At The Cutting Edge – Living Cell Technologies

The industrial backblocks of suburban Auckland may seem an unlikely setting for an international biotechnology company, but that's where you will find Living Cell Technology's New Zealand cell-processing GMP premises.

FORMERLY KNOWN as Diatranz, LCT's Managing Director Dr Paul Tan describes the firm as "one of the leading companies in the world when it comes to cell-based insulin treatment". Its small overheads mean LCT is able to invest more money in expanding on its current site, new staff, updating equipment, and its GMP cell production plant.

"We are a cell-based company, and see cell therapy as something ready for the market," Dr Tan says.

One of the projects LCT has been working on involves placing insulin producing cells, called islets, into the body to treat diabetes. Islets are natural aggregates of cells that produce insulin as well as glucagon. Islets comprise beta, alpha and delta cells. LCT's product encapsulates not only beta cells, which produce insulin, but alpha and delta cells. Collected from a unique herd of disease-free Auckland Island pigs, these cells have the specific requirements for responding to the body's demand for insulin.

"You can't better the sophistication that nature has assembled in the intricate regulating mechanisms within a cell."

The islets are protected from the body's immune system by being enclosed in gel capsules, and LCT's products do not require toxic immunosuppressing drugs normally used with transplantation.

"We are leading the charge for cell replacement without immunosuppression."

Fears about the possibility of transferring pig viruses to humans have so far proven to be exaggerated, with the November 2004 issue of the *Journal of Clinical Microbiology* publishing an article co-authored by Diatranz on the long term follow-up of human patients who re-

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NZBio Report

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FEB/MARCH 2005

The NZBio Report is the official journal of NZBio. NZBio aims to provide views on business, research and other topics relevant to our members. The NZBio Report is published on a two-monthly basis and sent to members free of charge.

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From The Chair:

NZBio Chair, Jim McLean

WELCOME TO the first NZBio Report for 2005. We have a lot to look forward to over the coming months, starting with the inaugural NZBio conference in March.

I would like to thank everyone who has been involved in helping organise this event; we are confident of it being a great success. The programme has a strong focus on New Zealand's advantages, and a top class line-up of national and international speakers.

While there are several benefits in living and doing business in New Zealand, NZBio is well aware that some significant hurdles exist. The areas of taxation and funding are ones we are currently placing resources into. We are continuing the work we started last year to address these issues; and will keep you informed on our progress.

In particular, we remain focused on high-level policy issues regarding funding for "proof of concept" stage biotechnology projects. By which we mean financing patented ideas to the stage they are commercially bankable as evidenced by their ability to then attract private equity. NZBio has been working with the Ministry of Research, Science & Technology, and advocating for a funding boost in this area. We have submitted two documents to Morst, which are currently under consideration. Lack of investment funds for early-stage work is a universal concern for biotech companies and it is here where a substantial increase in government funding offers the greatest chance for growth.

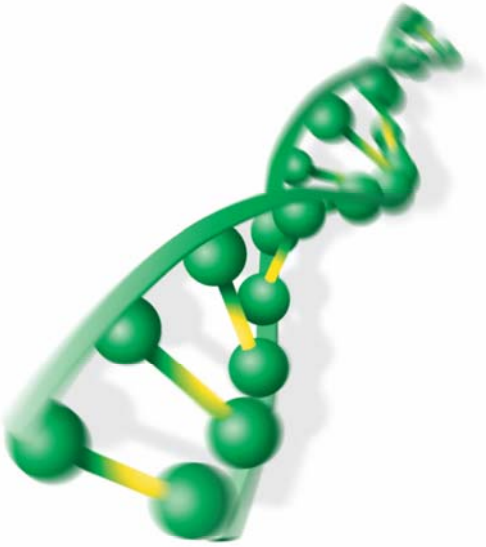
Our aim is to at least bring the level of proof of concept funding available to New Zealand biotech companies into line with other countries. This will require a funding increase of $60-70 million over the next five years. Without such an increase it will be very difficult for the sector to reach its full potential.

The feedback from last year's CEO Forum was extremely positive, and we look forward to an even stronger New Zealand presence in 2005.

NZBio has been pleased with Inland Revenue's response to our concerns about the current tax laws' impact on start-up stage biotech companies. One of the most pressing tax issues is the inability of biotech firms to carry losses forward, and we have engaged PriceWaterhouseCooper to provide expert advice and assist in our dealings with IRD.

Two more events this year that will be well worth attending are the trans-Tasman CEO Forum which will be held in April on the Gold Coast of Australia, and BIO 2005 in Philadelphia, from 19-22 June.

The feedback from last year's CEO Forum was extremely positive, and we look forward to an even stronger New Zealand presence in 2005. Events such as NZBio's conference, the trans-Tasman CEO Forum and BIO provide important networking opportunities and can act as business relationship catalysts.



Often, it all turns on how you pull things together

NZBio is the New Zealand biotechnology sector's industry body.

We represent a wide range of stakeholders, from global companies, to public and private New Zealand companies, research institutes and primary sector organisations.

We are the contact point for doing business with New Zealand biotech companies, and will help you make the right connections.

What defines New Zealand biotech? Agility, resourcefulness, responsiveness

The New Zealand advantage

- Biomedical science and drug discovery
- Large animal-based biotechnologies
- High animal health status
- Plant-based biotechnologies
- Innovative food and health technologies
- Bioprocessing technologies and biomanufacturing

Our key strengths

- World class science
- Global market focus
- Strong international connections
- Close national networks
- Effective project management skills
- Smart and lean approach to complex problems

NZBio

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The CEO Reports

NZBio CEO
Brian Ward

IN THE final months of last year NZBio submitted two reports to the then Minster of Research Science and Technology, Hon Pete Hogdson, which argued the case for increased funding for "proof of concept" projects. Early indications are that there is support for our position, but it is not a high priority in relation to other science funding initiatives. This is of extreme concern to New Zealand's biotech industry, particularly when we compare existing investment in basic and applied research with the resources available to convert discoveries into "investor ready" propositions. Creating such investor opportunities would seem the natural goal, if we are seeking economic returns from public investment in science and technology.

New Zealand is not alone in recognizing that biotechnology will be one of the most influential technologies of the next hundred years. Those countries we benchmark ourselves against, and many of the world's fastest emerging economies, are investing heavily in the development of their biotechnology industries. Throughout the world, biotechnology is strongly reliant on substantial public investment into basic and applied research, and at the "proof of concept" stage. Private investment from venture capitalists or corporates during these early stages typically does not happen, due to the high level of technical uncertainty.

At an international level, public and philanthropic investment in "proof of concept" funding is substantial, and the scale of these investments in the United States and Europe in particular, is massive. Closer to home, Australia is also ramping up its spend. A recent report on "Commercializing Australian Biotechnology" by Professor Michael Vitale for the Australian Business Foundation noted that "too often promising research programs disappear into the "funding gap" that lies between research and market development". On average, Australian companies receive up to $AU250,000 of public funds to develop an applied research project before company formation, and their US counterparts can expect up to $US5,000,000 from public and philanthropic sources.

The most critical factor determining our future success is an immediate and considerable increase in public sector investment.

Unfortunately, unlike the US and United Kingdom, Australia and New Zealand to an even greater extent, do not receive significant philanthropic investment. Vitale highlights the importance of "bringing concepts closer to the market before outside funding is sought". Recognising this need, the Australian Federal Government has shown its commitment to innovation by recently establishing the Commercial Ready Programme, providing $AU200M a year for five years, to help with commercialization activities at the "proof of concept" stage. In addition, state governments are also stepping up with funds to stimulate new and innovative companies.

The determination of major governments to publicly fund biotechnology research and development at high levels is establishing a formidable entry threshold for those countries that aspire to be leaders or even participants within this industry.

No doubt New Zealand has many of the ingredients necessary to establish a leadership position within certain industry niches. We have a tradition of internationally recognised leading-edge biological research. However, the most critical factor determining our future success is an immediate and considerable increase in public sector investment. It is all about the money. Biotechnology is a fast developing industry, and well funded, committed rivals can take advantage of the knowledge explosion and leverage their resources to erode our competitive advantage. Rather than watch the growth of this industry

play out internationally in a defensive position, which is the case under the current financial constraints, New Zealand has an opportunity to build on its strengths by investing at a level where success is more achievable.

The biotechnology industry is in a phase where access to capital is a strong determinant of sector development and future participation. To be in this race, New Zealand's biotech industry must have an operating environment that is at least comparable to our international competitors'. The overwhelming industry view is that lack of early stage investment is the biggest constraint. To be internationally competitive there must be adequate investment at the "proof of concept" stage. The majority of this funding can only be delivered by the Government, as it is elsewhere in the world.

