GREEN PAPER KEY QUESTION 13

- *How do we better support knowledge exchange and impact generation? What should be the role of research institutions in transferring knowledge to operational environments and technologies?*

Additional context from "Commercialisation Pathways" section of the Green Paper

- *We would like to understand whether current commercialisation supports are at the right scale and how we can enable greater collaboration and pooling of commercialisation expertise and opportunities across the research sector. We would like to consider what the most effective ways are of pairing scientific expertise with commercial expertise, and what the alternative commercialisation pathways are (to spinouts or licensing) that we may want to support in the research sector. We are keen to hear what a more collaborative model for people starting with an idea outside of the research system might look like, and what support the research system could provide in these cases.*
- *We have heard concerns from research organisations that funding contracts make them feel constrained to hold IP tightly rather than take a wider view of what the best use of the IP, both commercial and non-commercial, might be.*
- *We would like to understand what processes and structures could establish clear and appropriate roles for all parties in knowledge exchange.*

RESPONSE

Nick Roberts, Principal Scientist AgResearch; CSO ZeaKal

Gregory Bryan, Principal Scientist AgResearch; CTO ZeaKal

We would like to comment on the current practices of commercialising biotechnology invented in New Zealand research institutes; more specifically commercialising genetically modified organisms (GMOs). Unsurprisingly, New Zealand CRIs and Universities have relatively little experience in commercialising this area of biotechnology and this was eloquently described in the Green Paper "lack of scale and diversity to manage risk and build end-to-end excellence".

The suggestion of "pooling commercialisation opportunities" in the Green Paper may be one option for improvement; however, organisations that have successfully commercialised GM crops have highly focussed and significant teams that address all aspects from R&D, regulatory, product integrity, legal, market delivery and marketing. Below we describe our experiences in three broad headings with commercialising genetically modified plants; these are also relevant for other biotechnologies.

For context, in the last 30 years Nick has worked as a researcher for the University of Tasmania, the Australian Antarctic Division, the University of California (Davis), AgResearch Ltd, and as a co-founder for two start-up biotechnology companies (Algenetix and ZeaKal). He currently has dual appointments as a Principal Scientist at AgResearch and as the Chief Science Officer for ZeaKal (San Diego, USA). His focus is plant biotechnology, specifically metabolic engineering. He is an inventor on 17 patents (3 of which are currently provisional); a subsection of these have been licensed to ZeaKal for use in both row and biofuel crops while AgResearch is pursuing their application in forage species.

Over the last 27 years, Greg has worked as a researcher for DuPont Agricultural Products in Wilmington Delaware, AgResearch Ltd and as co-founder for PhytaGro and ZeaKal. He currently has

dual appointments as a Principal Scientist at AgResearch and as the Chief Technology Officer for ZeaKal (San Diego, USA). Greg has been involved in building the plant and fungal biotechnology capability in AgResearch since 2001. Greg also helped build the biotech commercialisation strategy between 2003 and 2010 which led to the development of three spin-out subsidiary companies (PhytaGro, Algenetix and ZeaKal).

Biotech Commercialisation Life Cycle

- The commercialisation of a genetically modified organism (destined for release into the environment) is usually a long and expensive road, even in countries where this is considered the norm. Consequently, the associated costs (where cost also equals risk) are usually only affordable/palatable to large plant biotechnology companies, and/or Venture Capital (VC) investors. As an example, Corteva Agriscience spends US$2.1B p.a. on R&D and commercialisation. Significant investment money needs to be raised; given we are referring specifically to GMOs then it is likely the investors are going to want to have most of the work done in the country/countries destined for release of the organism.
- CRIs have an important role in the different sectors of our economy as they specialise in sector/industry aligned research. This does provide opportunity for novel technology development, some of which has multisector and international applications. The large international AgBio players are moving away from research due to the complexity and timelines. This means CRIs will have increasing opportunity to provide international solutions in the future.
- CRIs do basic research well but understanding the need to find an acceptable balance of retaining some of the research and commercialisation dollars within the institute versus offshore operations are frequently at odds with the NZ research institutes financial KPIs. The most significant issue is the widely divergent cost structures. In our experience CRIs are approximately twice the cost per FTE of models such as a start-up. It makes investment of a start-up into a CRI fraught with risk.

