Representing **the best** of the plant science industry

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30 November 2015

Intellectual Property Arrangements Inquiry
Productivity Commission
GPO Box 1428
CANBERRA CITY ACT 2601

RE: PRODUCTIVITY COMMISSION INQUIRY INTO AUSTRALIA'S INTELLECTUAL PROPERTY ARRANGEMENTS

CropLife Australia (CropLife) is the peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers and formulators of crop protection and agricultural biotechnology products.

The plant science industry provides products to protect crops against pests, weeds and diseases, as well as developing crop biotechnologies that are key to the nation's agricultural productivity and sustainability.

CropLife welcomes the opportunity to contribute to the Productivity Commission Inquiry into Australia's Intellectual Property Arrangements.

The crop protection and agricultural biotechnology industries, like the pharmaceutical industry, face substantial costs and time periods required to satisfy government regulators that any risks to human health and the environment posed by their products have been identified and can be appropriately managed.

This mandatory regulatory intervention in the plant science market leads to elevated product development costs that would not be able to be recouped without a period of exclusive market access. As some of these products can be reverse engineered relatively easily, this exclusive market access period relies on protection of the intellectual property (IP) through patents (predominantly) and other IP safeguards. Without IP protection, it is likely that none of these crop protection or agricultural biotechnology products would ever be released in Australia.

CropLife believes that Australia's existing IP arrangements are, for the most part, working well and strike the right balance between promoting innovation and creativity, while still allowing competition and diffusion of knowledge. Specific areas requiring reform are noted in the CropLife submission.

Please do not hesitate to contact either myself or CropLife's Policy Manager for Crop Biotechnology, Mr Osman Mewett should you have any questions or require further information with regard to any aspect of this submission.

Yours sincerely

Matthew Cossey
Chief Executive Officer

Representing **the best** of the plant science industry

CropLife AUSTRALIA

CROPLIFE SUBMISSION TO PRODUCTIVITY COMMISSION INQUIRY INTO AUSTRALIA'S INTELLECTUAL PROPERTY ARRANGEMENTS

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1. INTRODUCTION

CropLife Australia (CropLife) is the peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers and formulators of crop protection and agricultural biotechnology products. The plant science industry provides products to protect crops against pests, weeds and diseases, as well as developing crop biotechnologies that are key to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than $17.6 billion a year to the Australian economy and directly employs thousands of people across the country. CropLife Australia is a member of CropLife Asia and part of the CropLife International Federation of 91 CropLife national associations globally.

The world's population is predicted to increase to 9.6 billion by 2050, requiring an increase in global food production of 70 per cent. Providing enough food in the context of production constraints, volatile consumption patterns and a changing climate will be an unprecedented scientific, economic and public policy challenge. The situation provides an opportunity for Australian farmers to both assist in the global food security effort and to profit from increased demand for their agricultural products. By adopting innovative farming practices, such as the sustainable and efficient use of crop protection products and genetically modified (GM) crops, the Australian farming sector will be able to produce more sustainably and with greater productivity.

Meeting the challenges presented by sustainably increasing food production to meet growing global demand will require science-based innovative production systems grounded in a strong, robust and workable intellectual property (IP) framework. In particular, innovative crop protection and biotechnology solutions can assist farmers in producing high yields with fewer natural resources by reducing water consumption, increasing a crop's nutrient uptake and reducing the need for other inputs.

The plant science industry's crop protection products include fungicides, herbicides and insecticides that are critical to maintaining and improving Australia's agricultural productivity to meet global food security challenges in coming decades. Each of these products is rigorously assessed by the Australian Pesticides and Veterinary Medicines Authority to ensure they present no unacceptable risk to users, consumers and the environment.

In 1995, it took the assessment of 52,500 compounds to develop one new effective crop protection chemical active. It now requires the assessment of more than 140,000 compounds and expenditure of more than US$250 million over a 10 year period to bring just one new successful crop protection product to the market. Without access to these tools, farmers may potentially lose as much as 50 per cent of their annual production to pests, weeds and diseases.

According to a Deloitte Access Economics report released in 2013, '*Economic activity attributable to crop protection products',* it is estimated that up to $17.6 billion of Australian agricultural output (or 68 per cent of the total value of crop production) is attributable to the use of crop protection products.

GM crops currently under research and development in Australia will help Australian farmers to combat environmental stresses such as drought, acid soils and salinity, which are being caused by climatic changes and previous non-sustainable farming practices. There is also considerable Australian research into GM traits that will bring health benefits to consumers, such as healthier starches and oils modified to be lower in saturated fats and with improved cooking qualities.

This submission will highlight the role that IP plays in modern agriculture and the effect that any watering down or removal of existing IP protections for crop protection or crop biotechnology products would have on the availability of novel traits, including GM crops or agricultural chemicals in Australia.

