

PRIME MINISTER'S SCIENCE, ENGINEERING AND INNOVATION COUNCIL

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Canberra

PROFITING FROM THE BIOTECHNOLOGY REVOLUTION

Summary

Recent advances in biotechnology will have profound effects in a wide range of fields, including agriculture. Some products of biotechnology are already appearing in Australian agricultural markets. It is rapidly becoming clear that we could lose the benefits of our research in agricultural biotechnology, including to large, foreign-based companies, which have the capacity to convert research into valuable products which are well protected by patents and licensing arrangements. The size and vertical integration of these companies allows them to control tightly the path to market for agriculture-based products. Australia must, therefore, develop sophisticated strategies to optimise the value of our research efforts, or we will not be able to negotiate the use of agricultural biotechnology ten years from now.

An ad hoc working group, chaired by the Chief Executive of CSIRO, Dr Malcolm McIntosh, identified a number of options to achieve this:

- Streamlining regulatory procedures, introducing public awareness campaigns, and examining research priorities;
- Facilitating development of expertise in handling commercial aspects of intellectual property (IP);
- Maintaining our germplasm (seed) collections as valuable national biological resources;
- Encouraging more production and commercialisation of Australian biotechnology; and
- Changing the international patent system to be far less supportive of monopolies in genetics

The working group recommended that these issues warranted further consideration by Government.

Presentations were given by Dr Oliver Mayo, Chief of Animal Production, CSIRO, and Mr Graham Windeatt, CEO of the Cotton Seed Distributors' Cooperative.

The paper was prepared by an independent Working Group for the PMSEIC and the views so expressed are those of the Working Group and not necessarily those of the Commonwealth.

Introduction

In what is probably the most profound technological revolution ever in terms of its effect on the human race, scientists are now able to define the biology of living organisms at the molecular level, and modify those organisms. This is opening up a wide range of exciting prospects in genetics, human health and pharmaceuticals, agriculture and many other fields. Some genetically modified organisms and their products (such as drugs, for both humans and animals) have already been commercialised. The prospect of high profits has encouraged a proliferation of organisations seeking to exploit the new technologies.

Australian researchers are contributing at the cutting edge, and some of the science will be outlined during the presentation to PMSEIC. This paper concentrates on the issues that need to be addressed so that Australia can maximise the benefits it can derive from the biotechnology revolution.

Industry Structure

Recognising the potential of the biotechnology revolution, large pharmaceutical and agrochemical companies have invested in extensive research and development in their own laboratories and have sought access to research in university and other research organisations. There has been a proliferation of small start-up companies, often spinning-off from universities and taking core inventions with them.

As well as doing their own research, the large companies are keenly interested in the activities of these small companies. The usual strategy is to wait until they fail, in which case the large companies can buy key patents and staff cheaply, or if they succeed, to buy them out quickly before they become too successful and expensive. The small companies are aware of these tactics; some aim to become a valuable acquisition by proving a technology and being bought long before producing and selling a product.

Only very large companies can afford the time and cost of the final stages of proving and bringing a product to market. The dominance of such companies in pharmaceuticals has been apparent for some time and it is now emerging in agri-business.

Several global companies such as Monsanto are rapidly achieving vertical integration from seed, through genetic manipulation, to processed food and its distribution. If this trend towards consolidation continues there may be only a handful of globally dominant agricultural biotechnology companies in another few years. By combining patents, production and exclusive arrangements, such companies will either own or tightly control the path to market for agriculture-based products. The European Union has just allowed patenting of genes, which will accelerate the trend. Australia must therefore develop sophisticated strategies to optimise the value of our research efforts, or we will not be able to negotiate the use of agricultural biotechnology ten years from now.

