CropLife AUSTRALIA

SUBMISSION IN RESPONSE TO PATENT AMENDMENT (HUMAN GENES AND BIOLOGICAL MATERIALS) BILL 2010

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1. EXECUTIVE SUMMARY

CropLife welcomes the opportunity to make this submission in response to the proposed *Patent Amendment (Human Genes and Biological Materials) Bill 2010.*

CropLife appreciates that the intent of the Senators introducing this Bill is to improve the access of Australians to important healthcare technologies. However, the Bill, in its current form, will have several unintended and very negative effects on innovation in many industries that are completely unrelated to human healthcare, including the agricultural biotechnology and crop protection industries. It will also reduce Australia's similarity to other national patent systems and it is highly likely that it would also contravene international agreements that Australia is a Party to including the TRIPS and AUSFTA Agreements.

Patent ownership does not imply freedom to operate. Many industries, including the agricultural biotechnology and crop protection industries that CropLife represents, face substantial costs and delays in order to satisfy regulators that their products are safe. GM crops and pesticides are regulated differently but both systems involve multiple federal and state regulatory agencies. This high level of regulatory intervention in the market leads to elevated product development costs that would not be able to be recouped without a period of exclusive market access. As these products are often simple to copy through reverse engineering, this exclusive market access period relies on protection of the intellectual property through patents. Without this protection, it is likely that none of these products would ever be released in Australia.

Furthermore, the Bill is unnecessary. CropLife believes that concerns about specific patents (eg. BRAC1 and BRAC2) are reflective of deficiencies in the patent system as a whole, rather than how it is applied to any particular technology. These issues can only be effectively addressed by more general reform and could commence with the Government implementing the recommendations of the Australian Law Reform Commission Report on Gene Patents. This comprehensive investigation provided ten pages of well considered recommendations that have never been responded to.

The Government should be encouraged to make the amendments recommended by the Australian Law Reform Commission in 2004 to ensure that no patents are granted on inappropriate subject matter – whatever that subject matter may be. Banning specific classes of materials from ever being granted a patent is a reactive measure that reduces certainty in the intellectual property system for all future technologies in Australia. If this Bill is passed, then no technology could be certain that it would not have its intellectual property compromised in the future by the Australian Parliament.

The Bill will reduce the flexibility of the patent system in dealing with new innovations. Currently, patentable subject matter is defined by reference to the Statute of Monopolies and the centuries of case law that have evolved from that legislation. This system provides patent offices and courts with an approach that is based on principles, rather than prescriptive lists about what is and is not patentable subject matter. The principles established in the National Research and Development Corporation (NRDC) case have been shown to be flexible enough to cope all of the technological change that humanity has witnessed in the second half of the twentieth century and it is more than capable of dealing with biotechnological innovation.

CropLife strongly opposes this Bill and calls on the Senate Committee on Constitutional and Legal Affairs to recommend that the Bill not proceed.

2. INTRODUCTION

CropLife is the peak body representing the pesticide and agricultural biotechnology industries in Australia. Our members provide all the biotechnology traits that are commercially available in Australia and include large international and small national companies. We are a passionate participant in discussions about future food security and sustainable agriculture and we have instigated programs such as ***drum****MUSTER*, ChemClear® and Agsafe Accreditation and Training, which aim to increase the safe use and disposal of pesticides in agriculture. We are also a member of the internationally based Excellence Through Stewardship program, which provides best management techniques for GM crops throughout their development, commercial use and eventual discontinuation.

Over the last half century, pesticides have proven to be indispensable tools in the sustainable production of high quality food and fibres. Since their introduction, farmers have been able to produce bigger crops on less land. Current pesticides protect anywhere between 25% and 55%[1] of total crop yields (depending on crop and pest). Pesticides allow farmers to maximise the benefits of other inputs, which include high quality seeds, fertilisers, and precious water resources. Extensive tillage (ploughing) of land has been reduced in favour of application of herbicides and soil erosion has decreased as a result. Losses of organic matter from the soil have also decreased. Appropriate use of modern pesticides to control invasive species and noxious weeds has been important in environmental management. Over the last decade or so, many more pesticide products have been developed based on natural compounds – the future development of these chemistries is threatened by the current Bill.

During 2010, GM crops were grown on 650,000 hectares in Australia[2]. This Australian GM production area consisted of two crops - GM cotton and GM canola. These crops have delivered a wide range of benefits to Australian farmers, including reducing pesticide use in sensitive areas, reducing water use, reducing fuel use and providing more flexible pest and weed control. However, these benefits are likely to appear quite small when they are compared to future GM crops that focus on water use efficiency, nutritional improvement and even greater flexibility in pest and weed control. These future benefits are gravely threatened by the current Bill.

CropLife has watched with interest the deliberations of the Senate Community Affairs References Committee and the public debate about BRAC1 and BRAC2 patents. Until now, however, there has been little opportunity to highlight the effect of the proposed reforms on agricultural innovation, as terms of reference have been limited to the effect of such patents on human healthcare.

This submission will highlight the role that gene patents play in modern agriculture and the effects that a revocation of these, and other patents on biological materials, is likely to have on the domestic availability of innovative products like GM crops and agricultural chemicals.

