Grasslanz Technology Ltd
Tennent Drive
Private Bag 11008
Manawatu Mail Centre
Palmerston North 4442
New Zealand

Phone +64 6 351 8255
Fax +64 6 351 8240
www.grasslanz.com

grasslanz®
unique plant opportunities

February 2011

Patent Amendment (Human Genes and Biological Materials) Bill 2010

Submission

by

Grasslanz Technology Ltd

Background

1. Grasslanz Technology Ltd is a wholly subsidiary of AgResearch Limited. Its main areas of activity are:

    - Development of plant varieties, grass endophytes and plant genes
    - Collaborative research and project management of plant technologies
    - Production and sale of high quality early generation seed stock
    - Protection of its intellectual property (IP) through patents, trademarks and plant variety rights
    - Licensing of those IP rights.

2. Grasslanz Technology Ltd licenses its plant varieties and grass endophytes for use by Australian companies in Australia. All of our key endophytic products are protected by Australian patents.

Proposed amendment to the Patent Amendment (Human Genes and Biological Materials) Bill 2010

Grasslanz Technology Ltd (Grasslanz) wishes to comment on the proposed amendment to the Patent Amendment (Human Genes and Biological Materials) Bill 2010 to prohibit the patenting of "biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature" where "biological materials" include DNA, RNA, proteins, cells and fluids.

The economic impact of such amendment

Grasslanz submits that proceeding with this amendment will have a substantial effect on Australian consumers and industries. It will also have a major financial impact on Grasslanz as a successful company.

Endophytes of interest to Grasslanz are fungi. These endophytes live within a plant and improve the ability of plants, in particular grasses, to tolerate abiotic stresses such as drought and improve their resistance to pests such as insects and modify their properties for such uses as bird control at airports. Such endophytes are proving valuable to Australian agriculture and economy.

Endophytes in rye grass

Perennial Ryegrass Toxicosis (PRGT) is a serious and widespread problem in livestock grazing perennial ryegrass. PRGT is caused by the alkaloids produced by a wild endophyte present in many perennial ryegrass cultivars and can affect sheep, cattle, horses, deer and alpaca . PRGT has found to cause heat intolerance, poor fertility and lamb rearing, decreased feed intake, increased faecal contamination of wool and flystrike, reduced milk production and meat quality and neurological conditions such as tremors and nystagmus. Other consequences include social effects as severe outbreaks are extremely stressful on the farmers, stock death by misadventure (e.g. drowning), and lowered immunity. Farm shearing and marketing schedules can also be affected. All factors which contribute to production losses and animal welfare concerns.

Perennial ryegrass (PRG) (Lolium perenne) occupies more than 6 million hectares of Australia where it provides important forage for grazing livestock.

Approximately 26.5 million sheep and 1.5 million cattle are at risk of PGRT in Australia. The average annual cost of PRGT to the Australian sheep industry is estimated to be $63.6 million. Of this total cost, $33.6 million is due to a decrease income associated with deaths (fewer sales), reduced flock fertility and reduced wool quality. The balance of the cost relates to an increase in expenditure associated predominately with additional labour and supplementary feed. A severe outbreak of PRGT is estimated to cost $12.15 per head in a merino flock and $20.86 per head in a prime lamb flock.

The annual average cost of PRGT to the Australian beef cattle industry is estimated to be $1.5 million. The cost of an outbreak is estimated to be $4.98 per head, giving an annual average cost per head of $1.00. The cost is substantially lower than for sheep because cattle appear to be less severely affected by PRGT outbreaks (Sackett and Francis)

Effective prevention strategies include the replacement of these toxic endophyte ryegrasses with ryegrasses containing beneficial novel endophytes. These are strains of endophytes that produce beneficial alkaloids that are not toxic to livestock. Novel endophytes have been identified as a viable and suitable long term strategy to prevent PGRT.

Endophytes in other grasses

Endophytes are important to many temperate grasses including tall fescue as they help protect the grass against biotic and abiotic stresses such as insect attack and drought conditions

Wild-type endophytes in tall fescue pastures can also cause similar adverse animal health problems. Novel endophytes can eliminate many livestock health problems associated with toxic endophytes whilst satisfying plant health and persistence issues.

The market in Australia

The proprietary seed market in Australia includes 2000-2500 metric tonne of perennial ryegrass, and 900 tonne of tall fescue. A great proportion of this seed sold contains novel, beneficial endophytes to eliminate toxicosis associated with wild endophyte.

