final report

Project code: A.BIO.0010

Prepared by: Bill Spooncer

Kurrajong Meat Technologies

Date published: June 2006

PUBLISHED BY
Meat & Livestock Australia Limited
Locked Bag 991
NORTH SYDNEY NSW 2059

Bioactives Workshop II "Evaluating Opportunities" 1-2 June 2006

Meat & Livestock Australia acknowledges the matching funds provided by the Australian Government and contributions from the Australian Meat Processor Corporation to support the research and development detailed in this publication.

Executive Summary

MLA's second bioactives workshop was attended by 52 people. Participants were meat processors, bioactives value adders, researchers and regulators. The workshop was intended to build on the 2005 workshop with a program that discussed markets and opportunities for collection of bioactives from the meat industry, overcoming hurdles including regulatory impositions and maximizing competitive advantages. The following is a summary of key points made during the workshop.

Following the previous workshop and other preliminary investigations, MLA has developed a 5-year plan for building capabilities for bioactives production in the meat industry. The plan was introduced at the workshop by Dr Philip Franks, Manager of Value Adding. Dr Franks told the audience that MLA's target is to facilitate the development of a $200 million business in bioactives from the meat industry over the next 5 years. It is expected that 5 new bioactives businesses will be created within the meat industry and that the businesses will return $50 million profit.

At the previous workshop 50 potential bioactives from the meat industry were identified. Professor Milton Hearn of Monash University has now suggested over 200 potential bioactives. The theme of the latest workshop was to set the framework for evaluating and selecting from the 200 potential bioactives with the aim of hitting the target of five success stories in five years time.

The workshop included a program of speakers and case studies to evaluate how examples of bioactives opportunities fit into a meat business:

Time	**Title**	**Presenter**
Day 1: 1 June 2006		
8.30-9.00	Registration	
9.00-9.30	Welcome and workshop plan	Dr Philip Franks
9.30-10.30	The perils of ignoring market dynamics - II	Dr Karen Dado
Break		
11.00-11.30	Introduction of Bioactives Analysis Model (BAM)	Dr Philip Franks
11.30-12.30	The bioactives value chain	Professor Michael Vitale
Lunch		
13.30-14.30	Bioactives supply chain gap analysis	Dr Lyndal Thorburn
14.30-15.00	BAM scenario analysis	Dr Philip Franks
Break		
15.30-17.00	Scenario analysis and group presentations	Group discussion
Day 2: 2 June 2006		
9.00-9.45	Functional foods in Australia and globally	Professor Linda Tapsell
9.45-10.30	AQIS – Overview in relations to bioactives	Anand Deo

Break		
11.00-11.45	Therapeutic regulation - TGA and GMPs	Paul Fletcher
11.45-12.30	Competitive advantage from IP	Duncan Ferguson
Lunch		
13.30-14.15	Competitive advantage	John Grace
14.15-15.30	Clover Corp – Nu-Mega ingredients	Guy Drummond
15.00-15.30	Lessons learned and wrap up	Dr Philip Franks

The next steps following the workshop are to develop a bioactives model and hold training sessions on costing bioactivities recovery. The MLA bioactives model will be a data base of yields, costs, prices and markets for over 120 potential bioactives from the meat industry. Once the model is developed a process of selecting projects, assessing economic feasibility, process R&D and product marketing will follow.

