

PRIMARY PRODUCER ACCESS TO GENE TECHNOLOGY

PREAMBLE

Australia was an early adopter of genetic manipulation research. The potential dangers were seen and we were represented at Asimolar in California in 1975, at a conference to discuss risk. The Australian Academy of Science set up the first committee, ASCORD, the precursor to the Genetic Manipulation Advisory Committee of the Australian Government.

There was and is, considerable financial support for genetic manipulation work from Government funding into Universities, the CSIRO, NH&MRC and grant giving bodies supported by Government. One such was the National Biotechnology Program, which from 1983 provided about \$5M annually for specific grants contracted to run over several years usually funding each more than \$100k annually. A significant number of grants went to rural interests from trees for saline conditions, control of internal/external parasites of livestock and the manipulation of plants by cloning and genetic change. Many aspects of breeding were considered, be it virus, bacteria, plant or animal.

The Rural Industry Research funds were another source of monies covering specific areas relevant to their electorate and significant amounts of these funds went to gene technology. Of more recent times, the Co-operative Research Centre scheme (CRCs) has introduced significant funds to potential rural applications from this technology.

Much money has been spent in Australia and very much more internationally on gene technology. For all the investment, commercial results to date are small, however, there has been intense activity in protecting the property arising from this investment under various schemes, patenting, plant variety rights etc.

THE FUTURE VALUE AND IMPORTANCE OF GENETICALLY MODIFIED VARIETIES

It is difficult to envisage where there will be no importance in the use of genetically modified organisms. Though over the years Australian scientists and the people of the land have excelled in selection and breeding plants and animals each advance has been stepwise and slow. The new biotechnologies, including cloning and genetic manipulation, allow identical copies to be made of a biological system, plant, animal, bacteria, virus, etc. Genetic manipulation can permit the quality desired in one living system to be introduced into another. Such qualities can be made into inherited traits, eg, the germ line is altered or they can be terminal traits where they are not carried through to the next generation either through sterility or not being included in the germ line.

Australia needs appropriate soil bacteria, salt tolerant trees, plants for human and animal nutrition capable of growing in a relatively harsh environment. Instead of utilising the animals that have adapted to our environment over tens of thousands of years as our meat source we have brought foreign animals, many not acclimatised to this environment. In the main it is only over recent years that we have brought in foreign genes from Africa and India more suitable but these traits are only slowly spreading by the usual breeding techniques.

Our imports of plants, animals including birds has introduced a situation where there is no vector controlling the pests that afflict them and instances where the soil does not contain organisms for the disposal of spoil from them. Humpty Doo was excellent for growing rice for consumption by local birds but little for export. Whereas we have a dung beetle for kangaroo droppings, we have none naturally for that from Buffalo, cattle and sheep.

Gene technology allows us to address many of the problems that our environment poses for competitive production of fibre and food. It will allow us to compete in international markets in cut flower and 'exotic' plants.

THE ABILITY OF PRODUCERS TO COMPETE USING TRADITIONALLY AVAILABLE VARIETIES

There was the belief that the new gene technologies were the panacea for a harsh environment and poor farming practice. No doubt there will be a quickening rate of change but, fundamentally, such will be governed by the commercial benefits that can be produced. In the main, change in practice is governed by profit. Just as there is little investment in research and development in the control of exotic diseases of people in under developed countries, such follows for purely small Australian rural problems.

Where the market provides an adequate return on the investment in research, development and marketing, commercial enterprise will provide products advantageous to supplier and user in terms of profit to both parties.

Where gene technology provides a market advantage to the user in terms of production cost efficiency, a user who cannot access this technology will be at a commercial disadvantage and can be expected to go out of business unless subsidised.

Already there are several applications of gene technology in Australia. Such includes cloning of plants, manipulated seeds, canola and cotton and a vaccine for the control of cattle tick. Many more are in the pipeline including exotic flowers for the cut flower market, vaccines for the control of internal parasites of livestock, salt tolerant eucalypt and herbicide and insect resistant plants. Pigs containing a second growth promoting gene have been produced in Adelaide but have not been commercially progressed for various reasons. The Secretariat of the Genetic Manipulation Advisory Committee should be able to supply a fairly comprehensive list of work in progress locally and internationally.

It would be reasonable to say that without access at a cost effective price, rural producers would be at a severe disadvantage in competing against imported products based on the new genetic technologies and would be non-competitive in many instances on the international market

THE COMMERCIALISATION OF AGRICULTURAL VARIETIES

In Australia, there is considerable caution in the public mind regarding the acceptance of genetic manipulation where in any way it can be perceived that their health and wellbeing could be affected.

Logically where there is no knowledge that such is being done there is no public reaction. There is no reaction that such work must be going on in laboratories nearby. The research itself does not suffer from the 'dangerous escape' syndrome associated with nuclear research. Cloning is not seen to produce environmental or personal risk.

