Submission to the Senate enquiry on gene patents

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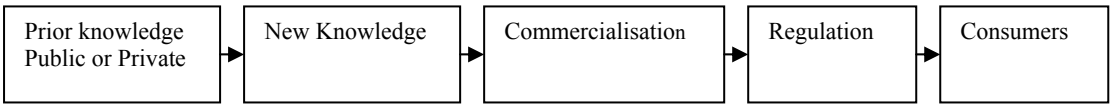
Background
My experience in this area of this enquiry comes from having been:
a; a director of a Cooperative Research Centre developing GM products for agriculture:
b; research director for a small, not for profit investment company investing in "for profit" companies developing GM and other genetic agricultural products:
c; an investor in a micro-company developing a new approach to modifying the composition of plants.

From my experience I therefore have an interest in the outcome of the Senate enquiry on gene patents.

The chain of activities in developing GM products that affect human health, human nutrition or crop production has be summarised below (Figure 1):

Figure 1



The generation of new knowledge requires access to prior knowledge. The prior knowledge may or may not be patented or be in the public domain. If patented then there are potential problems in commercialising any new knowledge. This is particularly the case if several organisations hold patents on enabling technology.

Assuming that it is decided to take the new knowledge further and commercialise it, a whole series of practical commercial decisions have to be taken. These include potential or actual regulatory issues. Regulatory issues are likely to cover efficacy, human safety and environmental impact.

Once all these issues have been addressed, marketing new knowledge as either knowledge or as products will determine commercial success or otherwise.

I will now consider the impact of these stages on development of new knowledge and products of considerable potential value to the community.

Access to prior knowledge and its impact on commercialisation
Suggested core principles:
a; it is reasonable that owners of prior knowledge should receive a return on their past efforts in developing new knowledge;
b; it is not reasonable that holders of prior knowledge should impede development of new knowledge or inhibit commercialisation of new products in the market.

c; cost of access should be delayed until commercialisation has occurred and payment for access to prior knowledge is part of the cost of purchase of the new product
d; the developer of new commercial products using new and prior knowledge accepts full responsibility of the product

If prior knowledge is in the private domain (patented or commercial secret) then the person seeking to generate new knowledge may need access to private prior knowledge before they can develop new knowledge. Access to enabling technologies may be withheld or charged for at such a rate by the owners as to make any further development commercially impractical.

The impact of this is that potentially important new developments in areas that are often of no or little interest to holders of private prior knowledge do not occur. In some cases the relationships between holders of necessary prior knowledge for developing new knowledge are so complex that it is impossible to develop new knowledge or product as the developers are unable to align all the differing interests of the prior knowledge holders. This is particularly the case with enabling, methodological technology patents.

If ease of access to prior knowledge can be improved and the costs of access shifted from the development of new knowledge to product sales (delaying payment for access to prior knowledge until there is a cash flow from the new and prior knowledge) it is likely that many more products will be developed by small companies that are outside the interests of the current (often large) prior knowledge holders.

Regulation
Suggested core principles:
a; the role of regulation is to ensure all or any of product efficacy, product safety for human use and minimising environmental impact of the product
b; regulation should be based on a sound scientific understanding of the issues raised in meeting regulatory requirements
c; the public should be able to comment on proposed release of GM products however objections must be based on sound science and the reasons for the objection spelt out so that the developer has a clear understanding of what the objection is about and can address it. To reduce frivolous objections a charge might be applied as is the case with the developer
d; meeting regulatory requirements are often the most costly part of the process of taking new knowledge to the market place. As the public are key beneficiaries of innovation, the costs of the regulatory process should be minimised. Any payment to the regulator (as with holders of prior knowledge) should be delayed until commercialisation has occurred and regulatory payment should be part of the cost of purchase of the new product collected at the point of sale of the product.

Regulation usually covers issues of efficacy, human health and environmental impact. These are reasonable requirements. However dealing with regulatory issues is often the most costly part of taking a new product to market. When the public is asked to

comment on a proposed release of a new product objections should not be on the basis of fear manipulated by anti-development agitators.

Ways to reduce the costs of regulation will increase the range of new products available to consumers. It will enable niche products for small, specific markets to be developed and taken to those markets. If the regulatory costs are too high they will never be developed.

Conclusions

The aim of any changes in the legislation should be to improve access to prior knowledge and shift the costs of access and regulation from upfront to commercial product sales. Such changes are likely to alter the business model of major companies from large profits on few products to smaller profit on a greatly expanded range of products whilst stimulating the development of small research companies and an increased product range for consumers.

Large companies often have all or many of the links to developing new GM products available in house. However innovation often occurs in public laboratories or small companies. Currently access to prior knowledge and dealing with regulation are major issues for public organisations and small companies making up a very large proportion of product development cost. Reducing and postponing these costs is likely to stimulate GM innovation in Australia.

The issues raised above are stifling the development of novel products. Besides increasing the range of new products in developed countries, increased access to prior knowledge and ways of minimising regulatory costs without reducing safely is of great importance for ensuring that poor people in developing countries have access to valuable products from new technologies at low cost.