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1 ADAS (2008) *Evaluation of the impact on UK agriculture of the proposal for a regulation of the European Parliament and of the council concerning the placing of plant protection products on the market.* Available at http://www.adas.co.uk/LinkClick.aspx?fileticket=BOSPfOEtvRs%3d&tabid=246

2 ISAAA (2011) *Global Status of Commercialized Biotech/GM Crops: 2010*.

3. SCOPE OF THE PROPOSED BILL

The issue of when patents should be granted on biological innovations is not new. It has been the subject of several expert inquiries over the last decade. None of these inquiries has recommended a ban on biological patents. CropLife notes that the vast majority of the debate has to date been centred around the effect of these patents on medical services in Australia. There has to date been little consideration given to the role that these patents play in agriculture.

The two year inquiry by the Senate References Committee on Community Affairs that reported to Parliament on 26 November 2010[3] was asked to inquire and report on:

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 the 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.

These Terms of Reference exclude consideration of the effect that the patenting of genes has had on the introduction of genetically modified (GM) crops in agriculture.

Similarly, the otherwise broad ranging inquiry by the Australian Law Reform Commission (ALRC) *Genes and Ingenuity* (2004) Terms of Reference were also taken by ALRC to exclude agricultural biotechnology. ALRC was directed to inquire and report on:

(a) The impact of current patenting laws and practices – including licensing – related to genes and genetic and related technologies:

(i) The conduct of research and its subsequent application and commericalisation;
(ii) The Australian biotechnology sector; and
(iii) The cost-effective provision of healthcare in Australia;

(b) What changes, if any, may be required to address any problems identified in current laws and practices, with the aim of encouraging the creation and use of intellectual property to further the health and economic benefits of genetic research and genetic and related technologies; and

(c) Any other relevant matter. [4]

The ALRC took these terms of reference to exclude agricultural biotechnology as was noted in paragraph 16.3 of the report, namely:

> *16.3 The biotechnology sector also encompasses areas* ***outside the scope of this Inquiry****, including those related to agriculture, food process, manufacturing and environmental management.* (emphasis added)[5]

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3 The Senate Community Affairs References Committee (2010) *Gene Patents* pp.1-2.
4 Australian Law Reform Commission (2004) *Genes and Ingenuity – Gene Patenting and Human Health.* pp. 7-8
5 *Ibid.* p.403.

3. SCOPE OF THE PROPOSED BILL *(cont.)*

CropLife notes that neither the ALRC Report, nor the recent Senate Inquiry recommended the introduction of legislation to ban genetic patents. Both inquiries recognise that issues associated with the granting of certain patents on genetic sequences are reflective of larger problems within the patenting system in Australia that will be better addressed by a more general approach to reform than a specific ban on particular patents. This was also the view of the Advisory Council on Intellectual Property (ACIP) in its recent report on patentable subject matter. CropLife supports these views.

While the ALRC Report and the Senate Inquiry were both focussed on the effect of genetic patents on medical services the Patent Amendment (Human Genes and Biological Materials) Bill 2010 has a much broader scope. The Bill proposes to amend subsection 18 (2) so that it reads:

> *(2) The following are not patentable inventions:*
>
> *(a) human beings and the biological processes for their generation; and*
> *(b) 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.*[6]

The amendments define biological materials as including "DNA, RNA, proteins, cells and fluids"[7]. This definition is obviously much broader than human biological material and instead captures every biological chemical, including those from plant and bacterial origins.

These amendments would ban any patents that may be sought on biological materials in agriculture, along with any patents on modified biological materials that are "substantially identical". This would capture patents on genetic material, as well as patents on chemicals that are based on biological materials, such as altered DNA and altered proteins. The loss of these patents would affect a range of industries, including technology providers of GM crop solutions and manufacturers of new pesticides that are based on natural compounds.

During his second reading speech, Senator Heffernan expressed the view that:

> *The Bill will not prevent or reduce investment in the biotech industry. The Bill is very narrow and only seeks to clarify and apply existing law.*[8]

For the reasons expressed above, CropLife respectfully, but strongly, disagrees with Senator Heffernan's view. The Bill, as it is currently drafted, bans patents on all biological materials and also bans patents on compounds that are considered to be substantially identical to biological materials. It is certainly not "very narrow".

The introduction of the phrase "substantially identical" introduces additional uncertainty as it is yet to be defined by law in Australia.

The Bill, in its current form, will have a devastating effect not only on the agricultural biotechnology industry, but also on newer chemistries in pesticide science that aim to imitate naturally occurring compounds. These newer pesticide chemistries are typically regarded as 'softer' pesticides, in that they are highly specific to certain pests, have negligible side-effects and are compatible with integrated pest management approaches. These effects will be considered in the next two sections.

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6 Commonwealth of Australia (2010) *Patent Amendment (Human Genes and Biological Materials) Bill 2010.*
7 *Ibid.*
8 Commonwealth of Australia (2010) *Parliamentary Debates*. Senate. November 24, 2010. (Senator Heffernan) Page 2100

4. EFFECT OF THE PROPOSED BILL ON GM CROPS IN AUSTRALIA

CropLife believes that the proposed Bill will prevent the introduction of GM crops in Australian agriculture. This is because there are high regulatory barriers to entry and without genetic patents the costs of overcoming these barriers will not be able to be recouped. Consequently, no company will invest in this process.