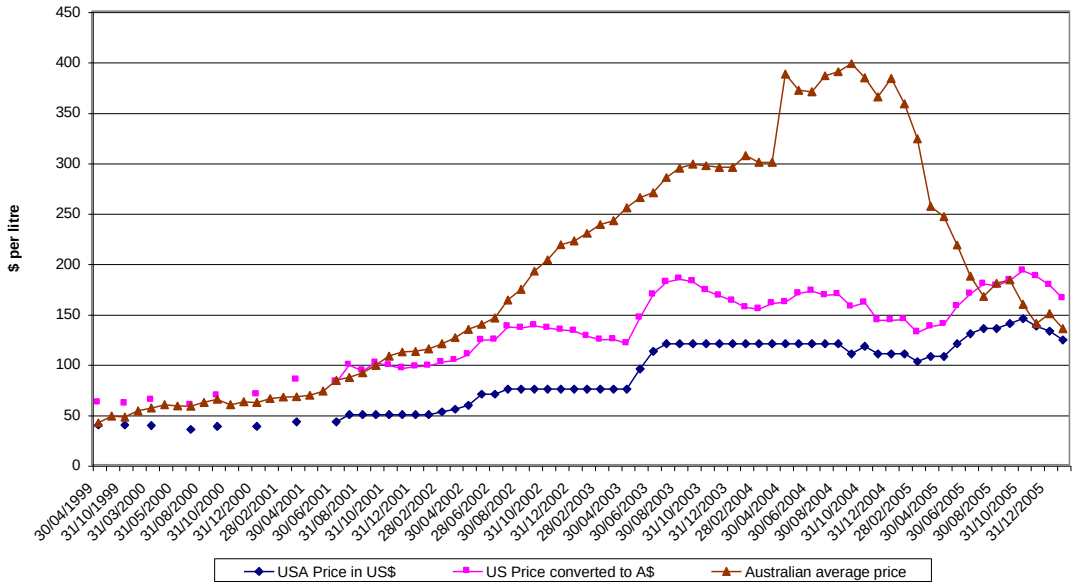
The objectives of the workshop were

1. To bring the industry up to date with the MLA bioactives program and results to date
2. To increase the industry's awareness of the issues involved in entering the bioactives sector
3. To demystify regulatory compliance
4. To raise awareness of the importance of competitive advantage in selecting bioactive projects.

The perils of ignoring market dynamics - II

Karen Dado, Director WHK Greenwoods

Foetal Blood prices 2000-2005



MLA commissioned an investigation of three examples of the fluctuating fortunes of value added bioactives to find out what lessons could be learned from the apparent expansion and contraction of demand for the products. The three cases studies were foetal blood, degreased bone chips (bone gel) for gelatin production and heparin.

Australia foetal blood prices went from $60 per litre in 2000 to $400 per litre in 2004 and back to about $130 in 2006. Foetal blood is the most widely used serum in tissue and cell culture. As demand for Australian blood increased in 2002-2004 smaller blood processors (value adders) were drawn in and prices were pushed up as the increasing number of processors sought to secure a portion of the supply. Supplies increased by about 50% as abattoirs took advantage of the high prices but Australian product became uncompetitive and customers turned to other sources. Prices subsequently fell to levels comparable to other suppliers, particularly the USA. The case study illustrates that super-normal profits are not sustainable.

The supply of bone gel from Australia has been affected by changes in requirements to exclude vertebrae from the raw material. Australian suppliers could not absorb this extra compliance cost were left with no competitive advantages despite being a GBR level 1 country. In addition, the 250,000 tonne market is in decline as digital photography replaces the need for gelatin-based photographic film. In this case the supply of Australian bone gel has ceased due to a decline in demand for gelatin in response to changing technology and an uneven playing field being created by regulators to favour US production.

Heparin from bovine and porcine sources was a widely used anticoagulant but with reaction to BSE and a synthetic heparin being introduced in 2002, demand for bovine heparin has disappeared.

These case studies illustrate the importance of anticipating the life of product before getting into the market. Changing regulations, technology of competitor products, raw material prices and customer preference can all cause a rapid collapse of apparently firm markets. The clean, green and BSE-free status of Australian derived bioactives is not sufficient to protect a product from excessive pricing or advances in alternative technology.