There is a close association between the success of the biotechnology industry and the future success our traditional industries.

In the New Zealand context, biotechnology will remain essential in terms of enhancing the competitive position of many of our existing industries, and also provide an opportunity to create new companies from the commercialisation of biological research. Many of these ventures will bring to the market technologies that further advance our competitive advantages in the primary industries. There is a close association between the success of the biotechnology industry and the future success our traditional industries. Beyond this, biotechnology companies provide the opportunity to sell high-value products into global markets. New Zealand has little choice over whether or not it will be influenced by biotechnology. We can decide if we will be an originator and significant beneficiary from the projected growth of the biotech industry, or predominantly an importer of innovative products from other countries, which may not necessarily meet our specific requirements.

If rapid growth in public funding for "proof of concept" stage projects is not forthcoming, then the technology content of our exports will remain low and we will continue to be heavily reliant on commodity products and prices. Like technology, people are internationally mobile, and if we cannot provide an environment where opportunities can be developed and realized, we risk losing our brightest and best offshore. We are also less likely to grow the number of well paid jobs. In the current investment environment, it is probable that some New Zealand companies will license technologies very early to keep projects alive, and consequently lose the potential downstream value from further development here.

The targets set by the Biotechnology Taskforce were realistic, but they run the risk of becoming unattainable unless the most important actions of the report are addressed. Undoubtedly, investment is the most critical issue for the sector and Government leadership is necessary to make up ground on our international rivals. If New Zealand is to remain competitive, the New Zealand Government needs to show the same commitment we are seeing from countries we frequently compare ourselves with.

Brian Ward,
CEO,
NZBio

NZBIO SPECIAL INTEREST GROUPS UNDERWAY

THE BIOTECHNOLOGY Taskforce identified the development of clusters and new networks as important for growing the industry in New Zealand.

There is an opportunity to bring together the respective strengths and interests of individuals and organisations throughout the country, through the formation of national special interest groups to represent identified biotech sectors.

These groups will create greater scale, leverage resources and activities, and span traditional geographic, commercial and academic boundaries. They also have the potential to become pre-cursers to "virtual centres of excellence", transcending geographic separations within New Zealand and internationally.

The NZBio Board has already allocated some specific funding to ensure the early development of special interest groups, akin to recent successful efforts in Australia. Representing their respective sectors, national special interest groups are broadly intended to:

- Provide the NZBio Board with policy and strategy advice in relation to growth of the industry and its sectors.
- Assist the NZBio Board to provide focus on government advocacy at a national level and provide a concise approach to driving the industry sectors.
- Assist NZBio to develop internal and external communications.
- Facilitate the transfer of information, research tools and products between interested parties.
- Provide a forum for interaction between New Zealand scientists. The emphasis is upon informal and interactive networking opportunities, on a national basis whenever possible.

Further, the national special interest groups are anticipated to:

- Become a committed and recognised voice for their sector.
- Be "event based" and actively engaged with their membership and community.
- Promote the "NZ Biotech Advantage" whenever and wherever the opportunity arises.

Special interest groups will be established in response to specific need, request and commitment from the sector's constituency. They will be established at a national level, and will also link closely with the regional networks operating in each geographic area.

Full membership of a national special interest group will be open to all paid-up members of NZBio – individuals and named corporate representatives, and no further membership fee is required. Membership to more than one special interest group will be possible, if an individual member feels their interests extend to more than one sector. Associate memberships may be available for receiving communications on upcoming activities and events. NZBio will be taking additional steps over the next few months to request and record each member's area/s of special interest, and will review this annually when memberships are renewed.

We have commenced the establishment of the first special interest group, encompassing the AgBio sector nationally. A committee has been appointed and the first meeting was held recently in Wellington. The NZBio/AgBio Group will meet again at the upcoming NZBio conference in March. All interested parties are welcome to attend.

We anticipate that a second and possibly third sector may be identified, and special interest groups established, by mid 2005. We look forward to an active and prosperous year.

Albie Neal
Project Manager,
Special Interest Groups

Director

DAIRYAUSTRALIA

The Australian Cheese Technology Program (ACTP) is a unique plan connecting leading R&D providers and scientists with the cheese-manufacturing sector. Its overall aim is to create a strong, innovative and globally competitive Australian cheese industry.

Interacting with the highest echelons of Australia's scientific and commercial advisors, you will take the lead in developing and advancing the program's strategic direction, thereby promoting science/technology excellence in this country. This will require extensive stakeholder consultation and communication.

Ideally you will possess a doctorate in a relevant natural product discipline plus an outstanding leadership record in food science in the private or public sector. Dairy experience, whilst desirable, is not essential. You will however be able to demonstrate achievements in strategy development and execution, resource management, negotiation, commercialisation and relationship building, to ensure that R&D projects are delivered to co-investors.

- *Australian Cheese Technology Program*
- *Pivotal cross-sectoral appointment*
- *Location – Victoria, Australia*

Please send a brief CV
(Word format, up to 5 pages)
phil@brookerconsulting.com.au or ring
Jeremy Wurm on +61 3 9602 1666, in confidence.
www.rustonpoole.com

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SOMETHING TO CHEW OVER FROM BLIS TECHNOLOGIES

THE FUTURE lies in chewing gum. We're not talking about any old chewing gum, this is something special - a highly efficacious gum that can combat the socially crippling problem of severe bad breath.

As one of the latest products from BLIS Technologies' stable of halitosis cures, the gum has defied a potential formatting issue, to incorporate all the benefits of the company's K12 remedy in a consumer friendly format.

"Technically, it's difficult to achieve good shelf life for live bacteria in a gum format, but with assistance from our contract manufacturer we've been able to find a way around this issue," BLIS Chief Executive Kelvin Moffatt says.

The big question now is: "Is probiotic gum an ingestible product or not?" This has been a bit of a regulatory grey area. "It seems to be okay in Australia and the US as a cosmetic, and we're pretty certain Europe will be the same."

The gum could be on the New Zealand market early this year, and will be aimed at a niche group of consumers with severe bad breath. At around $29 for a month's course, the gum will cost approximately the same as mouthwash purchased over a similar period.

However, the American populations' concern with having fresh breath has made it the market of choice for BLIS.

"Culturally speaking, Americans are far more concerned about having fresh breath than any other market in the world," Kelvin says.

The American populations' concern with having fresh breath has made it the market of choice for BLIS.

Originally formulated as a lozenge, regulatory delays in approving what would have been classed as a therapeutic saw the K12 remedy undergo a relatively quick format change so it could meet cosmetic category requirements as a mouthwash.

"We were lucky in that we had been working on a paediatric format, which gave us a lead in. We received a TBG grant from the Foundation for Research, Science & Technology, so we managed to develop the mouthwash in six months. It's not the ideal format, as it's not as convenient as a lozenge, but for halitosis sufferers efficacy was more important than convenience."

Regardless, there is already a well established market in America for serious bad breath remedies and repeat orders have already

started to come through. Fellow sufferers in Europe are next in line for the roll out of K12 mouthwash, with the company in negotiation with further distributors.

But it's not all about bad breath at BLIS. Other projects the company is involved in include a trial at Dunedin Hospital with children who experience recurrent ear infections and tonsillitis, and a dental caries product.

"There are a few other things in the background, but the Board has made a strategic decision to focus on K12, particulary in the area of bad breath. Like all companies in New Zealand we have limited funds, so need to use discretion.

"By late next year I think we'll still be talking predominantly about K12, but starting to look at some other products."

On the manufacturing side, BLIS has its own GMP facility based at the Allaron factory in Nelson, which is capable of producing two million units per year.

"If we sell more than that, putting in further manufacturing facilites is a problem we're more than happy to have."

Professor Yusuf Chisti – World Expert in Production & Processing of Biotechnology Products

ONE OF THE health discoveries of recent years – that eating fish seems to confer some protection against heart attacks – may in fact be attributed to microalgae. The omega-3 oils found in fish originate not in the fish themselves, but in the algae they feed on. The fatty acids in omega-3 oils reduce blood clotting by decreasing the stickiness of blood platelets and, it is thought, may play a role in stabilising heart rhythms and reducing inflammation.

Based at Massey University in Palmerston North, Professor Yusuf Chisti's interest has been in the feasibility of producing one particular omega-3 oil called eicosapentaenoic acid (EPA) directly from microalgae. EPA and its derivatives have proved useful in preventing and treating coronary heart disease, abnormal cholesterol levels and several carcinomas.

