Australian Government
Grains Research and Development Corporation

28 February 2011

Ms Julie Dennett
Committee Secretary
Senate Legal and Constitutional Affairs Committee
PO Box 6100
Parliament House
Canberra ACT 2600
Email: legcon.sen@aph.gov.au

Dear Ms Dennett

The Grains Research and Development Corporation (GRDC) is pleased to provide this submission to the Senate inquiry into the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (the Bill).

In summary, the GRDC has significant reservations concerning the Bill for the following main reasons, as explained in more detail in the body of this submission:

(a) isolated genes and genes as part of man-made constructs are both not a natural state of affairs, and therefore represent patentable subject matter;

(b) a non-obvious and innovative industrial application of a gene should be protectable by patents;

(c) limited accessibility to healthcare services is not caused by patents but by business models that are not exclusively applied to patented products;

(d) the grant of monopolies under the *Patents Act 1990* promotes investment in R&D and results in an overall gain by society; and

(e) prohibiting the patenting of genes and biological materials could lead to significant adverse impacts in the field of biotechnology research for the Australian grains industry.

The GRDC is a statutory authority established to plan and invest in research, development and extension (RD&E) activities for the Australian grains industry. Its primary objective is to support effective competition by Australian grain growers in global grain markets, through enhanced profitability and environmental sustainability.

In this endeavour the GRDC is a major supporter of biotechnology research carried out by organisations such as the CSIRO and the Australian Centre for Plant Functional Genomics at the University of Adelaide. Some GRDC-supported research conducted by these organisations involves the use of genes and biological materials over which patents have been granted to the GRDC and its research partners, usually as joint applicants (see Attachment 1). Accordingly, as an investor in grains RD&E, the GRDC is concerned that a prohibition on the patenting of genes and biological materials could lead to significant adverse impacts in the field of biotechnology research for the Australian grains industry and Australian grain growers in particular.

The GRDC understands that the Bill introduced by Senators Coonan, Heffernan, Siewert, and Xenophon, is drafted to amend the *Patents Act 1990* to prevent the patenting of:

(a) human genes; and

(b) biological materials existing in nature.

The GRDC understands that the Bill is closely related to the recently completed inquiry into Gene Patents by the Senate Community Affairs References Committee—which delivered its final report in November 2010. The inquiry was triggered in November 2008 by concerns over the attempt by the company Genetic Technologies Ltd[1] to enforce its patent rights in Australia over human gene variants that indicate a strong familial predisposition to breast cancer. The terms of reference for that inquiry directed the Committee to consider the impacts of gene patents on healthcare, medical research and the health and wellbeing of Australians, as follows:

> "The impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form, with particular reference to:
>
> (a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:
>
> (i) the provision and costs of healthcare;
> (ii) the provision of training and accreditation for healthcare professionals;
> (iii) the progress in medical research; and
> (iv) the health and wellbeing of the Australian people;
>
> (b) identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended, in light of any matters identified by the inquiry; and
>
> (c) whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials." [2]

The final report of the inquiry states that: "*had [Genetic Technologies] been successful in [enforcing its rights] it would have been able to become the sole tester for the BRCA genes in Australia, or to charge a licence fee to third parties for conducting the test."* [3] This statement is symptomatic of the very issue at the heart of both inquiries. Being able to make exclusive use of an invention is a prerogative of a patentee and is the basis of the intellectual property (IP) protection system. The whole pharmaceutical sector relies on IP protection for its operations. Billions of dollars are invested in developing new medicines, and the recouping of this investment is protected by patents. In return, the community gets access to the patented inventions and the benefit of generic medicine at the end of the term of the patents. The cost of medicines is not determined by governments, but by market forces and their ability to enter Australia's Pharmaceutical Benefits Scheme and similar schemes.