There are two main public perceptions that make commercialisation/marketing difficult:

a concern that genetically manipulated foodstuffs may not be 'safe'

that genetically manipulated growing material may be able to transfer those genes to some other growing material with deleterious effect.

The case of the Adelaide pigs is interesting. Like any animal there is a genetic structure to promote growth and the scientist put a second one of these into a pig plus a copy of a small fraction of a human 'protein'. To avoid damage to the pig from over growth a 'trigger' is required to 'turn on' the second growth promoter in this case, additional zinc in the diet. Regrettably the media made hay with the copy of the piece of human protein suggesting that a diet of such pig was essentially cannibalism. Others postulated that should one of these pigs escape and join with the feral pig population Adelaide could expect an invasion by pigs the size of hippopotami. For the company, it became too difficult and the subject is currently on hold.

The safety of genetically manipulated foodstuffs is in question by the Australian public. Regrettably the media is playing to this gallery as is at least one food packer. The Genetic Manipulation Advisory Committee Chairman, Professor Nancy Millis, talks of bioequivalence or equivalence. A genetically modified grain is not identical to its forebear and this can open up the question of safety in some circumstances.

Each case for substitution in the food chain by a genetically modified product has to be considered on its own merits.

THE COST TO PRODUCERS OF NEW VARIETIES

Idealists are prone to forget that bringing a new product to the market place has a cost that has eventually to be recovered if a commercial organisation is to stay in business. The current estimate to research, develop and market internationally a new pharmaceutical entity for treatment of people is about A\$350-400 million. Likewise a new chemotherapeutic for treatment of animals that will enter the food chain approaches that figure. At the other end of the scale new varieties of plants produced by selection and cloning without genetic manipulation, bears little cost additional to that of production.

Plant varieties produced by genetic manipulation that do not enter the food chain and where there is no risk of transfer of manipulated genes to another variety are less costly to produce but there is the additional cost of seeking to prove no risk.

Removing the profit motive will provide an environment similar to that of Soviet Russia in the period 1917 to date, where no new human drug entity, of significance, has been developed.

There is little doubt that any marketer of a new product will seek to price at what the market will bear. What the market will bear will depend on cost effectiveness compared with current practice and the competition from an alternative practice. Though the marketer of a new product may be protected by, for example, plant variety rights or patent protection, the right does not exist to withhold the product from the market where the right is held to gain a benefit, eg, make available in the USA but not Australia where protection exists in Australia because of a right. Likewise onerous pricing should be likely to place in jeopardy protection under a right, eg, cost to purchase in USA versus Australia.

OTHER IMPEDIMENTS TO THE UTILISATION OF VARIETIES BY SMALL PRODUCERS

Where registration of a 'variety' is required by the Commonwealth or State authority there will be cases where the manufacturer/producer does not proceed with marketing in view of perceived lack of financial return. In many areas of rural production, on the international scale, Australia is a small user. Producing sufficient data and documentation to satisfy authorities is an onerous, time consuming and expensive task and with inadequate financial return, many products may not be available to Australian producers. Though the 'clearance/registration procedure' has been simplified between Commonwealth and State, overseas data are not necessarily acceptable alone. Genetically modified viable material will require Australian support data before 'release' can be expected.

ASSISTANCE TO SMALL PRODUCERS – NEW VARIETIES AND PROTECTION OF RIGHTS

The Standing Committee will have available to it schemes currently available under Commonwealth and State legislation. There are many including the Co-operative Research Centre scheme, IR&D grants, Rural Industry Research Funds and contracted research to many organisations including the Universities and the CSIRO.

Logically enough funds tend to go where there is the greatest return and in consequence ‘niche’ products/industries may miss out. The axiom of supply and demand applies for without a commercial return on the investment it is unlikely that funds will be forthcoming.

I am not competent to discuss plant variety rights, the degree of protection afforded by them, the duration of protection nor the cost involved. With regard to patenting, a full international patent is expensive both with regard to application and maintenance which includes any necessary protection of the patent. Normally patent cost are borne, in toto, by the organisation owning the ‘intellectual property’ (IP) and often this cost is within the loan that may be obtained to develop the IP.

Patenting normally provides protection to the inventor for a period of twenty years. From the date of patenting of an entity entering the food chain or affecting human/animal health several years may elapse all of which are coming off the life of the patent. It is not remarkable to find that ten to twelve years have elapsed since the patenting of a potential human pharmaceutical leaving eight to ten years to recover the investment of some A\$350M plus – a not dissimilar picture exists for veterinary pharmaceuticals and a like climate exists or is shadowed for products entering the food chain.