GM crops are subjected to extensive regulation in Australia. In order to market a GM crop a company must invest many millions of dollars and years of work to generate regulatory data for several agencies at the state and federal level. Prior to receiving a federal government approval a GM crop must have:

- **A licence from the Office of the Gene Technology Regulator (OGTR)**
  The OGTR will only issue a licence if it concludes the use is safe to humans and the environment following a thorough risk assessment. The assessment is based on data and advice received from the technology provider (patent holder), the Department of Health and Ageing, the Department of Sustainability, Environment, Water, Population and Communities, as well as several other government agencies.

- **Approvals from the Australian Pesticides and Veterinary Medicines Authority (APVMA)**
  If the GM crop is insect resistant it also requires a registration from the APVMA as a biological pesticide. The APVMA assesses any environmental, agronomic and human health effects of biological pesticides. If pesticides are going to be used in a different way on a GM crop then this change in use also needs to be registered by the APVMA.

- **An entry in the Food Standards Code**
  GM crops require a food safety approval from Food Standards Australia New Zealand (FSANZ) before they can enter the Australian food supply (whether or not they are grown here). The FSANZ safety assessment focuses on the human safety of consuming the GM crop.

Many of these assessments are duplicative and it is not uncommon for a single crop to be assessed for human and environmental safety three times.

The difficulty of getting regulatory approvals can be seen with GM canola, which was approved by the Canadian Government in 1996 but not by the Australian Government until 2003. Despite federal approval, it was not allowed to be grown commercially until 2008 when NSW and Victoria lifted bans. It is still not available to growers in South Australia or Tasmania. These regulatory delays are very expensive for technology providers. They are also expensive for the Australian economy, with one conservative estimate valuing the benefit of GM canola to canola and wheat farmers as being $135 million annually[9]. It follows that between 1996 and 2008, this delay cost the Australian economy more than $1.6 billion.

It typically takes 8-10 years to get a biotech trait from the discovery phase to a point where it has received all regulatory approvals for commercialisation. It also typically takes $80-100 million dollars to develop[10]. This is about 10 times the investment in time and money that is required to bring a non-GM crop to market[11]. To date, the only potential for the biotechnology industry to recoup these costs has been in certain major broadacre crops during a period of exclusive market access. CropLife notes that this cost excludes most public institutions from being able to bring GM crops to market without assistance from the private sector.

Currently in Australia, GM crops have two main types of intellectual property protection – patents on genetic constructs and plant breeder rights.

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9 Norton, R.M. and Roush, R.T. (2007) *Canola and Australian Farming Systems*. University of Melbourne.

10 Janice Armstrong *GM drought tolerance – still waiting* Available at http://www.abc.net.au/rural/nsw/content/2009/10/s2727733.htm. Accessed on 13 January 2011.

11 Professor Ingo Potrykus *Regulation Must Be Revolutionized* Nature, July 29, 2010, Vol 466 p561

4. EFFECT OF THE PROPOSED BILL ON GM CROPS IN AUSTRALIA (cont.)

Patents protect the specific genetic sequence that has been identified to incorporate a specific trait into a crop, for example, herbicide tolerance. This sequence is based on a naturally occurring sequence, but will also contain several alterations to the natural form. In particular the gene's "promoter" and "terminator" sections will be altered. It is not clear to CropLife whether a gene with altered promoters and terminators would be considered to be substantially identical to the natural form, but it is certainly one possible interpretation.

Plant breeder rights are similar to patent protection except they are granted on an entire variety of a plant rather than a specific genetic sequence. In the case of the two GM crops currently available in Australia, the patents on the genetic trait have been licensed to several competing companies who specialise in Australian crop varieties. These companies are protected by plant breeder rights while the gene patent allows the technology provider to recoup the investment that was made to bring the trait into the marketplace.

If the Bill were to ban patents on these gene sequences, then there would be nothing stopping a competitor from cross breeding the GM trait into a different variety and claiming plant breeder rights. This process would take one growing season and would completely undermine the original technology provider's investment. With such a significant "free rider" effect, no company would invest in developing the technology in the first place.

The ALRC report also believed that Australia's biotechnology industry would be threatened if patents on genetic material were banned. The report stated:

> 7.27 *The ALRC does not consider that the* Patents Act *should be amended to exclude genetic materials or technologies from patentability. Such a reform would pose a significant risk to Australia's biotechnology industry, raise problems for Australia's compliance with the TRIPS Agreement, and be difficult to implement effectively.*[12]

This opinion was shared by the ACIP in December 2010 when it stated

> *We have concluded that no persuasive case has been made to introduce a specific exclusion to prevent the patenting of human genes and genetic products. In its review of* Gene Patents, *the Senate Committee stated that an express exclusion should be introduced only if there is a very clear case, and significant social and political consensus, on the need for such a change. We endorse this approach. Like us the Senate Committee found that there was neither the clear case nor the consensus justifying change at this time. Accordingly we do not recommend the introduction of a specific exclusion to prevent the patenting of human genes and genetic products.*[13]

The process of genetically modifying crops is important because it allows crop breeders to introduce new traits into crops more quickly and flexibly than is possible with conventional breeding. This ability to quickly produce new traits is vital because the world faces extremely serious food security challenges during the next forty years[14]. Ground water is declining rapidly and current estimates indicate that in 25 years time, we will not have enough water to feed the world's population. The amount of arable farmland is declining annually by about 1% and 25% is already degraded. Essential fertiliser supplies are dwindling and increasing in cost as oil prices rise and minerals deplete. Meanwhile, biofuels are competing with food for farmland and agriculture is particularly affected by environmental pressures with farmers being hit the hardest by climate change, increased storms, flooding, drought and new pests.