In chapter 3 of the final report the Committee discussed *'the impact of gene patents on the provision of healthcare, training for medical specialists, medical research and the health and wellbeing of the Australian people'*, and concluded that while there were *'a number of cases where the provision of healthcare or the conduct of medical research in Australia has been impeded, the evidence did not show that gene patents are systematically leading to adverse impacts in these areas.'* [4]

The GRDC notes that this has been corroborated by a detailed side-by-side analysis of the impact of patents on access to genetic testing for inherited susceptibility to breast and colorectal cancer in the US.[5] Both genetic testing methodologies are patented, the only difference being that the latter is nonexclusively licensed. The sole-provider model of Myriad Genetics has not led to higher pricing in the US as compared to the multiple-provider commercialisation model used for colorectal cancer susceptibility. In fact, Myriad's per unit costs are lower than testing for colorectal cancer susceptibility.

[1] Genetic Technologies is the exclusive licensee of Myriad Genetics, the US owner of the patents for genetic testing of the familiar breast cancer susceptibility genes ('BRCA patents').
[2] Senate Community Affairs References Committee, terms of reference.
[3] Senate Community Affairs References Committee, executive summary.
[4] Ibid.
[5] Cook-Deegan et al (2010) Impact of gene patents and licensing practices on access to genetic testing for inherited susceptibility to cancer: Comparing breast and ovarian cancers with colon cancers. Genetics in Medicine 12(4) S15-S38.

The Committee was unable to make a definitive recommendation in terms of prohibiting the patenting of genes, given the *'conflicting evidence as to whether a prohibition on the patenting of genes and other biological materials (a) would be effective, and (b) would not lead to unforeseen consequences in other fields of technology, particularly biotechnology research and development.'* [6]

While international IP law is not directly binding on Australian legislation, the Committee agreed with IP Australia's argument that a high degree of conformity between Australia's patent system and jurisdictions such as the US was desirable. Conformity of IP law is especially important among OECD countries, as most innovation in cutting-edge technologies comes from those countries, and inconsistencies in IP protection regimes could become a barrier to accessing those technologies. Various international treaties already deal with harmonisation of IP protection legislation and regulation, and readjustments to those happen from time to time to accommodate for trends in technology development.

In the specific case of gene patents, the outcome of ongoing litigation in the US[7] and in Australia will have a major impact not only on the patentability of newly discovered genes, but it may also impinge on already granted patents, and more seriously, on research and the commercialisation of products and services based on those patents. Passing of the Bill may also encourage companies to commercialise products but keep crucial background genetic information to themselves as trade secrets, depriving: (i) researchers of the ability to review that information in published patent specifications; and (ii) ultimately the consumer of the benefit from new derived products.

Furthermore, universities are able to attract industry investment by way of their IP assets, which include gene patents. This successful mechanism of technology transfer and increased university research could be hampered by the disallowance of gene patents.

The Gene Patents inquiry resulted in 16 recommendations, which overall reflect the level of uncertainty in the field. Rather than being supportive of the Bill, in GRDC's opinion the recommendations make a strong case in favour of maintaining the patent-eligibility of genes and biological compositions, as long as certain patentability criteria are met. The report of the ACIP Review of Patentable Subject Matter, released on 16 February 2011, recommends codifying the existing test for patentable subject matter, which would help to provide clarity. The ACIP review, as well as IP Australia's review of Australia's patent system, provides further support that the Bill is jumping ahead to unsubstantiated and potentially adverse conclusions.

In arriving at a conclusion, the Committee rightly noted *'the complexity of many of the legal and scientific issues underpinning the inquiry's terms of reference, and the equally complex way in which these interact with the development and delivery of healthcare services and the conduct of medical research in Australia.'* [8] According to the Committee, the recommendations are collectively intended to:

- increase the threshold requirements of patentability (improve patent quality);
- reduce the scope of patent claims;
- reinforce mechanisms and policies by which governments can and should intervene with the rights of patent holders; and
- assist judicial interpretation of the Act and establish an external accountability and quality control mechanism for the patent system.

Given that the *Patents Act 1990* already contains provisions for compulsory licensing (s133), patent acquisition by the Commonwealth (s171), and to satisfy reasonable requirement by the public (s135), the GRDC considers that existing legislation already addresses the general needs of the consumer in respect of access to technologies based on gene patents, without the need to put the patent-eligibility of genes to trial.

