Australian equivalent of the USDA. CSIRO has an extensive biotechnology research effort underway with projects to develop a wide range of value-added genetic traits

(Broker report by Godsey and Shimoda "Delta and Pine Land Company – Sell", Biosciences Securities, Inc, Orinda, California, February 1997, p11)

International trials of the CSD-CSIRO Australian cotton varieties has shown our varieties to be of exceptional performance in a wide range of conditions in cotton growing areas around the world, including the major production areas in the United States. The high performance of the Australian varieties opened up the opportunity of marketing the CSIRO conventional and transgenic varieties in the United States. One disappointing aspect of the CSD-Monsanto commercial interaction was that Monsanto excluded CSD from international marketing of their transgenic cotton varieties.

The results of CSD trials in the United States attracted a great deal of interest from other seed companies, particularly those associated with multinational organisations. This provided an opportunity for CSD and CSIRO to consider forming an association with one of the multinational companies which could provide extensive advantages to Australian agribusiness.

The Lesson: Outstanding science that generates valuable intellectual property can, through licensing, provide Australia with a lever to access technology of great benefit to Australia on advantageous terms.

Case Study – Lepton Test Kit

Abbott Laboratories developed a diagnostic kit to identify between two species of moths (Heliothis *armigera* and *panltigera)* with the CSIRO Division of Entomology and a Queensland SME (Pan Bio). The product has been technically very successful. Abbott is sufficiently pleased that they have commissioned the same group to do similar thing for the very competitive American market.

The Lesson: That CSIRO and an Australian SME, with access to the resources of a multinational, can work together and take genetically-based technologies to the world.

Case Study - Polyphenol Oxidase Technology

In early studies of grape berry browning, polyphenol oxidase was identified by the CSIRO Division of Horticulture as the enzyme which was responsible for the browning and degrading of colour quality of dried grapes. The same enzyme was also identified as a critical enzyme in postharvest management, particularly during processing, for such crops as potato, banana, lettuce, pineapple, apple, pear and many vegetables which are subsequently partially or wholly processed. This finding was immediately patented.

Fruit and Vegetables

The work for other fruit and vegetable crops is thus an offshoot of the original project, and as a result CSIRO advertised for expressions of interest in commercialising this technology in fruit and vegetable crops. All applicants have to satisfy CSIRO on two points: 1. that they are able to make the technology available in Australia under no less favourable conditions of price and time to market than in other countries, and where practical involve Australian industry in the development; 2. that they have control of sufficient enabling technology to take the polyphenol oxidase technology to market in the crops for which they nominated. To date contracts have been signed with Zeneca for lettuce and bananas, and with a small Canadian biotechnology company, OBI, for apples and pears. Contracts are under consideration, or in the final stage of negotiation, for potatoes. This is an example in which the polyphenol oxidase technology is valuable and has been able to attract commercial partners with access to full enabling technology to ensure access to the worldwide market. Royalties are returned on sale of polyphenol oxidase technology products to Australia.

In addition CSIRO has obtained an additional research contract from Zeneca to further the technology.

Transgenic Grapevines for Australia

The strategy for transgenic grapevines is different and because of the long period of time required to get a transgenic grapevine product to the market. The first transgenic grapevines in Australia were obtained nine months ago, but these plants have no commercial value. The first plants containing modified polyphenol oxidase activity will be available for planting in the spring of 1998. Given the long growth period of grapevines, evaluation of fruit will not be complete until the Year 2004/2005 and if successful, material will have to be multiplied-up for distribution to the Australian grapevine industry. The strategy for transgenic grapevines has been to concentrate on the Australian application so producing a different plan to access enabling technologies than would be the case for international exploitation. This route will allow us to minimize the enabling technology we have to develop ourselves while optimizing the enabling technology that either will be out of patent at the time and available for commercial application or is not protected in Australia and thus can be used.

The Lesson: Each application of gene technology needs careful planning to meet individual commercial outcomes.

ALTERNATIVE STRATEGIES

We have indicated through the examples above that our differentiated, partnership approach has resulted, and will result, in appropriate return to Australian industry.

However, an alternative approach might be for the intellectual property of Australian research institutions to be consolidated to present a more powerful portfolio for bargaining and deal making. The formation of a centralised intellectual property company of this sort was not a success in the United Kingdom and the consolidation of discoveries is likely to be of importance only where they are in the same business system. These cases can be easily accommodated in the strategic alliances discussed above. For example, in one strategic alliance that we are currently forging, CSIRO Plant Industry was able to present intellectual property positions and discoveries from three CSIRO Divisions and from the Research School of Biological Sciences of the Australian National University.

In our view, however, there are some major disadvantages of such a consolidated approach

- the link between research and the customer end-user is broken, lengthening the time-to-market and the chance of success. A consolidated approach would only work if the intellectual property to be aggregated was unencumbered and so available for sale or licence

- it is very unlikely companies with crucial enabling technologies and complementary assets would work with, and thus fund, anyone but that group with the expertise.

- a level of bureaucracy would be introduced that would add little value to the commercialisation process.

CONCLUSION

With the overall goal of bringing benefit to Australia through leverage of our intellectual property, CSIRO is at various stages of discussion with SMEs and multinationals about specific technologies or strategic relationships. We believe we are in this position because we enjoy a reputation for scientific excellence and a strong intellectual property position and because we are able to deal flexibly with the differing commercial requirements for our customers. Furthermore, we have spent a great deal of time training our research scientists to understand the commercial requirements of our customers, and to ensure specialist commercial and legal skills are available when needed.

It is our opinion that the establishment of a stand-alone IP company would greatly reduce the flexibility required to exploit agricultural biotechnologies, without adding any value other than cost and complexity, and so is a route less likely to be successful than that exemplified above.