Intellectual Property (IP)

In industries like electronics, profit from innovation comes from clever ways of doing things and how quickly a product can be brought to market. This is not the case in most areas of biotechnology. The race is to be the first to patent, followed by an often extended period of expensive development, then a period of very profitable monopoly sales for the remaining life of the patent. Takeovers of small companies are aimed at acquiring both patents (or

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knowledge that is close to being patented) and the scientists with the innovative skills to invent more. If alternative technologies do not emerge quickly to restore competition, biological monopolies can be extremely powerful.

In pharmaceuticals, only the monopoly purchasing power of a national health system can limit monopoly prices. But in agriculture, there are no naturally occurring countervailing economic forces. A new veterinary drug may be easily the best approach for a specific disease and may capture the entire market for its control. A genetic innovation may gain a company control over an entire crop, leaving farmers at a distinct disadvantage in terms of their profitability. In such cases, the company can not only control the price at which the grower can obtain seed, but also the timing and extent of seed availability, the agronomic conditions under which it is grown and, in future, the companies that can buy the crop.

The National Interest

A large market based on a large and affluent population is essential for the commercialisation of many biotechnology products, which is why the large multi-nationals have originated in the USA, Europe and Japan. In many areas of industry, Australia has suffered from having disproportionately few locally-owned producers and from having much of its production supplied by local branches of overseas based multi-nationals, who derive their technology from their overseas parents. These factors lie behind an incipient weakness in the industrial production and sale of biotechnological products in Australia.

The largest benefits from research and development come from commercialisation of the technology, which requires manufacturing, marketing and distribution facilities. When Australian researchers make a break-through there are few, if any, local firms able and willing to complete development and bring the product to market, or with the international infrastructure to sell it effectively. Accordingly, it is often sold overseas where it is beyond Australian influence, only to have Australian consumers buy the product back later at high prices.

The national interest comprises the collective interests of inventors, producers and consumers, and their various financial and other supporters. The interest of the Australian consumer is to have access to the product as soon as anyone else and at no greater price. This is particularly important for intermediate products (eg a herbicide or genetically modified plant) because lack of access or a higher price could adversely affect the competitiveness of all downstream production. The interests of the consumer can be protected if the technology is sold to an overseas producer on condition that the product is provided promptly and cheaply to Australian consumers. CSIRO has been able to obtain sufficient leverage that several recent contracts have included such provisions.

A more direct link to Australian consumers is provided when the technology is taken up by local industry. Fortunately there are a few Australian companies of sufficient substance to do some of this in biotechnology, but our size and small share of world innovation (approximately 2%) means that we will inevitably be in the position of seeking commercialisation of our biotechnology through alliances with multi-national companies. This is a commercial reality rather than a concern, but we should focus on ensuring maximum returns to Australia for the knowledge (or intellectual property) we produce.

Some Policy Options

Within the constraints of current funding, biotechnology research is flourishing in Australia. Continued innovation is important as new break-throughs will result in technologies that can compete with those already on the market and thereby reduce the adverse impact of global monopolies. For example, the Bt gene is not the only one that can be used to assist insect control in cotton growing. The sooner a wider suite of genes is identified, the sooner potential monopolies can be countered.

It is crucial to maintain a healthy rate of innovative research, but we can also improve the way in which we allow our IP to be commercialised and address other impediments. Several options might be considered:

1. Streamline regulatory procedures, introduce public awareness campaigns, examine research priorities

These are ongoing government responsibilities that need to be accelerated if Australia is to provide a positive environment for the development of gene technology.

Regulatory procedures: There is an obvious need for the application of gene technology to proceed in a regulated manner to ensure safe and sensible use in our communities. However, the lack of a well-defined regulatory framework for the commercialisation of gene technology continues to be an issue.

Without a clear regulatory framework Australian industry faces a major impediment to using biotechnology, whether from Australian research or from international sources. Any lack of early experience with the technology is likely to limit the competitive position of Australian agriculture and food industries, reducing the benefits the nation receives from its significant research investment. Consultations between the Commonwealth and the States are currently in progress.