These provisions are also aligned with Article 31 ('Other use without authorization of the rightholder') of the international Trade Related IP Rights Agreement (TRIPS). The GRDC accepts that the scope of the

[6] See above n 2.
[7] *Association for Molecular Pathology et al. v. U.S. Patent and Trademark Office et al.* ('Myriad Genetics').
[8] See above n 2.

'reasonable requirements of the public test', on which the grant of a compulsory licence may be based, needs further clarification and some reform may be needed taking into consideration its interaction with the *Competition and Consumer Act 2011* (which replaces the *Trade Practices Act*).

Although the *Patents Act 1990* was amended in 2006 to provide that a compulsory licence may be granted where the patentee has been found guilty of any proscribed anti-competitive conduct under the *Trade Practices Act 1974*, application of these provisions has not been tested enough in practice and the effect under the *Competition and Consumer Act 2011* is unclear.

Patent eligibility of isolated unmodified DNA or engineered DNA molecules requires more than identifying and isolating what has always existed in nature, and is independent of how hard it is to obtain the isolated compound and the degree of usefulness. Isolated DNA is not a product of nature, because the DNA molecule does not occur in that isolated form in nature.[9] Accordingly, the GRDC believes that isolated DNA that is utilised to create a useful product or service is an 'invention' that can be potentially patented rather than a mere 'discovery' that cannot.

In an *amicus curiae* brief regarding the Myriad Genetics case, the US Dept of Justice notes that even though patent laws do not embrace natural laws, physical phenomena, or abstract ideas, barring the patentability of genes would cast doubt on the patent eligibility of a broad range of man-made compositions of matter whose value derives from the information-encoding capacity of DNA, e.g. cDNAs, vectors, recombinant plasmids, and chimeric proteins, as well as countless industrial products, such as vaccines and genetically modified crops. This is not a situation in which natural substances *'serve the ends nature originally provided and act quite independently of any effort of the patentee.'* [10]

The plaintiffs in Myriad Genetics have not challenged the claims directed to recombinant vectors or other engineered molecules, e.g. cDNAs, vectors, and recombinant plasmids. Such engineered molecules should remain patent-eligible matter, notwithstanding the fact that sections of the DNA contained therein are perfect reflections of (i.e. identical to) their counterparts in the genome of an organism.

Accepting engineered molecules as patent-eligible matter, on the other hand, would defeat the purpose of the Bill, as the diagnostic methods based on isolation of a segment of DNA combined with its amplification and methods to identify the deleterious variants could still be patented, and thus would not eliminate the possibility of a service monopoly arising. For the proponents of the Bill to achieve their original goal of preventing service monopolies, the man-made constructs mentioned above would need to be excluded from patentability, thereby contradicting the essence of the *Patents Act*, which provides for IP protection to non-obvious industrial applications of these constructs.

While Cancer Council Australia is representing the interests of cancer patients in this specific issue, i.e. the accessibility of consumers to a health system at reasonable costs, high pricing of services is not specific to gene patents. The cost of highly sophisticated equipment, e.g. CT scanners, does affect the overall costs of the health system. If that were the sole reason for prohibiting gene patents, then this prohibition would be extendable to many other technologies.

The amendments to the *Patents Act* proposed in the Bill would have significant adverse impacts for the development of many health-related products and the provision of services based on those products. As the Institute of Patent and Trade Mark Attorneys of Australia attested in their submission to the Committee, without the possibility of obtaining patent protection, a number of well-known Australian biotechnology innovations may not have achieved commercial success. One third of the companies listed on the Australian Securities Exchange in the Pharmaceuticals, Biotechnology and Life Sciences Industry Group have applied for, or obtained, patents in the area of biotechnology.

In their *amici curiae* briefs in support of the defendants in the Myriad Genetics case, the Biotechnology Industry Association (BIO) and the Association of University Technology Manager (AUTM), mention that

[9] 66 US Fed. Reg. 1093 (5 Jan 2001). Utility Examination Guidelines.
[10] *Funk Bros. Seeds Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948).

in March 2000, American biotechnology companies lost US$50 billion in market value within two weeks following misinterpreted statements by US President Clinton and British Prime Minister Blair that patent protection on gene-based innovations would be narrowed down.