Models for Raising Money

- Raising the investment needed (e.g., ZeaKal Series A, B and C US$30M) takes a significant team and the commitment in these cycles is substantial. For each cycle the team needs to develop a strategy, science plan, business plan and engagement with multiple investors. It may take a year of work for 4 people per cycle. The more substantial subsequent rounds of investment generally with increasingly sophisticated institutional investors, leads to an increased focus on the management team, the execution of the "go to market strategy" and time to market. There is also more need for the cash burn to be managed to maximise runway.
- Understanding risk(s) and how to quantify them takes experience, this experience is typically lacking in New Zealand research institutes and can be seen by the unrealistic valuations placed on IP. CRIs are able to appropriately value the importance of research they are doing, but as this moves to a more commercial focus there is not a good understanding of the risks and timelines. This can lead them to inappropriately discount the risk and either overvalue the technology or in some cases overestimate the risk which can lead to abandonment of the technology.
- In some instances, it makes sense to form a partnership with VC by way of a joint venture, or perhaps a start-up. Typically, this will involve members of the original invention team, either full time, part time, or by secondment. The framework used to set up this type of

partnership needs to be insulated from the changes in parent organisation management. Typically, the time frames involved can span two or three changes in CEO and Senior management.

- The examples we have been involved in have not been effectively insulated. Often the new CEO brings a change in philosophy (sometimes driven by the government of the time) around the value and methods of commercialisation in CRIs. This can either benefit or impact a start-up venture and in the latter case if the structure is not adequate it can be highly detrimental.
- In addition, these are always risky ventures and to incentivise science staff involved they retain a dual appointment or the option of moving back to the parent organisation. The joint appointment creates a general challenge around trust and conflict of interest. Trust is often the thing that is impacted by a management change.
- Lastly, in the event of failure or successful exit the researchers end up in a problem of a funding black hole. CRIs are not set up to rapidly respond to funding changes. Failure to do so can lead to a substantial loss of research capabilities and reluctance of other researchers to engage in similar ventures in the future.

IP management

- While CRIs may have expertise in IP management, customer relationship management, contracts and the legal side of partnerships, these people are often in highly challenging roles working across many parts of the company and therefore their valuable skills are difficult to access. On paper it may appear these skills are covered in the parent organisation, but the practical reality is they are insufficient to support commercialisation of GM crops.
- IP generation and protection is expensive, time consuming and ongoing; however, to raise money for commercialisation it is a necessary undertaking. This requires an appreciation and experience at building a patent portfolio. It is important to treat IP as an investment rather than a cost as this will lead to a different approach to managing a portfolio.
- Similarly, experience is required to recognise that there are frequent opportunities to "extend patent life" and these should be continuously reviewed and explored to be able to attract further investment. In general, CRIs lack the budget to support an investible IP portfolio and to support extension of patent life. The solution is to either significantly increase investment in IP or to have a more supportive licensing approach that enables investors to set direction more freely. It needs to be recognised that the science teams and generally a few key individuals are responsible for the IP innovation, and thus the trust and conflict of interest issues need genuine solutions.
- Currently, it is highly unlikely a new GMO will be commercialised in NZ first; as such, licensing the technology offshore in such a way that it compliments rather than competes with the relevant NZ sectors maybe an option, but it is not without challenges. Licensing the same intellectual property for different applications in different crop species and different jurisdictions should be explored. Experience at doing this without endangering/threatening other potential license holders typically also benefits with input from science, which has not always been standard practice. The CRI plus their researchers and the private commercial entities have divergent incentives around management of money and science direction. When keeping the science team within the CRI and having a collaborative partnership with the commercial entity, conflict arises about priorities, resources, and funding. The strong

direction pull by the partners lead the CRI science team into a risky funding position where new innovation is stifled and the team can end up largely unfunded.

Key Principals

The first priority should be to develop an IP portfolio and a strategy for its management. All aspects of this requires high levels of expertise and resourcing.

A single commercialisation model does not fit all biotechnologies. As many alternatives (start-up, joint venture, licensing, etc) should be explored and this would benefit from seeking outside expertise with relevant proven track records.

The process can lengthy and requires a team effort; a hand-over process needs to be in place so that there is continuity within the team when one or more members changes.