Public awareness: Public acceptance of the benefits of the technology largely depends on effective public awareness campaigns that identify the forms and incidence of risk, and the means to assure the safety of genetically modified products. This is a joint government and industry responsibility.

Research priorities: Although some 5 to 10% of agricultural R&D is directed to gene technology, a greater proportion may be needed in future. Research funding and performing institutions will need to examine their resource allocation priorities to ensure that Australia derives the optimal long-term benefit from our participation in this technology.

2. Facilitate development of expertise in handling commercial aspects of IP

There have been remarkable success stories as well as disappointing failures in the management of public sector intellectual property in gene technology.

Many Australian research institutions are grappling with this area and searching for the best ways to handle the commercial aspects of biotechnology IP. Issues include how best to add

value to IP to a level that maximises returns to Australian business and institutions, to trade IP for access to other IP, and to structure spin-off companies when these are appropriate.

A number of factors influence the successful commercial application of intellectual property.

International trends are moving away from trading individual pieces of IP towards more complex development of products based on IP contributed by a range of groups. For example, some IP may be in the form of patents for the initial 'discovery' and other IP in the form of technology to enable the application of the 'discovery'. Biotechnology is extremely complex; there may be eight or ten structural elements involved in the function of one gene, all of which might be patentable.

Successful commercialisation of Australian IP has seen researchers themselves working closely with commercial partners and there is strong feedback from companies that they need to be in direct contact with the research group.

Many companies are working collaboratively with research groups towards innovations, by providing funding and 'enabling' IP; these links are valuable as the flow of IP and innovation is not one-way.

An important contribution that a large multi-national company can make to the process of commercialisation is the provision of financial resources to defend IP. This is especially important in the early phases of work when the likely returns from the discovery are not well defined but could be very large. By negotiating directly with multi-nationals, research groups are able to gain access to this resource at the very early stages of development.

One recent suggestion has been to establish a national gene technology commercialisation company to protect and exploit Australian biotechnology by trading with global companies that have the capacity to bring discoveries to market. While this proposal might provide small groups with access to a greater level of expertise, there are other ways of addressing this need. The notion that one organisation could effectively co-ordinate such complex interactions and deals on behalf of many parties is unrealistic. It would not be feasible to structure an organisation with the level of expertise required for effective commercialisation of a range of biotechnology as well as the financial resources to defend a large collection of patents.

So what should we be doing to improve our record in this area?

Research groups who have been able to commercialise their discoveries successfully are those who have acquired skills outside their normal area of scientific expertise. These skills have led to the production of sound business plans, an appreciation of the patent laws affecting the technology (and how to tap professional expertise), appropriate commercial structures for spin-off companies and structuring of royalty payments to obtain appropriate returns to the core research group.

Forums for exchanging know-how

Investment in improving these skills in research groups is a very direct and effective method of ensuring a greater number of Australian discoveries reach their potential markets with returns to Australia being maximised. We need to establish a framework for research and industry

groups to share with each other the ways in which discoveries have successfully been brought to fruition. To facilitate this process a program of workshops and training grants could be implemented.

For the latter there is a need to draw on strong legal/contracts and patent expertise, people who recognise what the global benefit can be. Education for this kind of expertise is difficult to achieve. Australian researchers and professional legal and patent people all need to hone their skills and strategies, drawing on each other's experience. There are no good 'sets of behaviour' covering how to deal with powerful international alliances.

Forums for sharing experience would be 'by invitation only' for public sector researchers and business managers involved in biotechnology R&D and commercialisation, bringing in some private sector people and legal/commercial/patent experts. Such fora could lead to targeting a global company with an Australian alliance covering several industries/crops, and driving a better bargain. The key aim is to avoid monopolies and create alternatives. It is important to ensure that those who are already good at strategy and negotiation continue to be good, while helping others who can potentially do well to link in quickly. Critical mass is needed to raise rapidly the level of competence and strategic know-how.