Introduction of the Bioactives Analysis Model

Dr Phil Franks, MLA

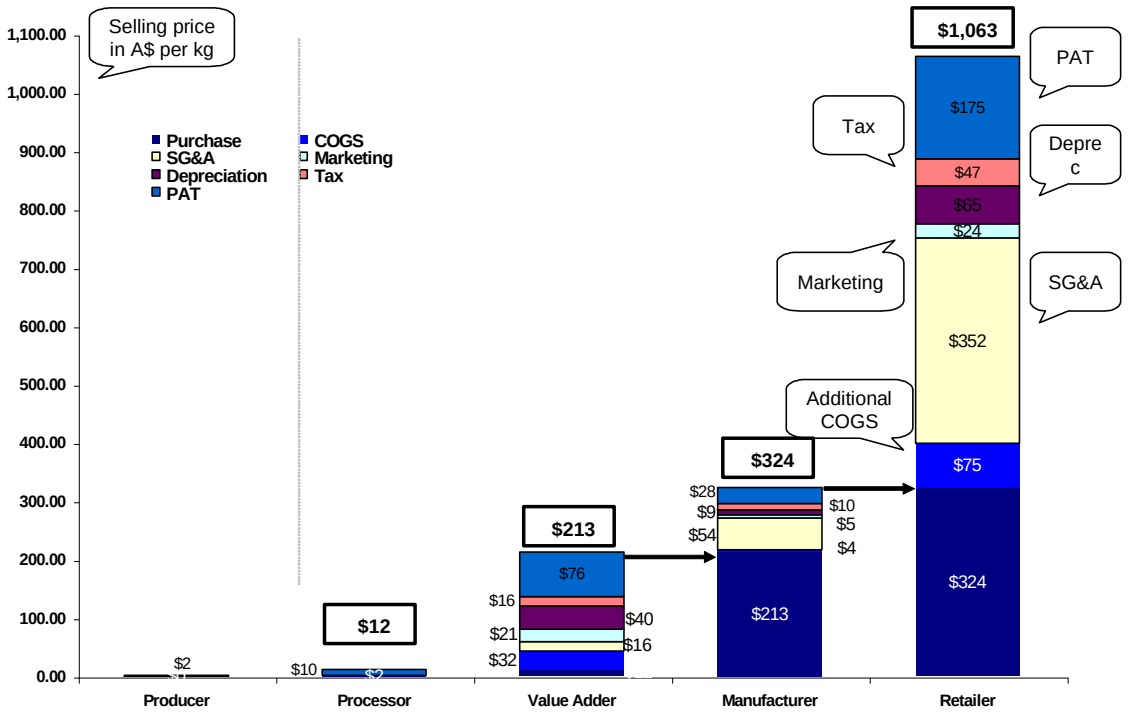
To meet the MLA target of facilitating 5 new bioactives businesses in 5 years time, a selection process starting with about 120 potential products is needed. Getting the products to market will involve economic feasibility assessments, process and product development, and product launch and support. Many products will fall by the wayside through this progression. The Bioactives Analysis Model (BAM) will gather together data on a wide range of potential bioactives to provide a high level overview which will help to select products that could go forward for project selection.

The data base will include information on yields of raw material per head, yield of value added products, bioactive content in wet tissue, global supply of product, potential Australian supply, market players and forecasts for growth of markets.

The Bioactives Value Chain

Professor Michael Vitale, Australian Graduate School of Management

Chondroitin Sulphate Food Grade Value Chain



Mike Vitale has conducted research and interviews in relation to 100 examples of bioactives. After trimming out those products that have very small or declining markets, or are unlikely to be acceptable to consumers he came up with a list of ten bioactives with promising markets. He has examined the value and profit margins as seven of these products progressed through the supply chain. Using the example of beef trachea as the raw material for chondroitin sulphate, Michael showed how the value goes from about $2 per kg (of final retail tablets) at the abattoir to $1,063 per kg as food grade chondroitin sulphate at retail outlets. In the chondroitin sulphate value chain, most value is added by the retailer and most profits accrue to the value adder and the retailer.

The example of transferrin diagnostic is more extreme where the original value of 15 cents per kg for blood at the abattoir translates to $145,000 per kg for finished product. In this case the profit goes to the manufacturer of the food grade extract and diagnostic grade product.