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12 Australian Law Reform Commission (2004) *Genes and Ingenuity – Gene Patenting and Human Health.* p. 119.

13 Australian Council on Intellectual Property (2010) *Patentable Subject Matter*. p.14.

14 Agrifood Skills Australia (2010) *Environmental Scan of the agrifood industries – A perfect storm of shortages.* Industry Skills Council.

4. EFFECT OF THE PROPOSED BILL ON GM CROPS IN AUSTRALIA (cont.)

While agricultural production will be challenged by these factors, demand for food is increasing rapidly. Population continues to rise and large economies in China and India are increasing their per capita consumption. As a result of these and other factors, the UN estimates that the world will need to grow 70% more food by 2050[15] if there is to be sufficient food for everyone.

From a domestic perspective, GM crops are vital in ensuring that our farmers remain viable in an international market place. If competing foreign farmers have access to productivity increases that are not available domestically, then it is very difficult for Australian farmers to compete. GM crops are already being rapidly adopted by Australia's agricultural competitors – in 2010 Brazil planted 25.4 million hectares of GM crops, Argentina planted 22.9 million hectares while the US planted 66.9 million hectares. Australia planted just 650,000 hectares in comparison[16].

Current GM crops are estimated to have delivered over $50 billion to farmers globally[17] during their first decade of cultivation and these economical benefits will increase as additional traits are included. As noted above, Australia has already forgone over $1.6 billion in productivity increases by delaying GM canola introduction by 12 years. This lost income is even harder to accept when it is remembered that Australia's main competitor in the global canola market (Canada) has had access to the technology for this entire period.

Australia has much to gain from lower water use in agriculture and is a world leader in research on GM drought tolerant crops. This research has been conducted by publicly owned entities such as the Molecular Plant Breeding Cooperative Research Centre and the Australian Centre for Plant Functional Genomics. The cutting edge nature of this research reflects the large investments made by many governments into agricultural biotechnology. These investments of public funds are also threatened by the proposed Bill.

This Bill would effectively stop the commercialisation of future GM crops in Australia because companies would refuse to risk their intellectual property by releasing it here. This would undermine hundreds of millions of dollars in private and public investment in this research and would have major implications for how Australian science is viewed globally. In addition to these effects, the competitiveness of Australian agriculture would be greatly reduced.

CropLife believes that these impacts need to be fully considered and they do not appear to have been in previous inquiries into genetic patents.

5. EFFECT OF THE PROPOSED BILL ON AGRICULTURAL CHEMICALS

Agricultural chemicals, commonly referred to as pesticides or crop protection products, are both naturally occurring and man-made (synthetic) chemicals that play a vital role in controlling the diseases, insects and weeds that harm or destroy our food crops and threaten public health. Agricultural chemicals offer a means towards meeting the challenge of producing more food with fewer resources (e.g. water, land, phosphorous).

The use of agricultural chemicals brings numerous benefits and makes a significant contribution to the lifestyles we have come to expect. These benefits are not confined to the users of pesticides, but reach the great majority of people across the world. The general public often take for granted or oppose the use of pesticides, but they make possible the year-round availability of high-quality, affordable food. Similarly, the environment and wild plants, birds and animals benefit from the carefully regulated application of agricultural chemicals.

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15 Reuters September 23, 2009 *World food output must rise 70 percent by 2050-FAO*.

16 James C. (2010) *Global Status of Commercialized Biotech/GM Crops.* ISAAA Brief no 42.

17 Brookes G. and Barfoot P. *GM crops – Global Social and Economic Impact 1996-2008* (2010)

5. EFFECT OF THE PROPOSED BILL ON AGRICULTURAL CHEMICALS (cont.)

Agricultural chemicals are subjected to extensive regulation by the Federal and state governments in Australia.

Pesticides sold in Australia must be approved and registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The APVMA administers the National Registration Scheme for Agricultural and Veterinary Chemicals. The Scheme registers and regulates the manufacture and supply of all pesticides and veterinary medicines used in Australia, up to the point of supply.

New pesticides must be subjected to a rigorous scientific risk assessment process before they can be approved and registered by the APVMA for sale in Australia. Manufacturers of pesticides provide the APVMA with detailed scientific information about the chemical to allow independent evaluators to decide whether it is effective and safe for people, animals and the environment, and not a trade risk. The information includes data on chemistry, manufacture, toxicology, residues, safety, environment and efficacy. Other Australian Government agencies also help the APVMA to evaluate agricultural and veterinary chemicals.