Professor Yusuf Chisti

Currently the only commercial source of EPA is fish oil, which fluctuates in price and quality, and can be subject to contamination with pesticides and heavy metals. Moreover, the demand for EPA is growing while the supply is fixed. Professor Chisti and his collaborators calculate that producing EPA from microalgae will be cost competitive with fish-oil-based EPA if the algae can be harvested for less than US$4 per kilogram.

Today much of Professor Chisti's research work is carried out in collaboration with former colleagues in the universities of Waterloo and Almería, where his interest in microalgae developed. Biotechnology retains the allure and excitement that first attracted him as a student. In no other industry, he says, is there so close an alliance between knowledge and wealth creation, between commercial success and research expertise. Many biotech companies are pure research entities, contracting out the application of their research, and many universities end up spinning off biotechnology enterprises.

> **"In no other industry is there so close an alliance between knowledge and wealth creation, between commercial success and research expertise."**
>
> **Professor Yusuf Chisti**

An editorial Professor Chisti has written for Biotechnology Advances is provocatively headlined 'Who needs a conventional dairy industry?' "Why not microbial milk?" the editorial asks. Many of the soluble compounds in milk are already being made by recombinant organisms. Microbial milk would mean ground water uncontaminated by nitrates. It would be pesticide and antibiotic free. It would be cheaper too (though the branding campaign could pose problems). Professor Chisti is being provocative – playing to the 'yuck' reaction – but his question is a proxy for those other larger ones: Where will biotechnology take us? How will it benefit us? What might it cost us? Who can say?

Industry training programme to be piloted

The Government is funding a $400,000 pilot programme to develop industry training within the

biotechnology sector, which will be led by Professor Chisti.

The pilot programme, which begins with a recovery and purification workshop later this month, will run high-level, enterprise-specific training for biotechnology firms. The content of the workshops – expected to concentrate on the areas of biotechnology science, processing, regulatory compliance and business – will be developed in consultation with industry

Professor Chisti hopes to run two further workshops this year, and three in 2006. The project will also call on Professors Ian Maddox and Richard Archer of the Institute of Technology and Engineering; Professor Barry Scott and Associate Professor Bernd Rehm of the Institute of Molecular Biosciences; Associate Professor Alan Murray of the Institute of Veterinary, Animal and Biomedical Sciences; and Dr Gavin Clark of Research Services.

The pilot forms part of the Government's Growth and Innovation Framework, which is funded through the Tertiary Education Commission's contestable funding initiative and is intended to promote closer collaborations between tertiary education organisations and industry.

Information on the programme is available at: http://www.massey.ac.nz/~ychisti/MasseyFlyer.pdf

This article is an excerpt from a feature written by Malcolm Wood and originally published in Massey Research, November 2004.

It has been reproduced with the author's permission.

THE SNOWBALL EFFECT NZ Pharmaceuticals & IRL Join Forces

REACHING A turnover of $100 million in the next 10-15 years is on the agenda for New Zealand Pharmaceuticals (NZP), thanks to a new research and development project between the Palmerston North-based company and Industrial Research Limited.

With nearly $2 million from the Government to build NZP's business and marketing capability, the deal is designed to deliver the building blocks for new drugs that will combat diseases such as cancer. More specifically, carbohydrate derivatives used to manufacture those drugs.

"This deal presents a significant commercial opportunity. We've looked at it very carefully."
Selwyn Yorke, NZP

"This deal presents a significant commercial opportunity. We've looked at it very carefully," NZP Market Development Manager Selwyn Yorke says.

Although primarily involved in extracting and purifying animal-derived biochemicals for the pharmaceutical industry, Selwyn says NZP had an interest in carbohydrates through its manufacturing and sales of the polysaccharides heparin and chondroitin sulphate.

Having licensed a carbohydrate synthesis technology from IRL, Selwyn says NZP has developed the product into a million dollar business in sales to world leading biotech firms.

"There is a snowball effect, the carbohydrate derivatives developed by the company to date with the help of IRL have led to a stream of offshore market enquiries from countries such as Japan, America, Germany and the United Kingdom."

Securing the Government funding took about 12 months, starting with an application for funding from New Zealand Trade and Enterprise (NZTE). When that proved successful, the business case was submitted to Tech NZ. With the contracts now signed, Selwyn says construction of a new manufacturing facility will hopefully be underway by the end of the year.

With technical and professional standards as good as any in the world and New Zealand's competitive cost structures, NZP's Managing Director Richard Garland says this project is the means to become a key player in a valuable niche global market.

NZP
New Zealand Pharmaceuticals Ltd

INDUSTRIAL RESEARCH LIMITED

NZBio Conference to Showcase Biotech Industry

The international biotechnology community will meet this March in Auckland, New Zealand, at NZBio's inaugural conference. This two-day event, on 14-15 March 2005, will showcase New Zealand's biotechnology industry, and *The New Zealand Advantage*.

Delegates are invited from a broad range of biotech businesses and related fields. The conference programme features an impressive line-up of expert speakers, a business partnering forum and networking events.

"We are pleased to have secured a number of high-profile speakers, including Roger Wyse of United States' investment firm Burrills and Erich Sieber of Inventages, who will provide perspectives on international developments within the biotech industry and emerging opportunities for New Zealand companies, " NZBio CEO Brian Ward says.

"Delegates will learn about New Zealand's strengths in agbio and biomedical science, as well as emerging high potential science. There will also be a focus on business opportunities, with a business partnering forum and dedicated space available for one-to-one meetings."

Session themes include: Positioning start-ups for commercial success; Building global biomedical partnerships; Leveraging New Zealand's strengths; and Leading-edge science. Full programme information is available on the conference web site at: http://www.nzbio.org.nz/nzadvantage/

Two post-conference workshops on 16 March will cover the regulatory environment for food-related biotechnology, and how to make the most of the media.

NZBio's 2005 conference will be held at the Sky City Convention Centre in downtown Auckland. The adjacent Sky City Hotel (www.skycity.co.nz) is offering a special accommodation rate for conference delegates, subject to availability.

Early-bird discount on the conference rate expires 14 February 2005.

To register, and for more information visit: http://www.nzbio.org.nz/nzadvantage/ or email: conference@nzbio.org.nz

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Tūāpapa Rangahau Pūtaiao

DRAFT PATENTS BILL: Could Do Better

Doug Calhoun
AJ Park

The Government released an exposure draft of the Patents Bill for discussion just prior to Christmas. Submissions can be made on that draft to the Ministry of Economic Development up until 11 March 2005.

The policy objectives of the Bill had already been signalled in previous cabinet papers released over the last four years by the Government. There is some confusion in policy direction in the Bill. In its initial cabinet paper the Government indicated that one purpose was to promote innovation and competition and to encourage technology transfer. The Bill itself says the main purpose is, "to ensure that a patent is granted for an invention only in appropriate circumstances". Its previous upbeat purpose has disappeared.

There are some small moves towards harmonisation with Australian law. However, this is more in the area of drafting style rather than substantive law.

Rights Protected

The rights protected will now include hiring, importing, keeping or disposing of any product invention. The language used to define these rights is taken from the Australian legislation. This is slightly broader than the rights under the current Act.

Enforcement

The Bill contains a clear definition of what constitutes infringement of a patentee's rights. It also establishes a new category of contributory infringement. A contributory infringer is someone who knowingly supplies the means for another to infringe a patent. Thus, if a patent were for a method of treatment, someone supplying the active ingredient for carrying out the patented treatment without the authorisation of the patent holder would be an infringer.

The Bill excludes from patentability methods of therapeutic, surgical and diagnostic treatment of human beings.

The Bill retains a "springboarding" exception to infringement, a part of the current law. This allows unauthorised use of a patented invention for developing information for regulatory approval.

The Bill is silent on what constitutes experimental use. This is unfortunate. The common law recognises that some forms of experimental use of a patented invention are permitted. However, the boundaries of that exception have never been clearly defined.

Eligibility

To be patentable an invention will need to be novel, inventive and useful. These categories carry through from the 1953 Act. However, in keeping with the main purpose of the Bill, the most fundamental change is in the novelty requirement for valid patents. New Zealand has gone from a local novelty to an absolute novelty standard. This means that to be patentable an invention must be novel over anything that was known from use or publication anywhere in the world before the New Zealand application was made for that invention.

The "usefulness" requirement has also been changed from being undefined to requiring that an invention must have a substantial, specific and credible utility. The language has been taken from the US Patent Office Guidelines which were developed in order to ensure that patents were not granted for partial gene sequences without an identified biological function.

Exclusions

The Bill excludes from patentability methods of therapeutic, surgical and diagnostic treatment of human beings. It excludes inventions if their commercial exploitation is contrary to public policy or morality. It also excludes plant varieties from patent protection.