Other examples of the value chain for type II collagen in cosmetics, immuno gamma-globulin nutraceutical and bovine serum albumin pharmaceutical grade were discussed. For all these examples, the increase in value along the supply chain was illustrated and broken down into the value and price adding components and profit margins.

Most of the raw materials supplied by the meat industry for production of bioactives, for example trachea used for production of chondroitin, are in huge over supply because they are not used in the food chain. There is no hope of meat processors moving up the value chain when simply supplying raw materials out of waste streams. Red meat processors will have to consider repositioning themselves on the value chain by getting involved in value adding or manufacturing if they expect increased returns from bioactives.

Bioactives supply chain gap analysis

Dr Lyndal Thorburn, Managing Director Innovation Dynamics

Key issues to consider for 5 Bioactives products

Product	Main Markets	Demand Factors	Competitors	Certification
GAG's	Nutraceuticals, Functional Foods, Human Therapeutics	Consumer interest in natural products and ageing populations	Porcine and Marine sources, Bacterial fermentation	HACCP certification for red meat processors
Deoxycholic Acid	Therapeutics, Research Market, Veterinary Feeds	Aquaculture, Increasing western interest in Chinese Medicine	Synthetic chemistry has been demonstrated	None for Research Market but HACCP for aquaculture
BSA	Research Market, Nutraceuticals	Increased cell-based manufacture and therapeutics development	Synthetic cell culture media and Dairy	None for Research market, GMP for therapeutics
Bovine Immunoglobulins	Nutraceuticals, Functional Foods, Veterinary products, Cosmetics and Research market	Consumer interest in natural products and Sports market	Dairy – further analysis required	HACCP for food use, None for research market
Taurocholic Acid	Functional Foods, Industrial, Research Market and Therapeutics	Demand for natural products, Energy Drinks, Sports Drinks	Synthetics, Consumer reaction to Bovine sourced ingredients	HACCP for food applications

Dr Thorburn has reviewed 130 meat processors and 18 bioactives value adders in addition to over 350 non-meat sources of bioactives to assess the bioactives supply chains in Australia. She identified and interviewed 73 companies involved in producing 147 different products from meat, dairy, plant, marine and other sources. Of 130 red meat processors, 19 were collecting materials such as foetal blood, gall, trachea, collagen and albumin for bioactives used in human therapeutics and research.

The markets for five bioactives from red meat sources were examined to identify gaps in the supply chain. The five products were glycosaminoglycans (GAGs including chondroitin), deoxycholic acid (a component of gall), bovine immuno globulins, bovine serum albumin and taurocholic acid (also a component of gall and the raw material for production of taurine). These products were assessed from the point of view of the main markets, demand factors, competitors and certification.

There are several markets for GAGs and demand is rising due to interest in "natural products" and an ageing population. There appears to be an opportunity for red meat processors to supply food grade chondroitin sulphate.

The market for deoxycholic acid includes pharmaceuticals such as corticosteroid drugs, research culture media and veterinary products such as aquaculture feeds. Demand is rising for deoxycholic acid in Chinese herbal medicine and aquaculture applications. However, there is competition from synthetic production and porcine sources.

Bovine immuno gamma-globulins (IgG) come from blood and milk. The market is in nutraceuticals and functional foods but most products are currently dairy based.

Bovine serum albumin (BSA) is also available from blood and milk. Markets are in nutraceuticals, functional foods, research, therapeutics and diagnostics. The demand is for natural sources of BSA. The demand for BSA in research applications can be met with high grade products that are processed to be free from IgG and protease. The demand from the food industry may be met from dairy sources. The therapeutics market may be a potential outlet for BSA provided that manufacturing is according to GMP.

Taurocholic acid is another extract from gall is used to manufacture taurine. The amino acid taurine is used in functional foods, cat food and pharmaceuticals. Demand is rising, for example in sports drinks such as Red Bull. Bovine gall is the main source of taurine but synthetics are also available. There is no production in Australia, possibly due to lack or awareness of the market or competition from synthetics.