The Office of Chemical Safety (in the Department of Health and Ageing) assesses whether the pesticide is poisonous (toxicology), advises on worker safety and recommends first aid and safety directions. The National Drugs and Poisons Schedule Committee (established by the Therapeutic Goods Administration in the Department of Health and Ageing) considers whether the pesticide should be included in a poisons schedule, which means that it must be handled with certain precautions depending on the risk. Department of Sustainability, Environment, Water, Population and Communities advises on whether the pesticide might harm the environment and how to avoid this.

After retail sale, state and territory governments regulate the use of pesticides.

The state regulations cover training requirements for users, licensing of commercial pest control operators, residue monitoring and enforcement of safe use. This post-sale system of monitoring is currently being reviewed and is likely to be harmonised federally in the near future.

This extensive assessment means that a large investment is required to bring a new product to market. On average, globally it takes 9.8 years and costs $256 million to bring a single agricultural chemical to market[18] with over half of those costs representing regulatory costs in terms of data generation and costs of assessments[19].

Many modern agricultural chemicals are designed to imitate naturally occurring compounds. These compounds are often preferred because they are toxic to a much smaller range of species than older chemicals tend to be. This reduces their environmental and health impacts significantly and in many cases the compounds are virtually non-toxic to everything other than the target species.

The imitation of nature, or biomimicry, has always been a successful way to develop technology. For example, the modern photographic and film cameras were invented by studying and imitating the way in which an eye works and the concept of a solar power comes from plants. One benefit of biomimicry is that it allows human inventors to build on millions of years of evolutionary innovation and this reduces the chance of failure and unintended effects.

[18] Phillips McDougal (2010) *Agrifutura Newsletter March 2010*. No. 125.

[19] *Ibid.*

5. EFFECT OF THE PROPOSED BILL ON AGRICULTURAL CHEMICALS (cont.)

Some examples of pesticides that were isolated from naturally occurring compounds are included in Table 1, below.

Table 1
NATURALLY DERIVED PESTICIDES

Insecticide class	Susceptible Pests	Origin
Spinosyns	Insects	Bacteria
Cry toxins	Insects	Bacteria
Nicotine	Insects	Plant
Pyrethrins	Insects	Plant
Sulphur	Fungi	Mineral

The above is only a short list and not intended to be comprehensive. The proposed Bill would remove patent protection from these and many other important forms of chemistries in Australia. The Senate should note that many of these chemistries are important in organic agriculture, as well as being important to conventional farmers. Currently, patent protection can be granted for the active ingredient, subject to the normal tests for patentability. The proposed Bill would remove that protection and allow competitors to "free ride" on the original technology developer's investment.

The market failure caused by this free rider effect would lead to the loss of naturally derived compounds and prevent the development of future chemistries in this area. The loss of these chemistries would have large implications for modern agricultural practices known as integrated pest management. Integrated pest management relies on these biological mimics because they have minimal harm to non-target organisms. Consequently, farmers can use these non-target plants and insects to control the target pest. The benefits of integrated pest management include a reduction in environmental pressures from farming and the increased sustainability of crop protection chemistries.

Overall, the proposed Bill would lead to a reduction in newer softer chemicals being used in agriculture and an increased reliance on older, more synthetic chemicals, many of which are currently subject to regulatory review. If industries have significantly reduced options then strategies for managing resistant pests and weeds will be compromised, potentially leading to further reductions in available pest control options and even more pressure for resistance development.

CropLife believes that these agricultural impacts need to be fully considered before banning biological patents. As noted previously, agriculture does not appear to have been considered at all in the previous inquiries regarding genetic patents.

6. INNOVATION REGULATION

Patents are central to the system of innovation in Australia. Changes made to the system need to be well considered as they may have implications that reach far beyond the initial intent of the reform. It is concerning that the proposed Bill is seeking change to the patentability of all biological materials, when inquiries have focussed solely on how genetic patents affect the delivery of human medicine.

While the lack of consideration of other industries affected by biological patents is concerning, CropLife also believes that many of the principles of patenting apply broadly and that many good suggestions have already been proposed for fixing any shortcomings in the current system. In this respect, it is important to note the comprehensive review of the patentability of genes that was completed by the Australian Law Reform Commission in 2004.

The ALRC report *Genes and Ingenuity – Gene Patenting and Human Health* made ten pages of recommendations regarding Australia's current intellectual property framework. These included many well considered amendments that would address the issues raised in relation to gene patents for all types of patents, not simply those relating to biological materials. Of particular importance to the current proposed Bill are the following two recommendations:

> *6-1* *Patent applications relating to genetic materials and technologies should be assessed according to the same legislative criteria for patentability that apply to patent applications relating to any other type of technology…*
>
> *7-1* *The* Patents Act 1990 (Cwlth) *should* **not** *be amended:*
>
> *(a) To exclude genetic materials and technologies from patentable subject matter;*
>
> *(b) To exclude methods of diagnostic, therapeutic or surgical treatment from patentable subject matter;*
>
> *(c) To expand the existing circumstances in which social and ethical considerations may be taken into account in decisions about granting patents.*
>
> *Rather, social and ethical concerns should be addressed primarily through direct regulation of the use or exploitation of a patented invention.*[20]

On 26 November 2010, the Senate Community Affairs References Committee tabled its report into Gene Patents in Australia. It also considered whether a specific ban on gene patents was warranted, given concerns raised about access to certain healthcare products associated with these patents. This Committee found that:

> *While the Committee heard of 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.*[21]

The Committee did not recommend altering the Act to expressly prohibit the patenting of genes and instead it called on the Australian Government to implement the recommendations of the ALRC comprehensive review and other general reforms to the patent system to ensure that it operates effectively for all patent applications.