These stand out in stark contrast to the Australian Patents Act which permits patents to be granted for such inventions. The Australian legislation was reviewed by the Australian Law Reform Commission in 2003/4. After extensive consultation it recommended against such exclusions. The New Zealand Government shelved its earlier intention to issue a discussion paper on gene patents and healthcare in the light of the Australian review. The policy confusion of the government

is illustrated by these exclusions. What are the reasons for now ignoring the Australian recommendations?

Examination Procedure

The other side of the eligibility coin, where the practical effects of the new law will impact, is in examination of patent applications in New Zealand. Examination will be far more stringent than it is under the 1953 Act. Examiners will not only be able to cite prior art without having to prove that it was available in New Zealand, but they will also examine for obviousness and for utility. The standard by which applications are accepted or not will be on the balance of probabilities. At present an applicant is given the benefit of the doubt in border line cases.

Patent specifications will need to be drafted more comprehensively than has been the case in the past. This, of course, will increase compliance costs.

The effect of this will be that patent specifications will need to be drafted more comprehensively than has been the case in the past. This, of course, will increase compliance costs, both in the preparation of patent applications and in their examination.

The Bill also introduces a provision allowing for the deposit of microorganisms in culture collections recognised under an international treaty in order to make it possible to put inventions into practice (where the invention requires the use of a microorganism which is not otherwise available). The need for such a change was recognised in 1988 by the Government appointed Industrial Property Advisory Committee. In the absence of this provision the validity of patents for microorganisms, or the use of microorganisms was in doubt.

Validity

Another illustration of the policy confusion in the bill is the removal of a pre-grant opposition procedure. Under the current legislation any interested party may oppose the granting of a patent after an application has completed examination but before the patent is finally sealed. The grounds of opposition include several not available to Examiners during the examination procedure. Oppositions will no longer be available.

Under the Bill there will be a three month period in which anyone may ask for re-examination of applications, but only on the ground that the invention was not novel or obvious from prior art.

Re-examination will also be available after patents have been granted.

Re-examination was introduced in Australia in 1992, but in addition to rather than to replace oppositions. In the first ten years that it was available it was used only 15 times. In contrast, in the tenth year after its introduction alone there were 217 opposition proceedings in Australia. The decision to remove pre-grant oppositions seems to run contrary both to harmonisation of procedures with Australia and to another purpose of the Bill, to provide greater certainty that patents when granted will be valid.

Also introduced is the opportunity for third parties to seek revocation of a patent after it has been granted in proceedings in the Intellectual Property Office. The grounds available to do this are the same as those available for attacking the validity of the patent in court. While such proceedings are a partial substitute for pre-grant opposition, they can only be started after a patent is granted and can be pre-empted by the patent owner suing for infringement.

Term

The patent term in the Bill is 20 years with no extensions. In 2004 the Government pulled the plug on a proposed economic study of patent term extension. It appears to have closed its mind to the recommendation of the Biotechnology Taskforce that patent term extensions ought to be available where regulatory procedures has delayed the ability of patent owners to exploit their invention.

Plant Variety Rights

The original intention of the Government was that the Bill would include amendments to the Plant Variety Rights Act. The intention of the Government is now, apparently, to release an exposure draft of a Plant Variety Rights Bill later in the year.

Trans Tasman IP Co-ordination

A few days before the release of the exposure draft of the Bill the MED and IP Australia announced that they had initiated a joint work programme, "to explore the possibility for co-ordination in areas of patents, plant variety rights and trade marks ... to provide for a seamless intellectual property rights processing regime in each of these areas."

In the accompanying media statement it said the intention was to "progress coordination both within existing laws and by aligning laws where possible".

The announcement did not invite any participation of the public in the work programme. It also did not mention the draft Bill which would leave substantive New Zealand law substantially different from that of Australia.

Again there are confused objectives. There seems little point in trying to create seamless processing where there are fundamental differences in the substantive law.

Conclusions

The 2000 Australian Ergas Report, recommended that patent legislation should strike a balance between encouraging innovation by granting exclusive rights, and diffusion of that innovation so as to make it available to the community. More stringent examination procedures were introduced in Australia in response to that report. The balance in Australia still recognises the importance of patent exclusivity in promoting innovation. However, the balance in New Zealand is tipped much more strongly in favour of diffusion of innovation rather than encouraging it.

The procedure from here is that submissions will be considered by MED and any changes made in the light of those submissions. The likelihood of the Bill being introduced by MED into Parliament before the election this year is pretty slim. However, there is this last opportunity to comment on it before it gets before Parliament.

Doug Calhoun,
Partner,
AJ Park

BEHAVIOURAL GENETICS STUDY WINS LILEY MEDAL

A study identifying a genetic connection between life stress and depression has been called a potential 'watershed moment' in the history of behavioural genetics.

Associate Professor Richie Poulton, Director of the Dunedin Multidisciplinary Health and Development Research Unit, was awarded the inaugural Liley Medal for health research by New Zealand's Health Research Council last November.

Using information from a multidisciplinary study of around 1,000 people born in Dunedin 32 years ago, the research team's results have provided an insight into the role of environment on gene expression.

"The secret of understanding how genes work lies in understanding how the environment turns genes on and off," Associate Professor Poulton says.

"The nature vs nuture theory is gone. It is the interplay of all these things and how they interact that matters."

The DMHD study was voted the second most important breakthrough in 2003 in any area of science by the American Association for the Advancement of Science, and has been published in the international journal Science. The 'watershed' praise came from Erik Parens, a senior research scholar at the United States' Hastings Center, a bioethics research institute.

Other projects Associate Professor Poulton is working on include examining the use of cannabis and a particular gene in the development of psychosis.

The Liley Medal is named after Sir William Liley, and recognises his contributions to health and medical sciences.

Richie Poulton

Going Global in 2005

Chris Boalch, Director of Biotechnology for New Zealand Trade and Enterprise, looks back on 2004 and previews NZTE's biotech activities for the coming year

New Zealand's international profile as a smart, niche player in the global biotechnology industry gained considerable traction in 2004 and the coming year promises a raft of further exciting developments. In key biotech markets, such as the United States, Europe and Japan, there is growing awareness that what is happening in New Zealand is worth taking notice of. That makes 2005 an important year for biotechnology. As the industry begins to forge its mark on the international stage, New Zealand Trade and Enterprise is poised to act as a partner and facilitator in accelerating biotech advancement.

NZTE's strategy for biotechnology in the coming year has woven the recommendations of the Biotechnology Taskforce with its own analysis of systemic issues and niche strengths into a comprehensive plan for growth. The overall three-pronged approach puts emphasis on building business capability, creating the right environment for growth and developing international connections.

NZTE's pathfinder programme is a crucial tool in the campaign. Roll out began in 2004 and will gather momentum in the coming months, with up to 25 companies being targeted to receive intensive case management and support from NZTE. These pathfinding companies have been selected on the basis of their innovation and their potential to deliver international success which will boost the national economy.

Focusing on New Zealand's agbio strengths and leveraging the application of biotech in our agricultural economy to open up new global market opportunities is also key to the strategy. The strength and diversity of the New Zealand delegation at BIO2004 surprised many of those attending and prompted the recent visit to New Zealand by Ray Briscuso, BIO's Chief Executive. While our emerging drug discovery companies attracted keen interest, agbio remains a fundamental drawcard, as evidenced by the alliance developing between the state of Iowa and New Zealand. A joint Iowa/New Zealand Memorandum of Understanding to stimulate biotechnology partnerships, facilitate co-investment and support joint technology platforms is under discussion and the strengthening relationship also promises to deliver New Zealand a key foothold in the North American grass belt.

With 25% of the world's research and development carried out in Japan, the potential for biotech collaboration is high.

NZTE will be leading an even bigger delegation to BIO2005 with up to 45 biotech companies expected to participate in the conference in Philadelphia in June this year. We also plan to have a new North American Advisory Board formed soon, to assist and advise companies wanting to get established in the United States.

In Europe, we will also be making our presence felt, building on the exploratory mission in 2004 to BioPartnering Europe. We will be back at the 2005 event and a European Biotech Opportunities Study is due for completion by the middle of 2005, mapping opportunities against New Zealand's capabilities. The secondment of an NZTE specialist to work on the ground in Europe and identify opportunities for Kiwi companies, is an indication of NZTE's commitment to building international connections in Europe.

Smart thinking around ways of progressing our biotech relationship with Australia is another goal for 2005. Major announcements are due soon on the first allocation of funds

New Zealand TRADE & ENTERPRISE

from the Australia New Zealand Biotechnology Partnership Fund and NZTE will be completing detailed capability mapping to determine exactly how New Zealand's biotech strengths dovetail with those of Australia, to support future collaborations.