A major issue for production and marketing of these products is certification or accreditation required by the end user. The research market may be the easiest to target because accreditation is not required. However, extraction systems must provide sufficient purity. There is growing demand in markets for food and nutraceuticals for humans and animals and HACCP certification is required to supply these markets. Therapeutics require production according the Therapeutics Goods Administration Code of GMPs and long term commitment is required.

Claims for functional foods

Professor Linda Tapsell, National Centre of Excellence in Functional Foods

Examples of General Level Claims in food advertisements 2005

Type of claim	Examples of wording
Nutrient function claim – general	*Assist in maintaining digestive health*
Nutrient function claim – specific	*Calcium is good for strong bones*
Diet claims – general	*A wide variety of food helps keep active kids healthy*
Performance claims	*Provides the energy that means children will perform better at all round at school* *Helps with recovery from exercise*
Enhancement claims	*Improve blood flow* *Boost concentration*
Symptom relief	*Relieve bloating, wind and abdominal pain* *Ease insomnia*
Risk reduction – non serious	*Optimal hydration*

Functional foods are foods that have a marketing advantage based on scientifically demonstrated benefits beyond basic nutrition. The marketing advantage depends on being able to make a claim on the label for example "contains calcium which is important for healthy teeth and bones". However, making claims is not straightforward and Linda Tapsell led the audience through the minefield of international and Australian regulations related to labelling foods.

Australian regulations relating to health claims are being introduced to replace the current requirements for nutritional and ingredient listings on labels. The new regulations should be gazetted by early 2007. The new regulations will introduce two classifications of claims. General level claims are low risk claims which have no negative impact if people act on the claim. High level claims carry a high risk that health could be negatively affected if people rely too much on the claim and do not seek other therapeutic advice.

General level claims will be permitted where the claim can be substantiated by the manufacturer. An example of a general level claim is "calcium is good for strong bones". High level claims need pre-market assessment and approval by FSANZ. Therapeutic claims of foods e.g. "chondroitin cures arthritis" are not permitted.

The main point about the new regulations is the level of substantiation that will be required to back up claims. Some claims are pre-approved, e.g. claims about the link between omega 3 fatty acids and heart disease. General level claims can be based on current and generally accepted information sources or can be a nutrient function statement from the FSANZ model list provided that it can be demonstrated that the food contains the ingredient in quantities required to achieve the outcome

Consumer research has shown that health claims on labels are not the only way to go and that a nutrient content claim, i.e. simply stating that a certain nutrient is present in the food, combined with appropriate PR can be effective. A manufacturer making a functional food containing a particular bioactive may find it sufficient to state the presence of the bioactive rather than go through the process of having to substantiate a health claim.

AQIS overview in relation to bioactives

Anand Deo, Food Safety Manager, AQIS

The presentation by Anand Deo of AQIS focused on EU requirements for blood products. Blood products exported to the EU must comply with European Commission Decision 1774/2002. AQIS' role as the competent authority is to accredit facilities and procedures as suitable to export to the EU. This involves a desk audit of quality assurance manuals to assess compliance with 1774/2002 in relation to hygiene and sanitation, sourcing, separation of EU eligible and non-eligible product, training, internal control, labelling and storage. The desk audit is followed by on-site audits to verify procedures and records.

Seven facilities producing blood products have recently been audited for compliance with 1774/2002. There are separate requirements for equine, bovine, ruminant and foetal bovine serum, mostly relating to sourcing of blood from healthy animals and under veterinary supervision. Apart from EU requirements the UK has separate requirements and Taiwan also has requirements for collection of serum.