The Advisory Council on Intellectual Property proposed another method of increasing patient access to biologically derived technologies, namely:

> *In the event that it is found that patents on other beneficial technologies (for example, patents for genes, genetic materials and related technologies) are unduly restricting patient access to diagnostic tests or other medical treatment, the Australian experience with pharmaceuticals suggests that the remedy to the access problem lies with a pricing mechanism, not with removing patent protection for these inventions.*[22]

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[20] Australian Law Reform Commission (2004) *Genes and Ingenuity – Gene Patenting and Human Health.* pp. 25-26.

[21] The Senate Community Affairs References Committee (2010) *Gene Patents* p. xi

[22] Australian Council on Intellectual Property (2010) *Patentable Subject Matter*. p.7.

6. INNOVATION REGULATION (cont.)

CropLife strongly supports the principle that patents for biological materials and technologies should be assessed according to the same criteria as other patents. We believe that changes to patent law need to be made carefully to ensure that there are not unintended consequences. In this respect we think that the recommendations by the ALRC were the result of a comprehensive inquiry by legal experts and these recommendations should be considered thoroughly before other measures are taken. This is particularly true when these alternate measures, such as a ban on genetic patents, are directly repudiated by the ALRC report, the Senate Inquiry and the ACIP report.

7. STRENGTHS OF THE CURRENT SYSTEM

The current framework of intellectual property protection in Australia is robust and contains a number of checks and balances. Overall, the patent system increases the transparency of research and the availability of private funding for this research. Problems with one or two specific patents do not justify a complete overhaul of this system. It would be much better for the existing processes to be properly used to ensure that the unjustified exclusive use of a technology is not permitted.

There are already several checks and balances on patent applications. IP Australia can limit the scope of patents when they are applied for. Patents can be challenged in the courts when they are believed to be incorrect by a competitor. If a patent holder misuses their market power the Australian Competition and Consumer commission can intervene and can force a company to licence its product to increase competition in the marketplace. In limited circumstances the Crown can also compulsorily acquire a patent. These processes balance the patent system to ensure that the right mix of actual innovation and reasonably priced access to innovation occurs. Importantly they are also technology neutral, which increases the predictability and flexibility of the patent system.

The current patent system also benefits from a feature of flexibility. The *National Research Development Corp v Commissioner of Patents* (1959) (the NRDC case) case is widely regarded to have established the key tests for patentable subject matter in Australia because it applies the text taken from the Statute of Monopolies in a modern context. The patent in that case claimed a novel treatment for killing weeds in crops with a known chemical that was previously not recognised as having this use.

The NRDC Principles established a flexible approach towards what could be described as a manner of manufacture. There are many interpretations of this case and this submission will not attempt to resolve these complex legal discussions. However, CropLife notes that the flexibility of the manner of manufacture test has allowed a legal concept that was developed prior to the industrial revolution to encourage innovation during a time of rapid technological change. This is not a minor point because arguably legislation would not have been able to respond as quickly to these changes in technology, so the existence of a functioning intellectual property framework through legal interpretation was vital. This flexibility is a major positive feature of the current system.

The necessity of flexibility in defining patentable inventions was specifically recognised by the High Court during the NRDC Case[23]:

> *The truth is that any attempt to state the ambit of s. 6 of the Statute of Monopolies by precisely defining "manufacture" is bound to fail. The purpose of s. 6, it must be remembered, was to allow the use of the prerogative to encourage national development in a field which already, in 1623, was seen to be excitingly unpredictable. To attempt to place upon the idea the fetters of an exact verbal formula could never have been sound. It would be unsound to the point of folly to attempt to do so now, when science has made such advances that the concrete applications of the notion which were familiar in 1623 can be seen to provide only the more obvious, not to say the more primitive, illustrations of the broad sweep of the concept.*

[23] National Research and Development Corporation vs Commissioner of Patents (1959) HCA 67; 102 CLR 252 (16 December 1959).

7. STRENGTHS OF THE CURRENT SYSTEM (cont.)

The NRDC judgement also spoke about the difference in patentability between a discovery and an invention:

> *The truth is that the distinction between discovery and invention is not precise enough to be other than misleading in this area of discussion. There may indeed be a discovery without invention – either because the discovery is of some piece of abstract information without any suggestion of a practical application of it to a useful end, or because its application lies outside the realm of "manufacture". But where a person finds out that a useful result may be produced by doing something which has not been done by that procedure before, his claim for a patent is not validly answered by telling him that although there was ingenuity in his discovery that the materials used in the process would produce the useful result no ingenuity was involved in showing how the discovery, once it had been made, might be applied.*

Another benefit of the current system is that it is well understood by investors in all but the newest areas of technology (where all regulatory approaches will suffer from a lack of familiarity). Since the granting of the first patents on genetic materials around 30 years ago, billions of dollars of investment has poured into biotechnology companies here and abroad. This investment was made on the understanding that the current system of intellectual property protection would remain. Importantly, some of this investment is still funding research that is yet to be patented and a rapid change in patentable subject matter would destroy the commercial prospects for that research.