Initiatives to grow biotech opportunities in Asia are also planned this year. NZTE is bringing together a consortia of agritech solution providers with a view to sending a high level mission to China in the middle of 2005. In Japan, there will also be a detailed investigation of biotech opportunities, leveraging off New Zealand's $10 million investment in World Expo 2005 in Aichi in March. With 25% of the world's research and development carried out in Japan, the potential for biotech collaboration is high.

Over the last year, New Zealand's biotech industry has built a solid foundation to support growth. In 2005 we will begin to see the fruits of that hard work, with biotechnology having an expanding impact on the performance of the New Zealand economy.

Chris Boalch
Sector Director,
Biotechnology

NZBio/*Auckland* Update

The Christmas NZBio/*Auckland* Networking Dinner last December was a lot of fun and it was great to see such a fantastic turnout – not only from those here in Auckland, but the support we received from others who travelled to dine with us. I'm looking forward to more of the same in 2005.

The first NZBio/*Auckland* event for the year will be held on Valentine's Day (Monday, 14th February), with a focus on relationships – JVs, M&As and licensing. Personal partners are invited to join us on this special night.

The big event for Auckland this year will be hosting the first NZBio annual conference, on 14-15 March at the Sky City Convention Centre.

We're honoured to be the host location, and look forward to sharing our fair city with all the out-of-towners attending. The conference is proving to be a hit already, with a larger venue than originally planned being secured.

Focusing on 'The NZ Advantage', we are confident it will be a great event!

NZBio/Auckland Christmas Function 2004
From left: Lester Clark, Duncan Mackintosh, Claire McGowan

Make sure you register early, before the Early-Bird rate expires on 14 February. All programme information and online payment facilities are available at: www.nzbio.org.nz/nzadvantage

Further events for the year include Goodwill & Great Wine functions, CEO dinners, workshops and guest speakers from New Zealand and overseas. If you're interested in attending or registering for any of the NZBio/*Auckland* events, please visit our website www.nzbio.org/auckland and check out the calendar. In the meantime, if you have any questions, drop me an email:

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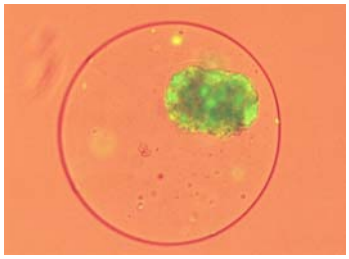
At The Cutting Edge - Living Cell Technologies

Continued from page 1

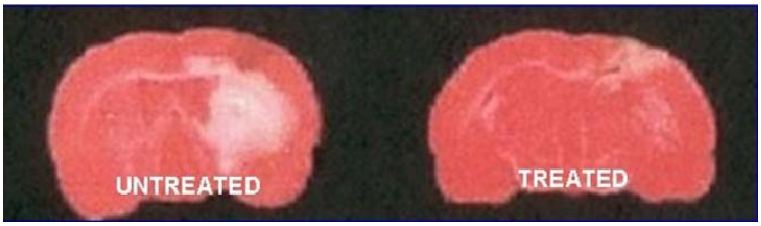
ceived pig islet xenotransplants. Eighteen patients were monitored for up to nine years for potentially xenotic pig viruses. The study reported no evidence of viral infection. There is also recent information indicating earlier observations on the in-vivo transmission of pig endogenous retroviruses (PERV) are faulty and due to pseudotyping of the viruses (Yang et al, J Clin Invest 2004; 114: 695-700).

The first phase of Singapore-based trials involving diabetic monkeys that have received LCT's DiaB-Cell diabetes product (the insulin producing cell transplant) is expected to be completed in early 2005.

With everything going to plan, human trials could begin by the end of the year. One unknown is how long the treatment will last, once it has been administered. Some individual variation is expected in the number of years the transplant remains functional, but the company knows that more than one transplant is safe and feasible, Dr Tan says.



Encapsulated Islet



Untreated rat brain. The white areas indicate stroke lesions.

Rat model treated with Neutrophincell.

New Zealand's current regulatory environment means the trials will be conducted by LCT Bio-Pharma Inc, an LCT subsidiary in Rhode Island, USA. Despite considerable interest from China and Italy, the company is committed to gaining FDA approval first. Once secured, Dr Tan expects more activity and growth in the US firm.

"Of course it would be nice to do trials in your own country. We'd want the benefits of our research to be realised here."

With a personnel list resembling a United Nations' line-up, LCT's management believes the company must be international to be successful. "For any biotech company to do well it must outgrow New Zealand. We can't capture all the necessary expertise from one country."

Having a presence in other countries has certainly been useful, with the US office assisting in gaining regulatory approvals, and the Italian research team, led by Professor Riccardo Calafiore, being the origin of LCT's gel encapsulation technology and the first place in the world to implant encapsulated human islets.

Other projects LCT is working on include treatments for Huntington's disease (NeurotrophinCell) and haemophilia. The company has deliberately targeted diseases that have no current treatment and that can be fast-tracked into clinical trials. Having already completed trials of a Huntington's therapy in rat models, primate studies will begin in 2005 in Rhode Island.

Following a spectacular debut on the Australian Stock Market last September, LCT went on to raise an additional A$4.8 million in October by placing 12 million shares with Australian and US investors. Money the company said at the time would be used primarily for its Huntington's research programme.

The applications for LCT's technologies span some of our most elusive diseases, or as Dr Tan puts it: "This technology is particularly good for diseases where cells are lost, for example; Huntington's, Parkinson's, Alzheimer's, stroke, brain and spinal damage."

Genetic engineering of crops without foreign DNA

Tony Conner & Jeanne Jacobs
Crop & Food Research

There has been considerable public concern over the use of GM crops in agriculture all over the globe. The debate has been especially intense in New Zealand and eventually led to a Royal Commission on Genetic Modification. This remains one of the most comprehensive assessments of genetic engineering technology in society and resulted in the publication of a very thorough report in July 2001. One of the main public concerns underpinning the antagonism toward genetic engineering involves the ethical issue of "playing God" by the transfer of genes across wide taxonomic boundaries. When it comes to such ethical issues, the opinions are deeply held, there is no room for compromise, and scientific knowledge and arguments play little role in resolving the debate.

Despite common negative attitudes toward genetic engineering, the general public is far more accepting of gene transfers within species, e.g the transfer of potato genes to other potatoes or apple genes to other apples. This viewpoint is consistent in public surveys conducted throughout the world. Investigations by social scientists in HortResearch have confirmed such views amongst the New Zealand public. We have experienced similar reactions from numerous discussions and debates with community and industry groups over the past 15 years.

However, the transfer of genes within species still requires the use of vector systems based on DNA from highly divergent species. These vectors are composed of "base DNA" with unique sites into which genes of interest can be cloned. The preferred approach of *Agrobacterium*–mediated gene transfer requires the use of so-called T-DNA borders. In addition, there is usually the need for the vector to carry a selectable marker gene to facilitate the identification of plant cells into which the transferred gene has been successfully integrated. All these vector components are generally of bacterial origin, which represents a source of DNA highly divergent from plants.

The complete genome sequence of all the major crop plants will be known within the next five to eight years.

We therefore took up the challenge to design a vector system in which all the DNA destined for transfer to a crop originates from within the target species. This required the identification of DNA fragments in crop genomes with the functional equivalence of important vector components. If these "intragenic" vectors could be built, the resulting engineered plants would essentially be non-transgenic "GM" plants with no foreign DNA. Such genetic events are similar to "micro-translocations" that can arise from radiation-induced chromosomal rearrangements – a technology that has been widely used in plant breeding for the past 50-60 years.

To construct a simple intragenic vector, the key component to find in plant genomes is the 24 base pair sequence equivalent to a T-DNA border of *Agrobacterium*. This sequence is recognised by the gene transfer mechanism of *Agrobacterium* and represents the point at which DNA transfer is initiated. In general, any DNA between two such borders is transferred into plant genomes. We initially searched the genome database of *Arabidopsis thaliana* because at the time it was the only plant species for which the complete genome sequence was known. This identified one DNA se-

Arabidopsis

quence with remarkable similarity to a T-DNA border. Another fragment of *Arabidopsis thaliana* DNA, containing a gene conferring resistance to chlorsulfuron, was inserted into the fragment of DNA containing the T-DNA border-like sequence. This completed the assembly of an intragenic vector in which all the DNA destined from transfer to plants is composed of two separate DNA fragments from chromosome 3 of *Arabidopsis thaliana*. Furthermore, we have demonstrated that this vector can be used to effect gene transfer to *Arabidopsis thaliana* using *Agrobacterium*-mediated transformation.