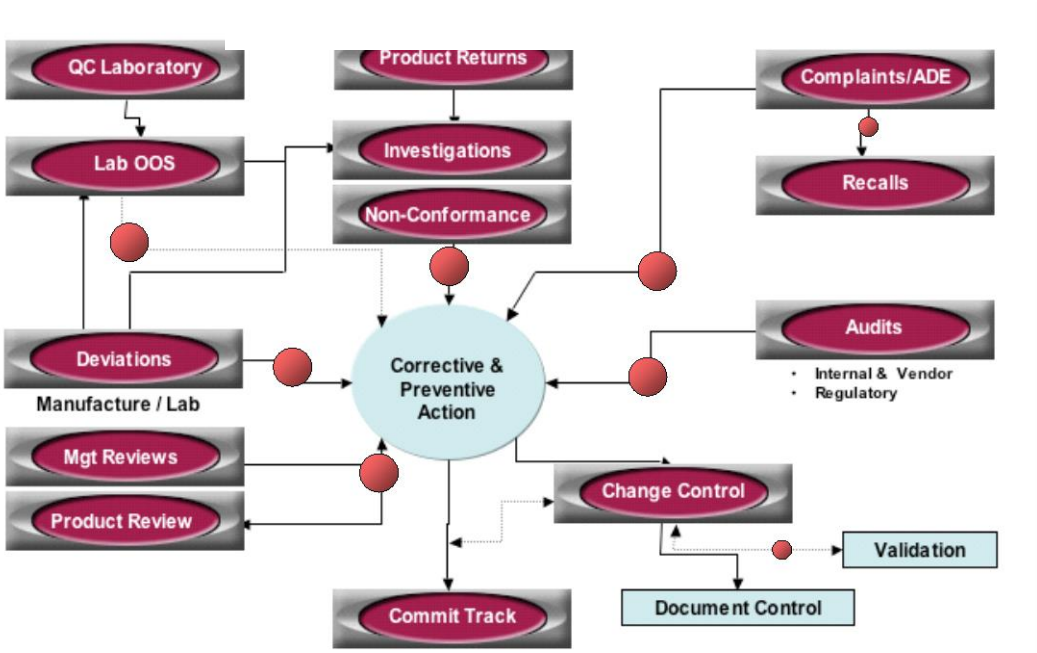
Audits of new and existing blood processing facilities will be carried out by AQIS Area Technical Managers in future. The frequency of audits will be based on risk and desk-top audits will be carried out to verify the traceability of products.

Anand explained that industry associations in other co-products sectors such as rendered products, hides and skins and pet food manage the listing of establishments for export to the EU and other markets. The industry associations negotiate conditions for compliance with overseas requirements with AQIS and arrange for independent audits of establishments. Suppliers of blood products may find it an advantage to form an industry association to represent members to AQIS and facilitate EU and other market access.

Therapeutic Regulations, TGA and GMPs

Paul Fletcher, SeerPharma

TGA's integrated quality system



In Australia, the Therapeutic Drugs Administration (TGA) is responsible for registering medical drugs and devices, GMP licensing and product surveillance or testing. The procedure for TGA control over therapeutic drugs depends on the product risks but manufacturing (which includes repackaging of products) must comply with good manufacturing practice (GMP) and is subject to compliance auditing by the TGA. The frequency of audit is from 12 to 36 months and depends on product risk and the previous compliance rating.

Paul Fletcher explained the elements of the TGA Code of GMP. While GMP amounts to a quality management system, the level of prescription of what is required is different from other more general quality management standards such as ISO9002. Paul said that the key to a successful GMP system is to take corrective and preventive action in response to any defects in product or production.