It should be mandatory for small players in universities (facilitated by the Australian Research Council), Cooperative Research Centre Program, State Departments etc to come to these fora. Otherwise, when they are targeted by global companies, their IP will be bought up cheaply and there will be minimal benefit to Australia, while the global company could reap large profits.

A related issue is the extent to which the universities can protect their innovations. While the initial costs of patent protection in a number of countries for even a single innovation are considerable, the returns to the public sector institution are uncertain and generally not large.

Development of alliances

Australia is becoming aware of the need to be strategic in order to achieve national benefit from biotechnology. We need to develop sophisticated alliances which might involve, say, CSIRO (drawing on university research groups as appropriate), an Australian user/funder such as a rural industries R&D Corporations, an Australian marketing agency and possibly other Australian agricultural companies, all working with and linking to an international company in biotechnology (with its enabling technologies, traits technology and genomics - available genes) and an independent international company in international distribution and marketing.

A pre-requisite is for Australian researchers to be supported to be creative, develop international links, and form centres of competence or receptors with which the global companies want to deal. Such centres will be attractive to smaller companies as well, through which alternatives can be developed to break monopolies. Australian research groups need to have the right alliances to give them leverage before they talk with the global companies.

Inclusion of a 'no Australian disadvantage' clause

Government funding for biotechnology should be given on the understanding that recipients agree to a 'no Australian disadvantage' clause in any sale, licence or partnership arrangement, or for technology only to be licensed, not sold.

The no disadvantage clause should be part of all Commonwealth research funding arrangements, including CSIRO, the Australian Research Council, the rural industries R&D Corporations and the Cooperative Research Centres. It could also be a requirement for publicly funded groups to have to obtain approval for the final step in a commercial agreement. There are precedents for this in the CRC Program and with at least some of the rural industries R&D Corporations. Similar considerations will need to be part of development assistance programs operated by AusAID and the Australian Centre for International Agricultural Research.

With such a provision in place, Australian institutions can bargain for performance-oriented exclusivity so that Australian companies have the best options available to use biotechnology in Australia and globally.

3. Maintenance of germplasm collections

The vast variety of Australian native plants provides a pool of genes that may have economically valuable uses - characteristics that can be profitably used through gene technology. Cultivars or varieties of economically significant crop plants have similar potential value as the 'homes' of modified genes. Australia has significant collections of specimens of these plants that can be propagated if necessary. Together the natural resources and collections represent a unique and highly valuable resource.

We have to ensure that the resource is not sold off cheaply, in the case of native plants, or allowed to deteriorate in the case of the collections. Australian groups should retain ownership of their cultivars. If CSIRO had not owned a set of cotton cultivars, it would not have had a negotiating lever with Monsanto in the Bt cotton case.

In each case, a strategy to ensure that Australia has long term access to these natural and collected resources must be developed.

4. Encourage more production and commercialisation of Australian biotechnology

Were such policies to be pursued, there are many approaches that might be advocated and policy tools used to promote them. Without Government leadership in this field, however, Australian IP will leave the country at a very under-developed stage, with little monetary return.

One policy that could be implemented within the scope of an existing Government initiative is to tailor the *R&D Start* grants of the Department of Industry, Science and Tourism so that they can encourage biotechnology commercialisation. *Start* funding is normally provided for a term of up to three years, with possible extension, under certain circumstances, to five years. Compared with many other fields, biotechnology faces additional hurdles during commercialisation, in that more time is required to take the development of the basic IP through the process of trialing and the regulatory framework that surrounds biotechnology, especially genetically engineered organisms. Consequently, a longer project time-frame of some seven to eight years is needed if many more companies are to be able to draw on *R&D Start* funding for production and commercialisation of biotechnology.

Encouraging existing medium-to-large Australian companies to grow and increase their portfolios of biotechnology innovations has the great merit that the companies already exist and know how to do business. It is likely that expansion of these companies would be encouraged by such marginal changes in policies and programs.