More recently we have found fragments of DNA with T-DNA border-like sequences in plant genomes from a diverse range of species. We have been able to design virtual vectors based on the DNA of every plant species we have attempted. These include potato, petunia, tomato, tobacco, barrel medic, apples, onions and rice. To date we have successfully constructed these vectors for potato and petunia.

The complete genome sequence of all the major crop plants will be known within the next five to eight years. The real future lies beyond such achievements, with allele mining from germplasm collections of plant breeders for all the variant versions of genes with altered function. This will identify many genes for immediate transfer back into the same crop and will allow highly targeted genetic improvement of crop cultivars. It will also be possible to specifically design new gene formulations by switching promoter regions to change where and when genes are expressed in plants or by using RNAi knock-down strategies to eliminate gene functions. Such strategies provide immense opportunities to manipulate the biochemical pathways of plants and produce targeted improvements in quality traits.

Gene transfer using intragenic vectors provides a key tool for precision breeding by the targeted design of micro-translocations within crop genomes. These vectors will provide a highly efficient way to transfer genes between individual plants within species. This is essentially equivalent to backcrossing desirable genes into a new genome location of elite crop lines in a single step. A further key critical advantage is that this can be achieved without the "linkage drag" associated with neighbouring genes introduced during traditional breeding.

This new technology raises some important implications for agencies regulating GM crops. Since the resulting plants contain no foreign DNA, it seriously challenges the definition of GM. The genetic outcome of using intragenic vectors mimics translocations via natural or induced mutations. Theoretically, identical plants could be derived from traditional breeding programmes. This approach to gene transfer also compromises the concept of GM testing since all the DNA sequences are already present in existing crops. Only if the exact DNA junctions of the "micro-translocations" resulting from the use of intragenic vectors are known, can such plants or their derived products be detected. This raises a further legal conundrum: if the products of intragenic vectors cannot be identified through routine GM testing, how can they be regulated? And finally, since identical plants can be theoretically derived through traditional breeding and the use of intragenic vectors, it reinforces the concept that there is nothing inherently unsafe with GM technology.

The intragenic vector concept is designed to allow the production of improved plants without using DNA from outside the gene pool already available to plant breeders. The resulting plants are not "transgenic", although they will be derived using the tools of molecular biology and plant transformation. We anticipate that this concept will provide a socially acceptable and responsible way forward for the development of GM crops.

Drs Tony Conner and Jeanne Jacobs are scientists at Crop & Food Research, Lincoln

TAKING NEW ZEALAND BIOTECH TO THE US MARKETPLACE

The Due Diligence Process – What does it involve?

Due diligence is the detailed investigation of a business, the aim being to identify any problems within the business, especially those with the potential to result in future liabilities.

A New Zealand biotech may find itself subject to the due diligence process in the following circumstances:

– Where it proposes to merge with, or be acquired by, another company;

– Where it is involved with a significant commercial transaction, such as a significant collaboration or licensing arrangement;

– Where there is to be an initial public offering of shares in the company; or

– Where there is to be some other form of external investment in the company.

The extent of the due diligence process will depend largely on the nature of the transaction. Where there is a merger, acquisition or external investment, the process is likely to be significantly more complex than where a biotech enters into a standard commercial transaction.

'The extent of the due diligence process will depend largely on the nature of the transaction. Where there is a merger, acquisition or external investment, the process is likely to be significantly more complex '

However, regardless of the nature of the due diligence, a biotech which is likely to be subjected to the process needs to prepare well in advance by undertaking its own internal due diligence to ensure any potential issues can be rectified so as not to dissuade potential purchasers, business partners or investors.

Although the due diligence process will usually involve a review of a number of areas of a biotech's business, a central focus will be on the company's intellectual property rights including patents, copyright, trade marks, and confidential know-how.

Intellectual Property Due Diligence

An intellectual property due diligence involving a biotech business will generally seek to establish:

– The biotech's intellectual property assets and whether there are problems with ownership or control of those assets. The biotech will need to provide evidence of a clear chain of title in its intellectual property, from the inventor, author or previous owner. The value of intellectual property assets may be weakened by the lack of an assignment of all interests from the relevant inventors, creators or authors. Where there are contracts granting rights in intellectual property, these will be reviewed to identify geographic and other restrictions on the ability of the business to use what it believes are its current or potential intellectual property assets.

– The economic and strategic value of a biotech's intellectual property assets and the extent to which these provide effective exclusivity in the market for the company's products and services. The economic value of intellectual property will depend on its scope (ie the extent to which it is limited in terms of geography, time or potential contractual restrictions) while the strategic value will depend on whether it fits within a company's business objectives and whether it can be enforced against others in the industry.

– The potential licensing or other strategic uses of the intellectual property.

– Any potential liability for infringing third party intellectual property.

Patents

Patents form the cornerstone of many biotechnology businesses. Due diligence of a biotech's patent portfolio will cover the following areas:

– The biotech's key product candidates and platform technologies will be investigated to determine whether they are adequately covered or protected by patents. The length of each patent's unexpired term will also be investigated.

– Whether a biotech's inventions have been protected in key territories and whether procedures are in place to ensure all renewal fees have been paid for those territories.

– Employment contracts and research contracts will also be reviewed to determine

how the ownership of intellectual property is dealt with in the business.

– The due diligence process will seek to establish whether there have been any challenges or opposition to a biotech's patents. It is also important to consider whether the patents actually provide useful protection or whether they can be designed around.

– Due diligence reviews will also consider any pending or threatened actions as well as areas where there is potential risk for such action. Questions may arise as to whether any other party has offered the biotech licences to its technology, or has threatened to sue. There may be further questions around whether the biotech is aware of any relevant third party patents and, if so, whether it has sought infringement and validity advice in respect of those patents.

Confidential Know-how

Confidential know-how also forms an integral part of the intellectual property of any biotechnology organisation. In some instances, biotechs may prefer to protect information as confidential know-how rather than as patents.

The due diligence process as it relates to confidential know-how will address the following issues:

– Lab books are an extremely important mechanism for recording know-how. Such records are especially important where a researcher leaves. Detailed records will prevent work from being lost or replaced unnecessarily.

– Consideration will be given as to whether key employees are covered by confidentiality obligations. A person undertaking due diligence may also give consideration as to whether there are appropriate mechanisms in place to ensure levels of confidentiality are maintained. Confidential reports and documents should be properly marked and circulation restricted.

–Consideration will also be given to whether the business has adequate procedures in place to identify new inventions and consider patentability at the earliest opportunity.

–A biotech undergoing due diligence will need to produce the standard form confidentiality agreements it uses for dealing with third parties. These agreements will be examined to determine whether there is adequate provision to ensure the return of all materials disclosed if a transaction does not go ahead or is terminated and whether agreements contain adequate restrictions on the use of materials, including provisions for their return.

Copyright

Copyright is an important mechanism for biotechs to protect their computer software in particular. In New Zealand and the United Kingdom copyright arises automatically in original documents and software. Although the same is true for the US there is also a registration system for copyright which confers additional rights on the copyright owner.

Biotechs which engage independent consultants to develop their software will need to be able to show that copyright in this software has been appropriately assigned to the biotech. Where businesses are using third party software there will be checks to determine whether appropriate licences are in place and to ensure the biotech is not breaching the terms of those licences.

Trade marks

Trade marks will not usually be a priority for a biotech. However, the core business and product names will require protection. Once the patent on a drug expires, a well-known brand may give a product a competitive advantage over other products in the market. Any person undertaking due diligence of a biotech business will wish to ensure that the biotech's key brands are protected.

Conclusion

Due diligence is a critical element of any major transaction. A biotech which has spent some time ensuring it has its affairs in order will not only have a less onerous task when it becomes the subject of a due diligence but will also find it has enhanced the value of its intellectual property assets if it has addressed any potential intellectual property issues well in advance of commencement of the process.

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For an overview of Simpson Grierson's Biotech expertise and related service offering visit:
http://www.simpsongrierson.com/Biotechnology/Life_Sciences.html

NEW ZEALAND'S MARINE ENVIRONMENT
A Bioactive Treasure House

Dr Vicky Webb

New Zealand is the world's most oceanic nation of significant size (exceeding 250,000 km²). We have the fourth largest EEZ (Exclusive Economic Zone) which is 16 times the land area. New Zealand's position astride an active plate boundary has created one the most diverse seabed topographic settings to be found around any nation. This setting includes canyon systems in excess of 10,000 m deep, over 800 identifiable seamount features, some of the world's longest deep sea trenches, extensive shelf canyon systems, active undersea volcanism, hot and cold water vent systems, unique fiord ecosystems, and isolated offshore islands. This translates into a high level of species endemism, an outstanding biodiversity and therefore a potentially high number of unique bioactive molecules which are the life blood of the biotechnology industry. NIWA, with its close association with the marine environment, is well positioned to foster the development of high-value pharmaceuticals, nutraceuticals, agrichemicals and novel materials.