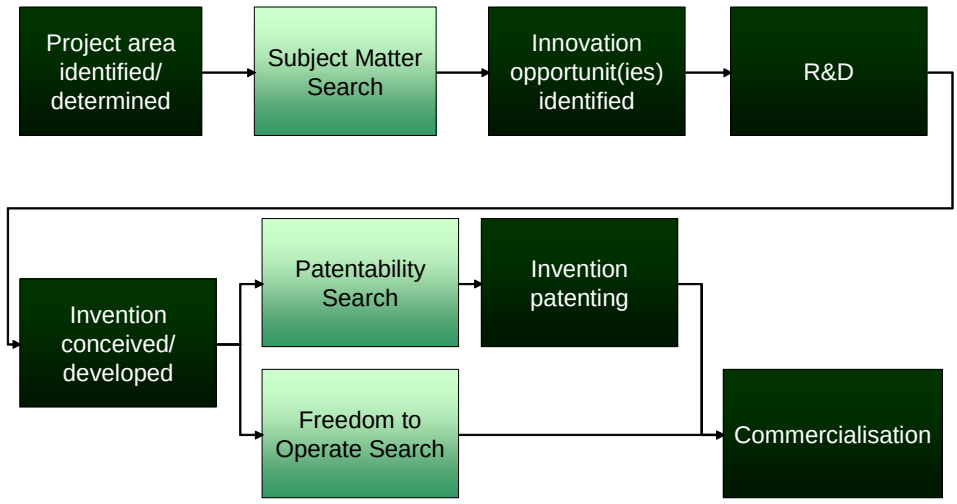
Previous speakers including Lyndal Thorburn noted that if bioactives are aimed at the therapeutics market they will have to comply with TGA requirements for registration and manufacturing according the Code of GMP whereas HACCP accreditation is appropriate

for food or veterinary products. There was discussion about whether products containing red meat bioactives would be regulated by the TGA or have to comply with the FSANZ Food Standards Code. This question was not answered but it was noted that FSANZ and the TGA are in discussion about this issue and there should clarification in the future.

Competitive advantage from IP

Duncan Ferguson, MLA

The Innovation process



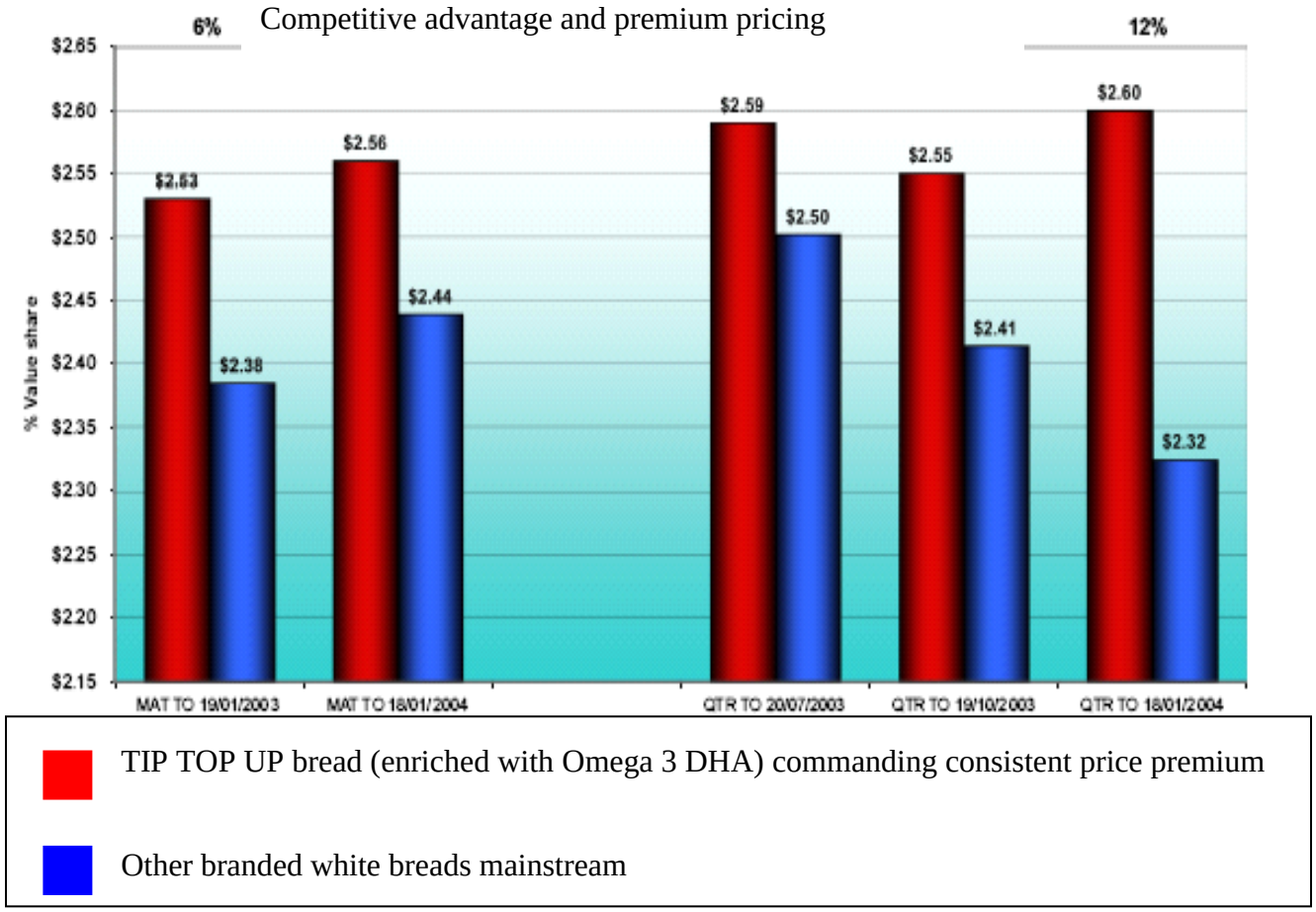
Bringing products to markets generally involves building intellectual property. Recognising and protecting intellectual property can provide the competitive advantage needed for a successful business. Duncan Ferguson from MLA explained the types of information including trade secrets, trade marks and patents that constitute IP. Patents may provide the highest level of protection of IP but patenting is a long term and expensive process. Also, the value of a patent is limited by the resources to protect a patent. However, once the IP is protected it can be used to extract value by licensing out, by selling IP that is not being utilized or by sharing IP in joint ventures.