On the other hand, growth of start-up companies in Australia is handicapped, compared with Europe and the USA, by the lack of a large domestic market and by much less ready access to venture capital: these problems are not readily addressed in the same way.

Takeovers of promising Australian companies are relatively easy and our economy will continue to be at a disadvantage because of this. Consideration should be given to relevant aspects of Australian commercial law, particularly on how we should best protect the results of Australian research. In doing this, Government would need to take into account the broad directions in Australian corporate law reform. One possible approach is for Government to protect its domestic research through its contracts with private companies. This could be done by, for example, provisions in the contract that would permit intellectual property to revert to the Government in the event of acquisition by another company. However, it would need to be recognised that any such restrictions on intellectual property disposition would reduce the value of that property.

Incentives to set up cooperatives (which make takeovers much more difficult) and possibly other strategic relations would also be worth considering.

5. Change the international patent system to be far less supportive of monopolies in genetics

Because gene technology is novel, patent systems have had to make decisions on the breadth of the protection given and the nature of the invention that it is patentable. There is a view that in some cases, broader than necessary patent protection has been given, particularly in the case of naturally occurring genes. This in turn has led to the potential or actual exercise of significant market power.

Given that the commercialisation of gene technology is very expensive, it is doubtful that an adequate level of research and technology transfer will occur unless reasonable protection is given to the intellectual property of the organisations owning the research results. Without this they would be unlikely to recoup costs. Limiting the coverage of a patent, compared with the coverage allowed in many other countries, would probably adversely affect the biotechnology industry in Australia and could have commercial implications for access to the technology.

Nevertheless, Australia's position in relation to the negotiation or renegotiation of relevant international agreements needs to be informed by strategic assessments of the extent of the control of important inputs to agriculture industries by a handful of dominant companies. Care would be needed to ensure that any changes at the international level did not restrict investment in R&D that might be beneficial to Australia, because of inadequate patent protection.

Given the significance of this issue, the Australian Government could explore the feasibility of establishing an international initiative, through APEC or the OECD, or with like-minded countries (similar to the Cairns Group on free trade). It could examine the consequences of the exploitation of market power by global companies as a result of intellectual property rights. This is of concern to a range of developed countries, particularly those that are not in a position to use anti-trust legislation to ensure effective competition. The outcomes might influence World Trade Organization forums such as the Trade Related Intellectual Property agreement (TRIPS).

In many ways the USA is the key. If that country were prepared to work with Australia and others it is probable that agricultural biotechnology monopolies could be avoided; Australia might take the initiative to discuss the issues with the US Department of Agriculture.

Conclusion

The scarcely believable developments in biotechnology are being reflected in new products, new companies and new business relationships. Competition is intense and driven by research. It can be expected to encourage competing technologies and products to emerge, often rapidly.

To reap just rewards for Australia's investment in research we need to ensure our basic work continues to yield innovative IP. At the same time we need to be smart about how we negotiate with commercial partners so that Australia reaps the benefits of our inventions without disadvantage.

We need to assist and encourage industry uptake of IP through innovative programs and procedures, and by ensuring that the regulatory procedures are in place to allow new technology to have a well-defined and prompt passage to market.

Australia has a great advantage in that new agricultural technology is usually very effectively and widely taken up by producers. However, a range of impediments has meant that gene technology has not been adopted with anything like the zeal with which it has been in the United States and Canada. Australia needs mechanisms to help develop technological innovations, and then take a patent or commercial position that provides leverage for the technology to reach the international marketplace and obtain a privileged position for producers and consumers.

The opportunities of gene technology for agri-business far outweigh the impediments. A small number of inexpensive but coordinated policy initiatives - along the lines discussed in this paper - could rapidly improve Australia's positioning for the biotechnology revolution.

Recommendation

That the issues identified by the working group, on opportunities and options for profiting from the biotechnology revolution, should receive further consideration by Government.