NIWA's current research activities in the biotech area include the discovery and development of: skin care products, non-steroidal anti-inflammatory drugs (NSAID), and antifouling products.

The consumer demand for natural products in the skin care market continues to grow. However, currently very few products are based on marine bioactives. Ngāi Tahu Seafood has teamed with the NIWA biotech team to identify and develop skin care products derived from fish by-catch and by-products. The programme integrates the strong research skills of NIWA with the commercialization and marketing capability of Ngāi Tahu Seafood. We screen for: anti-oxidants (anti-ageing), vasodilators/vasoconstrictors (blood flow), skin repair agents, and UV protectants. This year we will be establishing a non-animal test system to verify safety and efficacy. Chemical structure is also determined to facilitate IP protection. Several compounds are currently under-going purification prior to chemical structure elucidation.

Ngai Tahu Seafood has teamed with the NIWA biotech team to identify and develop skin care products derived from fish by-catch and by-products.

Our research in the pharmaceutical area aims to identify NSAID's. The programme is a joint venture, named TerraMarine, between NIWA, Crop & Food Research and Malcorp BioDiscoveries. Additional support comes from the Universities of Auckland and Otago, two clinicians and two industry advisors. The partnering is crucial as it takes advantage of the skills and resources of the different teams and organisations. NIWA, for example, has a large collection of marine samples primarily of sponges, tunicates, bryozoa and other sedentary organisms, and marine microbes. Besides biotechnology expertise and the collecting ability, NIWA has considerable expertise in aquaculture. This is potentially important for short term supply of complex bioactive compounds. Crop & Food Research provides a complementary collection of terrestrial plant samples along with farming options for many plants and expertise in natural products chemistry. Malcorp BioDiscoveries bring screening capability. The universities provide expertise in natural products chemistry and formulation. The clinicians provide expertise for clinical trials as well as focus to ensure the products that come out of the programme will be useful in the clinic. Although the programme is young, we have identified potentially useful compounds for the NSAID market and preliminary animal trials have commenced.

NIWA is also pursuing industrial opportunities. Globally there is an urgent search for antifouling paints/products to replace current environmentally unfriendly products such as tributyltin (TBT) and copper-based paints. The fouling of underwater structures by marine or-

ganisms is a major cost for shipping, and seriously affects underwater structures such as oil platforms, pipes (including the intakes to power stations), and aquaculture structures etc. Many marine organisms produce highly toxic compounds to prevent fouling or stop predation. These compounds, by their very nature, offer exciting potential for antifouling products. In 1998 our team started to explore the use of an extract from a toxic microalga (isolated in Wellington Harbour) as an antifouling product. A partnership developed between NIWA, ESR and Victoria Uinversity to continue this work. While the algal toxin showed some promise, further chemistry is being sought before more formulation trials commence. In a new programme, other marine toxins are under investigation for incorporation into both antifouling marine paint and plastic products.

Novel natural bioactive compounds are in increasingly high demand across all market sectors. The marine environment is poised to play a significant role as a source of these valuable commodities.

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In need of a remedy

Steve Walsh, of Marsh Limited, discusses a recent product liability claim.

An animal remedy had been developed by a scientific laboratory over a number of years. Due to its complex nature it had had an extensive period of trialling and further development before finally being released to market. Following the first application there were mixed results and a number of the animals died, prompting the farmers to sue the product developer / manufacturer for product defect.

After the insurers had reviewed the case extensively, they attributed the cause of death of the animals to a number of factors. Their conclusion was that death had resulted from a combination of:

- A high toxicity level in the remedy;
- Incorrect accompanying instructions for application; and
- Incorrect application by the farmers themselves.

In the end, they made only a partial pay-out, for the "portion" of the claim that they deemed to result from the high level of toxicity i.e. the product developer's product liability. The sum paid amounted to approximately 70% of the total claim.

This example serves to illustrate the complex nature of product liability claims. Although the farmers may have seen the loss as being entirely the fault of the product developer, in fact the developer was only partially liable. The remaining 30% liability fell with the farmer himself for the incorrect application of the product.

Tips from this claim?

The insurer will not pay out on any claim unless they are satisfied that the loss is covered under the policy. This will involve extensive research into the cause of the loss.

If you are looking to use a newly developed product on your farm, location or site, it's absolutely crucial to ensure you have up to date instruction material and that you have carefully researched how the new product should be applied (and work).

If you're developing a new product, no matter how much testing has gone into its devlopment, you must allow for "user error". Instrucions must be clear and transparent and able to be understood by any potential user.

And it's important to have a robust product liability insurance programme in place. Contact your insurance broker for an obligation-free insurance programme review – this will ensure that you have the correct policies and protection in place. If your insurance broker doesn't offer a free review, contact Marsh – we do!

OMEGA 3's FUTURE DIRECTIONS

Differentiating ALA, EPA and DHA

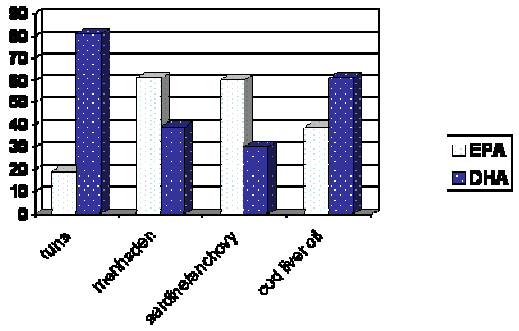
Wendy Morgan* & Michael Green**

In August 2004, a group of scientific researchers in the area of Omega-3 fatty acids met in Brisbane to discuss the current level of knowledge on Omega-3s with reference to the specific roles of alpha-linolenic acid (ALA), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) and the application of that knowledge to product development, consumer communications and claims.

Wide variation in fish oils

Fish oils vary widely in their fatty acid composition and new sources of Omega-3 fatty acids can provide concentrations of individual fatty acids. Early research focussed on EPA rich oils such as menhaden but more recently DHA rich oils such as tuna oil and microalgal oils have been the subject of research. It has been shown

Figure 1. Comparison of proportion of EPA and DHA in different fish oils



that conversion of ALA by the body to the more active longer-chain metabolites is inefficient. It is estimated that 10% or less ALA is converted to EPA with only 2-5% reaching DHA.

Effects of different Omega-3 fatty acids

A wide range of subject areas were discussed at the workshop including infant development, cardiovascular disease, mental health, depression, gene expression, inflammatory disease, exercise performance and immune function. Professor Peter McLennan, Director of the Smart Food Centre, University of Wollongong discussed new research which indicates that DHA has specific roles in heart function (see Box 1)

Box 1: Adequate levels of DHA can:

- Make the heart muscle stronger and more powerful.
- Stop the fatal arrhythmias that take place during a heart attack.
- Give the heart muscle a greater ability to adapt and cope with increased stresses and pressures.
- Enable the heart to use less oxygen to do its job, to pump more efficiently, and to reduce the average heart rate - providing greater reserve capacity.

In summary, the workshop came to the following conclusions based on discussions of each of the eight listed subject areas:

Subject	Implicated key fatty acid based on strength of evidence
Infant development	DHA
Brain – mental health & depression	EPA, data on DHA mainly epidemiological
Brains – gene expression	ALA(?), EPA and DHA
Cardiovascular	Fish oil, DHA, not ALA
Exercise performance	DHA
Biomarkers of Omega-3 status	EPA + DHA in RBC phospholipids
Inflammation	EPA and DHA
Immunology	Fish oil

Everyday foods enriched with Omega-3 DHA

A new biomarker for Omega-3s

A new approach to understanding Omega-3 fatty acid status, the Omega-3 Index, was examined. It is expected that a simple, rapid measure of Omega-3 status will be further developed to guide clinicians in advising their patients and will provide an opportunity to link this biomarker to dietary intake of Omega-3s and foods containing them.

Future sources of Omega-3s

The future of microalgal and plant sources of long chain Omega-3 fatty acids were discussed with microbial oils being short term sources and GM plants probably taking another 10 years for commercialisation.

Recommendations for Omega-3s

The public health implications of the research findings, the development of recommended intakes of Omega-3 fatty acids in Australia and revised authoritative advice and progress on health claims for foods in Australia and New Zealand were discussed at the workshop.