A ban on patenting biological materials would not only affect these investment decisions, it would undermine confidence in the entire Australian regulatory system for intellectual property. If Parliament is going to ban patents on biological materials, despite the fact that this will breach important international agreements, then what is to prevent Parliament from banning other forms of innovation?

Decisions about patentable subject matter need to be made as part of a broad policy, not on the basis of individual technologies, in order to maintain predictability and hence investment in these technologies. This was also the view of the ALRC:

> *In the ALRC's view, concerns about the patenting of inventions involving genetic materials and technologies should not be addressed by the introduction of legislative requirements that would relate only to the patentability of this type of invention. Such an approach may set an undesirable precedent for the way in which the patent system should accommodate new technologies in the future. The current requirements for patentability are technology-neutral and are able to adapt to new technologies as they arise. Introducing specific rules for inventions involving genetic materials and technologies may suggest that special requirements for patentability should be implemented for future technologies that raise a different set of issues. Such an approach would unnecessarily fragment and complicate Australian patent law.*

8. INTERNATIONAL IMPLICATIONS

The current Bill almost certainly infringes on Australia's international obligations under the TRIPS and AUSFTA treaties and would reverse decades of work aimed at harmonising Australian and International approaches to patents.

TRIPS

The *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994*[24] (TRIPS Agreement) establishes the minimum standard of patent protection that each member of the WTO must provide under its national laws.

TRIPS contains several provisions that relate to patents but the most relevant conditions are found in Article 27 where it states

> ***Article 27***
> *Patentable Subject Matter*
>
> 1. *Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*
> 2. *Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.*
> 3. *Members may also exclude from patentability:*
>
> (a) *diagnostic, therapeutic and surgical methods for the treatment of humans or animals;*
>
> (b) *plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.*

All of these paragraphs are relevant to the current inquiry.

Article 27(1) requires that patent protection must be available for "any inventions…provided they are new, involve an inventive step and are capable of industrial application".

The current Bill would prevent the patenting of products in a subset of the category of "biological materials," even when these products would be novel, involve an inventive step and would be capable of industrial application. This would restrict patent protection for new softer agricultural chemicals and the GM crop industry. Assuming the biological materials at issue constitute an "invention this would be inconsistent with the obligation in TRIPS to make such patents available.

CropLife understands that the Bill's proponents argue that the biological materials to which the Bill purportedly refers are natural phenomena that have long been accepted as "not patentable inventions". However, the Bill, as currently drafted, would not only exclude genes as they exist in nature but also would exclude from patentability biological material isolated from its natural environment or synthetically or recombinantly produced. The Bill also expressly applies to proteins, cells and fluids, thereby potentially impacting a large cross-section of the biotech industry.

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[24] World Trade Organization (1995) *Trade-Related Aspects of Intellectual Property Rights*

8. INTERNATIONAL IMPLICATIONS (cont.)

Moreover, to determine the meaning of "invention" as used in the TRIPS Agreement, principles of treaty interpretation require consideration of its "ordinary meaning." The ordinary meaning of "invention" as set out in the Oxford English Dictionary is "something devised or produced by original contrivance; a method or means of doing something… originated by the ingenuity of some person…" Thus, the ordinary meaning would include new chemical inventions made by human ingenuity, such as isolated and purified genetic materials, or other biological materials, as referred to in the statute, that are modified or derived from natural sources that may be deemed "substantially identical" to something that exists in nature.

In addition, TRIPS Article 27.1 provides the obligation that such patents be "available… without discrimination as to… the field of technology." As noted the Bill is limited to a particular category of invention, that is "biological materials". The Bill provides for explicitly different treatment of inventions relating to "biological materials". Therefore, it would appear to be an example of *de jure* discrimination within the meaning of TRIPS Article 27.1[25]

The ALRC report also considered whether a specific ban on genetic patents would violate the TRIPS Agreement. It found that

> *The non-discrimination provision places constraints on the degree to which gene patents may be singled out for special treatment – for example, through new exclusions from patentability or defences to claims of infringement. However, the extent of these constraints is not clear*[26].

CropLife believes that the permitted exceptions to these obligations that are permitted by TRIPS are not applicable. The "biological materials" defined in the Bill do not fall within, or are not limited to, the scope of the permissible areas of exclusion from patentability for "diagnostic, therapeutic and surgical methods" in TRIPS Article 27.3(a) and "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes" in TRIPS Article 27.3 (b).

Australia also may exclude inventions from patent eligibility under TRIPS Article 27.2, for those inventions where "the prevention within their territory of the commercial exploitation of which is necessary to protect *odre public* or morality." The European Patent Office has taken this exclusion to include:

> *…inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour….In general this provision is likely to be invoked only in rare and extreme cases*[27].