2. 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 license its product to increase competition in the marketplace. In limited circumstances, the Crown can also compulsorily acquire or license 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) 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[1]:

> "The truth is that any attempt to state the ambit of s6 of the Statute of Monopolies by precisely defining "manufacture" is bound to fail. The purpose of s6, 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."

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."

[1] National Research and Development Corporation v Commissioner of Patents (1959) HCA 67; 102 CLR 252

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.

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 Australian Law Reform Commission (ALRC) in 2004[2]:

> "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."

2.1 *D'ARCY V MYRIAD GENETICS INC*

The recent decision of the High Court of Australia in *D'Arcy v Myriad Genetics Inc*[3] has challenged the traditional view of Australia's patent system as one that is sufficiently flexible to accommodate changes in technological development and has also seen Australian practice diverge from that seen in Europe and many other countries. While it is still too early to understand what the full impact of this decision will have on the Australian patent system, CropLife believes it may be necessary for the legislature to revisit the definition of what might be considered 'patentable subject matter' in Australia in order to promote clarity and certainty within the system.

It is not the specific decisions in *Myriad* that causes the most concern to CropLife, rather it is how IP Australia and the courts will extrapolate these in future cases and examinations of patent applications. A level of predictability is needed for applicants to invest in innovation and we need to ensure that misplaced political focus does not restrict innovation. In this regard, the consultation paper issued by IP Australia appears to interpret the decision in a very restrictive way. By doing so, IP Australia is safeguarding the predictability and effectiveness of Australia's patent system, which should be acknowledged.

[2] Australian Law Reform Commission (2004) Genes and Ingenuity – Gene Patenting and Human Health.
[3] [2015] HCA 35

3. REGULATION OF INNOVATION

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.

CropLife believes that many of the principles of patenting apply broadly and that many reviews over the last decade have made proposals 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 ALRC 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 issues commonly raised in relation to gene patents. Of particular importance 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 (Cth) 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.*

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[4]:

> "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."

The Committee did not recommend altering the *Patent Act 1990* 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 (ACIP) proposed another method of increasing patient access to biologically derived technologies, namely[5]:

> "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."

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 there are not unintended consequences. In this respect, we consider 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.

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4 Senate Community Affairs References Committee (2010) Gene Patents
5 Australian Council on Intellectual Property (2010) Patentable Subject Matter

4. WHO BENEFITS FROM INTELLECTUAL PROPERTY RIGHTS FOR AGRICULTURAL INNOVATION? THE CASE OF OGURA OILSEED RAPE IN FRANCE

Intellectual property rights in agriculture are increasingly being questioned in society due to arguments that they are unfairly balanced in favour of the developer at the cost of the consumer. There is, therefore, a trade-off required between the need for investments in R&D to produce new innovations (future benefits) and the distribution of the benefits from existing innovations to users and society (present benefits).

A 2014 study by consultancy firm Steward Redqueen developed a framework that compared IP regimes based on *the probability of innovations happening* (the incentive) and *the consumer benefits once the innovation is available in the market*. This framework was then applied to the development and adoption of oilseed rape hybrids developed using 'Ogura' technology in France and compares the actual situation (non-exclusive use of IP) with exclusive use of IP and also a situation without IP.[6]

This study found that:

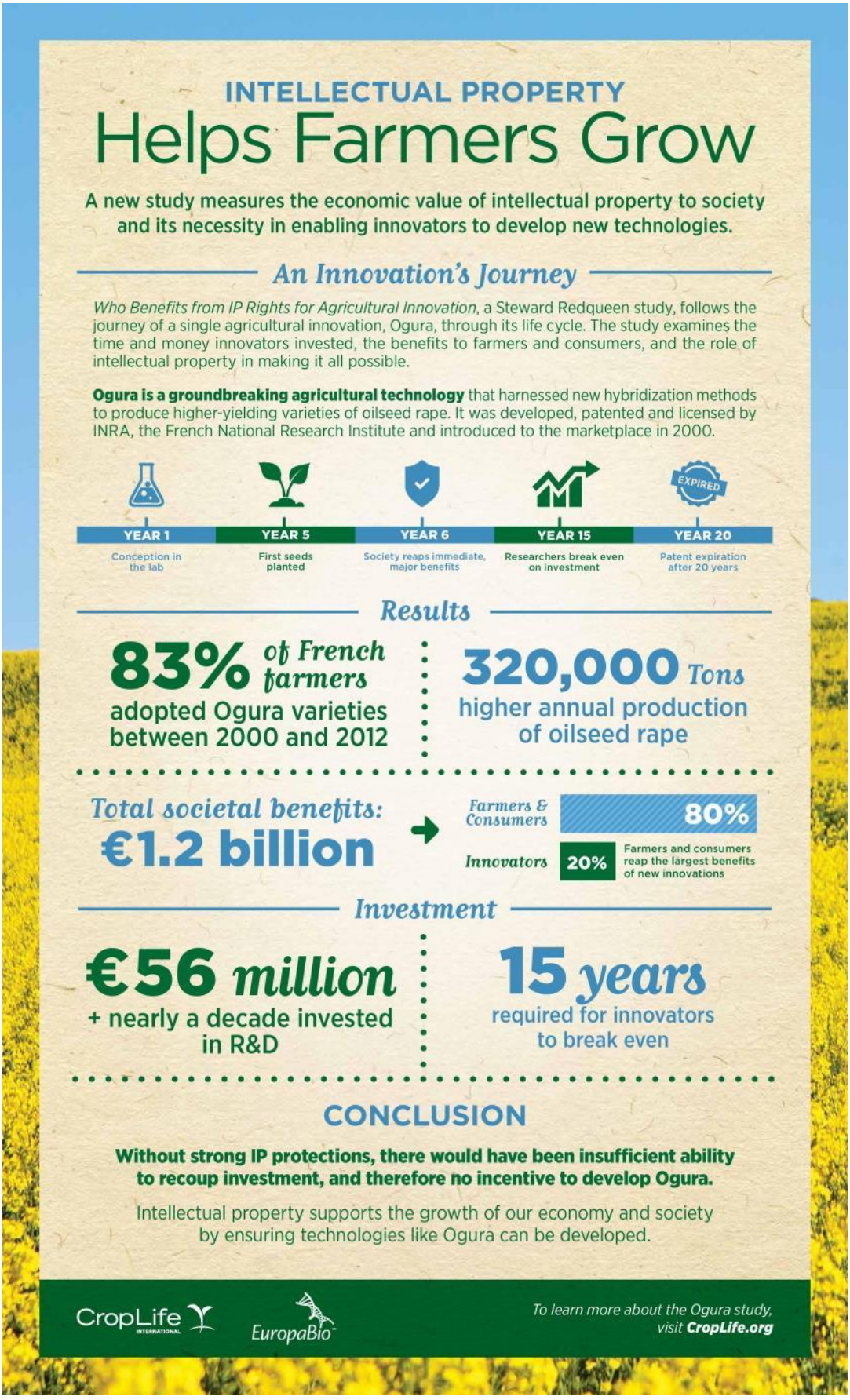
- Even under favourable market conditions (increasing crop prices) it took the developer and seed companies almost 15 years to recoup their R&D investments;
- The Ogura hybrids were adopted by 83 per cent of farmers and will have delivered €1.2 billion economic benefit over the patent life; and
- About 80 per cent of this total economic benefit accrued to farmers and further downstream to processors and consumers.

The report made the following observations about the impact of IP rights on agricultural innovation:

1. Intellectual Property rights are essential to enable innovation by providing innovators the ability to recoup investments and fund new R&D.
2. Stronger IP rights increase the probability of innovations happening.
3. Most of the social welfare coming from patented innovations accrues to farmers and further downstream towards processors and end consumers, which in the case of Ogura, is about four times higher than what accrues to the technology developer and seed companies combined.
4. The market power of an agricultural technology is primarily determined by the ability to increase performance (in this case yields) and not by the strength of its IP rights.
5. Even when IP rights are used exclusively, the pricing power of a seed producer is constrained by the presence of alternatives and the heterogeneity of farmer preferences.
6. The absence of IP rights would have a considerable cost for society since the key innovation incentive would be eliminated and thus the chance of new innovations happening and their economic benefits would be significantly reduced.

The following infographic provides a good summary of the key findings of this study.

[6] Steward Redqueen (2014) *Who benefits from intellectual property rights for agricultural innovation?* The case of Ogura oilseed rape in France, consultancy report commissioned jointly by CropLife International and EuropaBio. Available at: https://croplife.org/wp-content/uploads/2014/11/Ogura-Final-report.pdf