In the USA, many years of research by Chiron Corporation went into developing a Hepatitis C screening methodology. Chiron's patents were capable of attracting the necessary funding that has resulted in a reduction from a 1:25 chance of contracting Hepatitis C from a blood transfusion in 1989 to nearly zero.[11] This is the sort of impact analysis that needs to be weighed against bringing down the costs of individual genetic tests.

Similarly, biotechnology and genomics are already revolutionising agricultural R&D. Much of the already substantial investment by industry depends on the patentability of genes. Population pressure and climate change require our focus and the conditions to increase the present levels of investment. In the present situation, incentives for investment are more critical now than ever.

The amendment to subsection 18(2)(b) of the *Patents Act 1990* proposed in the Bill, affects 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. The Bill's wording clearly affects biotechnology in the widest sense, including the application of several biological compositions to agricultural R&D.

If the Bill is simply driven by the desire to curb costs to consumers and their right to an affordable health system, the same may apply to the consumers' right to access to food, and thus the same principles would apply to genes and other compositions of matter relevant to agricultural R&D.

As elaborated above, the GRDC believes that given the weight of the evidence provided by many submissions, many of the perceived issues do not lie with the patent-eligibility of genes but rather with commercialisation models, insurance policies, and a paucity of test cases and clarity regarding the enforcement of compulsory licensing arrangements.

The GRDC agrees that improving the quality of patents in Australia by raising the inventive step threshold and mandating that a patent claim be enabled across its entire scope would add value to the patent system. Also, the level of evidence required to show the utility of a claimed invention should be tested more rigorously to this end.

The GRDC would be pleased to hold further discussions with the Committee on the issues raised in this submission or how gene patenting impacts on grains research activities in Australia. If you would like to hold further discussions with the GRDC, please contact , Program Manager, Germplasm Enhancement, on or email

Yours sincerely

PETER F. READING

Managing Director

[11] Alter HJ & Houghton M (2000) Hepatitis C Virus and Eliminating Post-Transfusion Hepatitis, Nature Medicine 6(10) 1082-1086.

ATTACHMENT 1

GRDC patents involving genes

*Publication No.	Title
Group 1	
AU 713434 B2	Fungus Resistant Transgenic Plants
WO 2005/122751	Nucleic Acid Molecules and Their Use in Plant Male Sterility
WO 2007/137361	Transcription Regulators for Reproduction Associated Plant Part Tissue Specific Expression
WO 2007/092992	Plant Egg Cell Transcriptional Control Sequences
WO 2007/014433	Polysaccharide Synthases
WO 2007/131276	Enzymes for Degrading Herbicides
AU 710189 B2	Genetic Sequences Conferring Nematode Resistance In Plants And Uses Therefore
WO 2005/103258	A Plant, its Use as the Nutraceutical and the Identification thereof
WO 2007/045040	Cereals with Altered Dormancy
WO 2008/006169	Polynucleotides And Methods For Enhancing Salinity Tolerance In Plants
AU 744714 B2	Method for Altering Storage Organ Composition
Group 2	
AU2005/254583	Anther Specific Promoters and Uses Thereof
WO 2007/048207	Specific Expression Using Transcriptional Control Sequences In Plants
WO 2008/04681	Polysaccharide Transferase
WO 2000/018926	Use Of Bifunctional Alpha-Amylase Subtilisin Inhibitor Promoter Sequence Of Barley To Confer Expression In Seeds
AU 2001/297906	Method and Means for Producing Barley Yellow Dwarf Virus Resistant Cereal Plants

*Publication number refers to an application or granted patent number representing a patent family. Patents are national in scope and hence there will be at least one patent in each jurisdiction where protection is sought.

Group 1: Claims for genes included in the patent.
Group 2: Regulatory DNA sequences included in claims but no genes.