The Australian National Health and Medical Research Council (NHMRC) released its proposed new Nutrient Reference Values in December 2004 and for the first time, the very long chain Omega-3 fatty acids have advisory intake levels.

To reduce chronic disease risk, the NHMRC proposes levels of 190-610mg/day for men and 90-430mg/day for women. In 2004 the UK Scientific Advisory Committee on Nutrition recommended the equivalent of 450mg EPA and DHA per day and the International Society for the Study of Fatty Acids and Lipids (ISSFAL) recommended 500mg EPA and DHA per day for cardiovascular health. Few people in Australia or New Zealand would consume more that 450mg EPA and DHA per day. In fact, the median intake has been estimated at less than 30mg per day!

Dr Wendy Morgan

The National Heart Foundation of Australia is presently re-writing its position statement on Omega-3 fatty acids. A new food standard for health claims in Australia and NZ is being developed with a pre-approved health claim for Omega-3s and reduced risk of heart disease under scientific review. The new food standard on health claims is expected to be finalised in 2006.

Conclusions

The workshop demonstrated the important role of scientific researchers in ensuring relevant and accurate regulations and policy recommendations relating to Omega-3 fatty acids as the science is evolving rapidly. The different roles of Omega-3 fatty acids in the body indicate the benefits of high DHA oils for heart disease prevention and other health effects.

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GM on the Menu

Genetic modification made it into the news again last week, albeit briefly. This time GE-Free New Zealand had found food on the supermarket shelf which was labelled "Genetically Modified". They demanded the product be immediately withdrawn. A strange reaction from a group who have always appeared to advocate choice. I took advantage of the free advertising GE-Free NZ had provided and went in search of Stagg's "Four Bean Chilli". I found it in Woolworths next to the Watties baked beans and bought a few cans. That this may be the first GM-labelled mainstream food to hit the shelves made it a satisfying addition to my birthday dinner.

The New Zealand Food Safety Authority responded to the protests by stating the can was labelled according to the law. They pointed out the size and position of the print was similar to allergy warnings where there actually is potential for harm. Further, they said those who were concerned would bother to look.

This event came only days after Jeanette Fitzsimons claimed that GM was unlikely to form part of any coalition talks with Labour because the anti-GM groups had "won the GM battle". In her speech to the party faithful she mentioned GM only in passing and vowed to "maintain New Zealand's GM-free status". To accept these statements one has to suspend disbelief and ignore the hundreds of GM experiments occurring in our universities, CRIs and companies in the advancement of medicine, agriculture and biological science. One needs to ignore the GM corn episodes which have been detected and those which undoubtedly have not been detected, as well as the legitimate production of GM plants here before ERMA. Finally, to truly believe New Zealand is GM-free one needs to ignore the GM-derived meal imported to feed chickens, cattle and other animals, and the GM ingredients, enzymes and medicines which slip under the GM labelling radar.

If the anti-GM groups succeed in keeping all GM-labelled products from our shelves and preventing every release of a GMO for use in agriculture, they will have succeeded to some extent. They will certainly have succeeded in holding back a technology which is being enthusiastically embraced around the world by millions of farmers who have the choice to use it. Monsanto will soon be selling enough GM seed to plant a billion acres. It's not a matter of 'if' for New Zealand but a matter of 'when'. GM outside New Zealand has the potential to erode our competitive advantage in agriculture by allowing our international competitors to grow food more efficiently, with less environmental impact and with added health benefits. Monsanto has already announced a GM soy bean with constituents to rival olive oil. We need new technologies to stay competitive. Anti-GM groups have sought to deny us this new technology.

The appearance of a can of GM-labelled food so soon after Jeanette Fitzsimons' proclamation must be a body blow. No doubt the anti-GM groups will try to put as much pressure as possible on Progressive Enterprises to withdraw the product from their Woolworths and Foodtown supermarkets. Perhaps they will picket stores in a campaign similar to that run against KFC and Inghams last year, which aimed to pressure the organisations to use GM-free chicken feed. Incidentally, KFC sales increased last year - a sign perhaps that most consumers aren't interested in the GM issue and trust our regulators to maintain food safety.

For me, I prefer to support those companies who base their decisions on sound science and safety rather than those who pander to the NGO, anti-GM, anti-technology agenda. Stagg's Four Bean Chilli is on my menu. In the words of Dilmah Tea founder, Merrill J. Fernando,

"Do try it!".

Dr William Rolleston
Chairman,
Life Sciences Network

Member Profiles

UK TRADE & INVESTMENT

The role of UK Trade & Investment (UKTI), based at the British Consulate General in Auckland, is the British Government organisation that supports both companies in the UK trading internationally and overseas enterprises seeking to locate in the UK.

The close bilateral ties between the UK and New Zealand are the bedrock of a growing trade relationship worth more than $2.4 billion. We are not simply markets for each other's goods and investments - companies in both countries see collaboration and partnership as a key to a successful future. The enlargement of the EU opens the door to an even larger market for New Zealand goods and services, using the UK as a springboard. There have been several encouraging examples of British and New Zealand companies collaborating to develop product, test ideas and refine processes.

Now, with the support of New Zealand Trade and Enterprise and UK Trade and Investment, NZ biotechnology companies are being actively encouraged to look at links with, and in, the UK. An MOU was signed in London in June between our two governments' trade and investment arms to provide access for NZ biotechnology companies to the UK trade and investment support. This will encourage more NZ companies to look at the UK as a place to invest (more than 32 already operate there) and make it easier to tackle the new EU markets in Eastern and Southern Europe more easily from a UK base than from New Zealand.

Brian Murray is the Trade Development Manager for Biotechnology at UKTI and responsible for the promotion of this growing science.

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1904–2004 Healtheries 100 YEARS

Healtheries is a New Zealand privately owned,100 year old business and one of the world's leading health food and supplement manufacturers. The distinctive red Healtheries logo adorns more than 750 different products spanning a health food, supplement and beverage product range unrivalled in Australasia. The company's range includes vitamins and minerals, garlic and herbal supplements, cereals, rice wafers, a wheat and gluten free range and herbal and fruit teas. In many categories, Healtheries is the market leader and almost every New Zealand supermarket, health food store and pharmacy is a Healtheries stockist. The company employs more than 250 people, has two New Zealand factories and exports to all five continents.

Exports represent 40 per cent of the company's sales and 40 percent of Healtheries' exports are accounted for by sales to Australia where the company is represented in supermarkets and health food stores.

Biolane™Green Lipped Mussel Extract for arthritic and joint pain is one of Healtheries' flagship export products and is sold in more than 25 countries around the world. In Singapore, Healtheries vitamins and supplements are sold through pharmacy outlets and a range of Healtheries Colostrum products is sold throughout China.

Research is a key driver of the product range. A highly qualified team of 18 technical and research staff integrates the latest international scientific research with proven and tested ingredients. Supplements are formulated to ensure therapeutic doses are delivered.

Product certification plays a major role in Healtheries' quality control procedures. Certification includes, Medicines Licence, GMP Registration, HACCP (Food Safety), MAF (Ministry of Agriculture & Fishery) Certified Dairy Premise, MAF Certified Meat / Fish Premise. Healtheries also has a contract manufacturing operation.

www.healtheries.co.nz

Member Benefits

CORPORATE MEMBERSHIP BENEFITS

- An industry body that is working to improve the investment, taxation and regulatory environment for biotechnology companies in New Zealand
- A "champion" to address industry actions identified in the Biotechnology Taskforce Report, and to ensure these actions are progressed
- Pro-active monitoring of the operating environment and action on changes that affect industry development
- Access to high level networking forums like the trans-Tasman CEO Forum to expand contacts and business opportunities
- Communications that ensure you are kept up-to-date on issues relevant to the New Zealand biotechnology sector
- Weekly newsletter
- Bi-monthly copy of the electronic publication 'NZBio Report'
- News service hosted on the NZBio web site
- Progress reports on policy and regulatory issues
- Access to submissions, industry reports, position papers, and policy documents
- A single point of contact for information on regional, national and international networks and sector related government policy
- High quality training and development opportunities delivered through the annual conference, and a series of workshops and seminars
- Opportunities to influence industry strategy and direction through NZBio initiatives and projects
- Raising your corporate profile through the NZBio Report, newsletter, web site, conference and NZBio networks
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- Progress reports on policy and regulatory issues
- Access to submissions, industry reports, position papers, and policy documents
- High quality training and development opportunities delivered through the annual conference, and a series of workshops and seminars
- Career information
- A discount on the annual conference registration
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