APPROPRIATENESS OF CURRENT VARIETY PROTECTION RIGHTS - ADMINISTRATIVE ARRANGEMENTS & LEGISLATION IN RELATION TO GMOs

No comment

OPPORTUNITIES TO EDUCATE THE COMMUNITY OF THE BENEFITS OF GENE TECHNOLOGY

‘On the whole, the news media have not done a particularly credible job of reporting scientific and technological events to the public over the last 30 years. They tend to overdo the bizarre or the scare aspects at the beginning of a case and seldom follow through to summarise adequately the resolution of an issue. They tend to over-focus on the catchy phrase and the spectacular event while neglecting

the general trends that may be changing our lives. Some needed fundamental changes appear to be occurring slowly in the media's attitude on reporting scientific and technological news. The printed media's coverage appears to be far more extensive and possibly more responsible to-day than it was 30 years ago. The roles of the media and the public opinion polls in assessing our technology are almost sure to grow' (Lawless 1974, Technology and Social Shock: 100 Cases of Public Concern over Technology p453, Kansas City: Midwest Research Institute.)

In the main, the media in Australia have been of little assistance in bringing to the notice of the public a balanced view of gene technology. Equally, the scientists and technologists have been their own worst enemies in so many instances in providing useful information to the community. Regrettably, we, the public, are interested more in disasters and tragedies than good news.

The logical place to start talking of benefits is in our schools but the public hold the perception that our teachers are few in number who are happy giving a balanced view on evolving technologies. Environmental purity seems to hold sway without a healthy debate on differing views.

Recently the first Australian Consensus Conference on *Gene Technology in the Food Chain* was held in old Parliament House, Canberra, March 10-12 1999. The outcome of this conference to me seemed to be that the subject be treated with caution and this included the requirement that all genetically modified food be so labelled. A like conference in Europe, I believe, was more positive in its outlook. Industry may look somewhat askance at the recommendation on the formation of a new statutory body with responsibility for GMOs (Genetically Modified Organisms) with well balanced representation whose deliberations are public. If this 'body' were to require 'certainty of safety' one would expect industry to withdraw, to a large extent, from research and development on gene technology associated with the food chain and certain environmental areas.

We, who are involved in gene technology, have to do more in espousing the benefits of the technology clearly citing advantages and disadvantages. Somehow we have to deal with "the fear of the unknown". Regrettably, scientists can never be sure that there is no risk even though they cannot perceive of one, yet it is this on which the media focuses.

The media could do well to consider the place it should play in enhancing society's awareness of gene technology, realising that it can add to the problem in seeking to 'over-focus on the spectacular'.

CONCLUSION

Over the last month I have had the opportunity of attending the annual conference of the Co-operative Research Centre Association. There are more than 60 CRCs attracting Government funding in excess of \$150M annually to which is added the 'in kind' and cash contributions of the partners, Universities/CSIRO/industry, giving an

expenditure greater than \$500M annually. Many of the centres are involved in gene technology associated with primary production. A week after the CRC Conference, 'Open Day' was held at the CSIRO Division of Animal Production at Prospect, NSW. Like its fellow Division of Plant Industry, Canberra, much of the work is associated with gene technology.

Regarding the points to be addressed by the inquiry, one may conclude that in Australia:

- to remain commercially competitive on a local and international scale, access to the benefits of gene technology at commercially competitive rates is essential for the ongoing viability of our primary industries,
- where a need has been identified for resolution of a problem or a benefit to be gained by gene technology such will have been included in the strategic utilisation of gene technology when sufficient commercial benefit can be gained,
- our scientists/technologists, in the main, are aware of the current coverage by plant variety rights, patent protection and commercial partnerships and agreements and are less prone to work in areas already "owned" than they were 10-15 years ago,
- the income tax system is not conducive to risk taking. Many countries allow capital losses in investing in high technology areas to be written off against income. Though Australia's investment in research is comparable, pro rata, with developed countries, our investment in development is poor and until our tax regime changes, is likely to remain so. It follows that the research tends to be done in Australia and the development overseas with the consequent loss of property and return on our research expenditure,
- a fair return on investment is required and Australian primary producers have to meet this cost or be subsidised so they can obtain the benefit. Products based on gene technology governed by international property rights should be available to Australian primary producers at no greater cost than their competitors internationally,
- approval to market and use products based on gene technology should be no more onerous in Australia than in other developed countries. Australia should seek to approve the availability of such products using international data where feasible and permit commercial availability, speedily, to avoid our primary producers being placed at a commercial disadvantage on the world market,
- it must be borne in mind that the use of gene technology must not place Australia at a commercial disadvantage because of its use,
- the Government should take on its shoulders the responsibility for upgrading community knowledge of gene technology co-ordinating all aspects from school education to media education. It should become the responsibility of all receiving

research and development grants to allocate a proportion of funds received in providing community information on their work.

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