



Submission to the Senate Legal and Constitutional Affairs Committee inquiry regarding the Patent Amendment (Human Genes and Biological Materials) Bill 2010

This paper, prepared by Meat & Livestock Australia (MLA), is written in response to the call for submissions by the Senate Legal and Constitutional Affairs Committee in its inquiry of the Patent Amendment (Human Genes and Biological Materials) Bill 2010.

Executive summary

This submission seeks to bring to the Committee's attention that many of the same problems encountered with human gene patents also exist in cattle, sheep, goats and plants. Over the years we have witnessed that general discoveries of nature are increasingly being sought to be patented. This is hampering important research into understanding the naturally occurring genetic makeup of animals and plants, which in turn impairs our industry's ability to retain a competitive advantage over other nations.

We see no benefit in patenting naturally occurring genes, markers or segments of DNA as these on their own are not of value. Rather, the value lies in the detection of the correlations between commercially-important traits and enormous numbers of single nucleotide polymorphisms (SNPs) or genes across the whole genome. The value of this research becomes negligible if some of these SNPs are individually protected.

Unlike other industries, research organisations in the meat and livestock industry are starting to move to a "knowledge for all, not just some" mindset, by sharing their genotype sequences and combining datasets to improve the predictive power of the statistical correlations. In organisations that choose to keep this knowledge in-house there's a preference to keep the marker or gene association 'confidential' rather than patenting it.

We believe it is in the interests of the Australian livestock industry and the international scientific community that current legislation is amended to ensure unfettered access to naturally occurring gene sequences to reflect this changing reality

Introduction

Meat & Livestock Australia (MLA) is a producer-owned company which invests approximately \$75 million annually in research and development, on behalf of 47,000 cattle, sheep and goat producer levy-paying members and the wider red meat and livestock industry within Australia. Approximately half of this investment is provided by the Commonwealth Government.

Within Australia, MLA is a significant investor in sheep and cattle related research. MLA commissions research, development and extension services throughout the food chain (on farm and off farm) to enhance Australia's competitiveness and sustainability.

Programs and projects investigating the genetic and genomic arrangement within sheep, cattle and plants, comprise approximately 15% of MLA's on-farm R&D portfolio, and those programs and projects involve partnering and co-investment with prominent publicly-funded and private genetic research and delivery organisations throughout Australia.

Despite Australia's historical distance -to-market disadvantage, the Australian meat and livestock industry has been able to compete successfully internationally, delivering high quality red meat and livestock throughout the world. Much of this competitive advantage has been achieved through improving the quality of the Australian livestock industry as a result of genetic research and development and improvement programs, including improved pastures, better understanding of production characteristics and increased ability to predict progeny traits.

Genetic and genomic programs

MLA's genetic and genomic improvement programs are encountering many of the same issues currently being debated in humans, as these same problems also apply to gene discovery in animals and plants. More and more, we are seeing that general discoveries of nature have sought to be patented. This patenting is hampering the evolution of our research and our understanding of the underlying causes for genetic variation in animals and plants, and improvement in our national genetic improvement programs.

As understanding of genomics develops, it is becoming clearer that interactions amongst sets of genes play a dominant role in determining the performance of animals and plants, and that the single patentable gene is an almost meaningless concept in the majority of cases. This means that patents can restrict the commercial application of this new knowledge despite the patented genes having minimal impact on the trait(s) under investigation.

If the protection of genes and gene markers continues, it will be imperative for MLA and the research organisations involved to reassess their current strategy and investment in genetic and genomic research, development and implementation. At this point in time there are no obvious ways to avoid the loss of research effectiveness or the substantially higher transaction costs. This has the potential to stifle our ability to continually improve the productivity and sustainability of the Australian meat and livestock industry.

Gene patent issues

Genes are the building blocks of life. Research identifies how DNA controls the phenotypic expression of life. There is still a great deal to learn about genes, particularly how they relate to traits and contribute to disease susceptibility. Gene patents inhibit ongoing access to the most basic information.

DNA (deoxyribonucleic acid) contains the instructions used in the development and functioning of living organisms. Genes and gene markers within the DNA carry this information. Understanding what genes affect life and how the DNA pathways interact is about uncovering and discovering what happens naturally.

Unless genes are genetically modified (which is the subject of a different type of debate) then their discovery (or more simply, observation) doesn't contain an inventive step. For

practical purposes, the observation leads to a knowledge of the correlation between the specific DNA sequences at one or more genome locations, and the performance of the animal or plant. The establishment of this correlation does not involve any inventive step – it is purely a question of statistical analysis. Discovering the link between specific gene segments and their expression (enzyme or protein production) is just simply a mapping process.

The standard method emerging for use of genomic information in all fields of research and application is whole genome wide associations. This area of work is solely focused on establishing the correlations between genetic makeup and trait performance as outlined above, usually with very large numbers (up to 1 million single nucleotide polymorphisms (SNPs) currently, but higher in the near future) of randomly placed SNPs or locations in the genome. Whole genome association is guaranteed to detect the correlations and effects associated with patented genes as well as unpatented genetic material. This is clearly unworkable and renders the concept of a specific, isolated and protectable segment of DNA meaningless.

The proposed research exemption outlined in IP Australia's latest round of suggested Patent Act amendments only partially covers our research. MLA is not a research organisation; instead we need to contract others to conduct research for us.

Evolution of genetic research

We see no benefits in patenting naturally occurring genes, markers or segments of DNA. Ten years ago it was a commonly held view that the protection of some of these gene markers would assist in leveraging the research outcomes to license. However, history has shown this has not been the case. While businesses (outside cattle and sheep genetic diagnostics) may desire to patent their products, large animal health genetic diagnostic organisations in Australia have a preference for keeping the marker and gene associations (unless very high) confidential, as a trade secret, rather than patenting them. Thus these large animal health organisations will still continue their research into genetic correlations whether the patent system exists or not.

The increased complexity of the debate on food security and sustainability requires agriculture to develop new innovation pathways. We require the ability to understand what is happening naturally within cattle and sheep and the ability to apply that knowledge to improve productivity, improve animal health and address issues around health, production system, ethics, sustainability etc, broadly within Australia. The approach that is evolving very rapidly in all fields is based on the recognition that knowing specific gene sequences or locations is of itself not of value, and that statistical associations, increasingly with enormous numbers of SNPs, are what matters, and these associations must be determined for every population into which a particular test is intended to be applied. Based on this, research organisations and industry stakeholders, such as breed societies in the animal industries, are sharing their genotype sequences and seeking to combine datasets in order to be able to improve predictive power of the statistical correlations.

This is moving rapidly to a “knowledge for all, not just some” environment. We believe it is in the interests of the Australian livestock industries that current legislation be amended to reflect this changing reality, and further, that it is in our interest as an active participant in and beneficiary of, the international scientific commons.