CropLife is aware that there are small sections of the public who are concerned about GM crops and/or agricultural chemicals. However, this low level of concern does not meet the above description of an action that is contrary to *odre public*. In fact, the provision of government funding to activities involving both of these technologies indicates that, at least in some instances, a public benefit is perceived from the use of these technologies.

Furthermore, there is no indication in the Bill that the prevention of commercial exploitation of biological material inventions is necessary in Australia. In fact, the proponents of the Bill intend to permit others "free and unfettered access[28]" to such materials, thereby expanding their potential commercialisation. Therefore the Bill would be inconsistent with Australia's obligations under TRIPS Article 27.1 and do not fall within the scope of the permissible exceptions.

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[25] See Report of the Panel, *Canada – Patent Protection for Pharmaceutical Products*, WTO Doc. No. WT/DS114R (Mar. 17, 2000)

[26] Australian Law Reform Commission (2004) *Genes and Ingenuity – Gene Patenting and Human Health.* p. 91.

[27] European Patents Office (2010) *Guidelines for Examination in the European Patents Office*. p. 328

[28] See *Explanatory Memorandum to the Patent Amendment (Human Genes and Biological Materials) Bill* 2010, available at http://parlinfo.aph.gov.au/

8. INTERNATIONAL IMPLICATIONS (cont.)

AUSFTA

The Australia-United States Free Trade Agreement (AUSFTA)[29] entered into force on 1 January 2005. The agreement also includes obligations in relation to patent law and the necessary scope of such patents. CropLife believes that these obligations are certainly breached by the proposed Bill.

The AUSFTA contains the following relevant text:

> ***Article 17.9 : Patents***
>
> 1. *Each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. The Parties confirm that patents shall be available for any new uses or methods of using a known product. For the purposes of this Article, a Party may treat the terms "inventive step" and "capable of industrial application" as synonymous with the terms "non-obvious" and "useful", respectively.*
>
> 2. *Each Party may only exclude from patentability:*
>
> *(a) inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law; and*
>
> *(b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.*
>
> 14. *Each Party shall endeavour to reduce differences in law and practice between their respective systems, including in respect of differences in determining the rights to an invention, the prior art effect of applications for patents, and the division of an application containing multiple inventions. In addition, each Party shall endeavour to participate in international patent harmonisation efforts, including the WIPO fora addressing reform and development of the international patent system.*

There are many similarities between this text and the TRIPS text on patents. However, article 27(3) of the TRIPS agreement, which allows plants and animals to be excluded from patentable subject matter, is not included. Consequently, it is totally beyond doubt that the proposed Bill on genetic patents is in violation of this agreement.

The AUSFTA includes processes for dispute resolution and it is likely that this Bill would trigger these processes. Options to resolve the dispute are numerous, but as noted by IP Australia during the recent Senate inquiry, it is likely that a breach of this agreement would impact on Australia's exports to the US, inward technology transfer from the US and trade with the US more generally. It is extremely unlikely that the effects of such a dispute would be limited to the biotechnology industry.

Harmonisation of international intellectual property laws

It is important that Australian patent laws are similar to the patent laws in other countries, to enable the reciprocal flow of intellectual property. For example, the crop protection and biotechnology industries spend hundreds of millions of dollars to develop products in other countries (often in the US). This intellectual property may then be brought to Australia and when this happens it represents a substantial investment in Australian agricultural innovation.

[29] (2005) *Australia – United States Free Trade Agreement.* Available at http://www.dfat.gov.au/fta/ausfta/final-text/Final_text_ausfta.pdf

8. INTERNATIONAL IMPLICATIONS (cont.)

The importance of harmonised systems was recognised by the recent report on Gene Patents written by the Senate's Community Affairs References Committee. The report noted that

> *The patent system is relatively uniform across a number of countries, following many years of efforts to harmonise intellectual property systems. This has occurred as an aspect of international cooperation in the areas of economic and trade development*[30].

The Advisory Council on Intellectual Property noted in its Options Paper on Subjectable Patent Matter that

> *The need for inventors to tailor patent applications to different jurisdictions adds additional costs to innovators. Accordingly, it is desirable that changes to Australian law increase rather than reduce international harmonisation. One submission said it is important that Australia has access to the most effective and efficient technology, the majority of which are invented outside Australia.*[31]

Similarly, the ALRC report noted:

> *7.24 The Australian biotechnology industry relies on foreign investment and partnerships with overseas entities to commercialise the results of research involving genetic materials and technologies. Australia's adoption of a position that diverges from the general international consensus would likely have adverse implications for Australia's participation in the global biotechnology market. For example, it might affect adversely the extent to which foreign entities participate in, and provide capital investment for, research and commercialisation of genetic materials and technologies in Australia*[32].

A ban on biological patents would increase the level of disparity between Australian IP law and other jurisdictions. This would further stifle foreign investment in Australian biotechnology and reduce, or significantly delay, technology transfer from overseas.

30 The Senate Community Affairs References Committee (2010) *Gene Patents* p. 89.
31 Advisory Council on Intellectual Property (2009) *Patentable subject matter OPTIONS PAPER* p.30
32 Australian Law Reform Commission (2004) *Genes and Ingenuity – Gene Patenting and Human Health.* p. 173.