Businesses should make sure that they are in control of their IP by conducting audits to account for the IP in the business and to establish what protection is in place. Record keeping is important to show when IP is acquired. US patents are granted on a first to invent basis and records may be needed to back up a patent claim. Part of the IP audit is to do searches to check what other IP might be protected and to confirm that the business has freedom to operate in particular areas.

The following talk by John Grace gave several examples of competitive advantages in the biotech industry achieved through prompt filing of patents.

Competitive Advantage

John Grace, IBIO and Guy Drummond, Clover Corp



John Grace discussed examples of competitive advantage in the biotechnology industry. What gives a product competitive advantage is people, patents, ability to control margins, regulation and science and technology. John illustrated these aspects of competitive advantage with a range of examples from the biotech industry. One striking example is the example of Tagamet. This product inhibits acid production in the stomach and is a treatment for peptic ulcers. The product was launched with no competition, hence the competitive advantage of having patent rights. Tagamet was eventually replaced by Zantac, a similar product but with enough difference to circumvent the Tagamet patent and with fewer side effects. With the competitive advantage of reduced side effects, Zantac replaced Tagamet in the $20,000,000 ulcer treatment market.

Guy Drummond explained how omega 3 DHA from tuna oil was brought to market. DHA is an important component of human nutrition particularly in infant feeding. However, the DHA content of human milk appears to be declining. DHA is available from marine oils but the trick is to incorporate the DHA-rich oil into foods. Clover

developed micro-encapsulation techniques with Food Science Australia and this has led to a range of products suitable for inclusion in infant formulae, bread and baked foods and beverages and soups.

Therapeutic claims about DHA cannot be made on food packaging and Clover has used other approaches such as PR campaigns to get people to understand the benefits of DHA enriched food products and why they should pay a premium for DHA-enriched foods. Apart from the micro-encapsulation technology, Clover’s principle competitive advantage is in applications technology and finding ways of using the encapsulated tuna oil in food products. Clover also has competitive advantages over new entrants to the market due to secure raw material supplies, knowledge of refining technology, selling and marketing approaches, track record and innovation.