Grasslanz invests considerable money into research and development of endophyte innovations suited to temperate pasture grasses. About 10 -15% of about $4m (NZD) which is both Grasslanz funding and leveraged funding from NZ government, is directly invested into Australian specific research. Australian agriculture also greatly benefits from the products of research undertaken in New Zealand.

Grasslanz products dominate the novel endophyte market of perennial ryegrass and tall fescues in Australia. They are an efficient and effective strategy to eliminate and/or minimise toxicity in livestock grazing pasture. Without the option of friendly endophytes, Australian agriculture will continue to have a huge cost in lost production and expense in livestock management.

See, for example, the following articles, copies of which can be supplied on request.

Sackett , David and Francis John 2006. Meat and Livestock Australia Limited Final Report Animal Health and Welfare Project code AHW.089/B.AHW.0089. *Economic assessment of the impact of Wild Endophyte-Infected Perennial Ryegrass (Lolium perenne) on the productivity of sheep and cattle and the profitability of Australian livestock enterprises.* New South Wales, Australia

Reed, K.F.M, Scrivener, C.J, Rainsford, K.A. and Walker, L.V. 2005 Neotyphodium Research and Application in Australia in *Neotyphodium in Cool-Season Grasses (Roberts, West, Spiers)*

Endophyte research and development

The key activities of endophyte research and development include:

- Identification, classification, and taxonomy of endophyte strains which also involves establishing knowledge on strain verification, viability and purity.
- Endophyte chemistry and effects on insects
- Agronomic validation of endophyte strains
- Inoculation into trial species
- Animal performance and safety trials for many classes of stock and international standards.
- Alkaloid impact on food chain for human consumption
- Seed production, packaging and storage (and also research on these parameters)

On average it takes about 10 years from identification to commercialisation but of course some take a lot longer than this. Patent protection is usually sought shortly after identification of a useful novel endophyte. So that ten or more years of patent life expires before revenues from commercialisation commence.

Reliance on patents

Development and commercialization of new technologies requires substantial investment. Investors need the benefit and confidence of patents to protect IP during the lengthy period of R&D investment so that the expense can be recouped. If this bill were to be passed and patent protection for key Grasslanz products were not available Grasslanz would need to drastically alter its business model which relies heavily on securing protection for its research output.

For example, Grasslanz current patented endophytes live in seed and it would be simple to multiply the seed and produce many subsequent generations that contained this special fungus and exhibited its special qualities. Hence, without patent protection of its propriety endophytes Grasslanz would have no right to prevent this seed multiplication and could not justify the prices it demands for seed which prices are necessary to recover the initial investment in R&D and support future investment.

Royalties from seed sales generates the majority of funding towards further research and development which fuels innovation for the future of Australian agricultural.

The development and commercialization of high quality new biological innovations is a long and expensive process. Long term protection is essential in the ability to recoup costs.

Furthermore, Australian industry often needs to be educated about these products and the benefits they will deliver; the uptake and adoptions of these innovations by Australian farmers can often take some time. Hence the need for long term protection of the novel products. Patent protection is the only IP type that can ensure that happens. PVR protection is more limited.

COMPARISON OF PATENT AND PVR

Patent right and PVR provide different and useful protection to Grasslanz.

A patent provides the protection of a novel concept (which is part of the inventive step) which has lead to a technology being developed, while a PVR more narrowly protects only the specified developed technology

Patents have a broader coverage; it stops others from entering the same space with similar/look alike products and with product having the same or similar function.

Patents protect the utility of a product, conversely, the means by which PVR are granted are based on morphological characteristics which for the most part have no bearing or relevance to the efficacy of the product in the market place.

Considering, for example, one of the endophytes developed by Grasslanz –AR37. This has significant alkaloids- epoxy janthitrems that help pasture and turf grass grow and survive. If Grasslanz solely relied on PVR then another party could apply for PVR for a similar endophyte that produced the same alkaloids (e.g. epoxy-janthitrems) and effectively fulfilled the same agronomic purpose but grew slightly differently on an agar plate. That third party may be granted PVR based on its looks! The sale of that endophyte may not be an infringement of the PVR. Patent protection ensures that such similar endophytes are protected and, without our approval, cannot be sold in Australia.

If the bill passes and patent protection is no longer available, then investments in Australia by Grasslanz Technology in related technologies (endophytes, GMOs, etc) will cease;

New technologies will not be developed and commercialized for Australian industries, e.g. bird control at airports, insect control in pastures and cereal crops, etc.

The biggest losers from this amendment will be Australian consumers and industries and as a business Grasslanz will suffer.