INTELLECTUAL PROPERTY
Helps Farmers Grow
A new study measures the economic value of intellectual property to society and its necessity in enabling innovators to develop new technologies.
An Innovation's Journey
Who Benefits from IP Rights for Agricultural Innovation, a Steward Redqueen study, follows the journey of a single agricultural innovation, Ogura, through its life cycle. The study examines the time and money innovators invested, the benefits to farmers and consumers, and the role of intellectual property in making it all possible.
Ogura is a groundbreaking agricultural technology that harnessed new hybridization methods to produce higher-yielding varieties of oilseed rape. It was developed, patented and licensed by INRA, the French National Research Institute and introduced to the marketplace in 2000.
EXPIRED
YEAR 1
Conception in the lab
YEAR 5
First seeds planted
YEAR 6
Society reaps immediate, major benefits
YEAR 15
Researchers break even on investment
YEAR 20
Patent expiration after 20 years
Results
83% of French farmers
adopted Ogura varieties between 2000 and 2012
320,000 Tons
higher annual production of oilseed rape
Total societal benefits:
€1.2 billion
Farmers & Consumers
80%
Innovators
20%
Farmers and consumers reap the largest benefits of new innovations
Investment
€56 million
+ nearly a decade invested in R&D
15 years
required for innovators to break even
CONCLUSION
Without strong IP protections, there would have been insufficient ability to recoup investment, and therefore no incentive to develop Ogura.
Intellectual property supports the growth of our economy and society by ensuring technologies like Ogura can be developed.
CropLife INTERNATIONAL
EuropaBio
To learn more about the Ogura study, visit CropLife.org

5. THE IMPORTANCE OF INTELLECTUAL PROPERTY PROTECTION FOR NOVEL TRAITS, INCLUDING GENETICALLY MODIFIED (GM) CROPS

The robust nature of Australia's existing IP arrangements supports the introduction of novel traits, including 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 would invest in this process in the absence of IP protection.

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 different agencies, including:

- **Office of the Gene Technology Regulator (OGTR)**
  The OGTR carries out risk analysis to identify and manage any risks posed by new GM crops before allowing field trials and before seeds can be commercially produced and sold to farmers.

- **Australian Pesticides and Veterinary Medicines Authority (APVMA)**
  The APVMA is responsible for the registration, quality assurance and compliance of all pesticides and veterinary medicines up to the point of sale. This includes regulation of pesticides created by, or used on, GM crops.

- **Food Standards Australia New Zealand (FSANZ)**
  FSANZ undertakes a mandatory pre-market safety assessment of all GM foods before they are approved for sale or consumption in Australia.

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

The most recent annual report on the global socio-economic and environmental impact of GM crops from the British consultancy firm PG Economics indicated continued considerable economic and environmental benefits to the farmers and general public in countries where GM crops are grown[7]. The report indicated that the net benefit at the farm level in 2013 from growing GM crops was US$20.5 billion. For the 17 year period (1996-2013) covered by the report, the global farm income gain has been US$133.5 billion. Australian GM cotton and canola farmers have realised a benefit of more than US$885 million in the period 1996-2013[8].

The PG Economics report also notes that GM crops have contributed significantly to reducing the release of greenhouse gas emissions from agricultural practices. This resulted from less fuel use and additional soil carbon storage from reduced and no-tillage farming systems associated with GM crops. In 2013, the permanent CO_2 savings from reduced fuel use were the equivalent of removing 940,000 cars from the road and the additional probable soil carbon sequestration gains in 2013 were equivalent to removing 11,520,000 cars from the road[9]. This is equal to 71 per cent of all motor vehicles registered in Australia.

The report notes that crop biotechnology has contributed to a significant reduction in the environmental impact associated with herbicide and insecticide use on the areas devoted to GM crops. From 1996-2013, the use of pesticides on the global GM crop area was reduced by 550 million kg of active ingredient (8.6 per cent total reduction) and the environmental impact associated with herbicide and insecticide use on GM crops, as measured by the Environmental Impact Quotient indicator, fell by 19 per cent[10].

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7 Brookes G and Barfoot P 2015. 'GM crops: global socio-economic and environmental impacts 1996-2013'. *PG Economics*, Dorchester, May.

8 Australian GM cotton farm income benefit US$2844.3 million 1996-2013; GM canola farm income benefit US$341 million 2008-2013.

9 Brookes G and Barfoot P, *Op. cit*

10 Brookes G and Barfoot P, *Op. cit*

If GM crops had not been available to the 18 million farmers growing them in 2013, an additional 18 million hectares of conventional crops would have been required to produce the same tonnage produced by GM crops for 2013 alone[11].

Bringing a new GM trait to market is a significant investment made by the plant science industry. To determine the relative cost and duration of the process, CropLife International commissioned consultancy firm Phillips McDougall to survey the plant science industry's largest developers. The survey found that it takes 13 years research and development (R&D) plus US$136 million to develop each new GM crop trait[12].

The cost and duration of new GM trait development, particularly navigating the regulatory process, highlights the need for a transparent and workable regulatory system based on sound science and harmonised risk assessment. Improvements to state and territory participation in the national gene technology regulatory framework will help remove unnecessary barriers to innovation and trade for Australia, assisting the nation in achieving a clean, green and sustainable agricultural sector.

The high level of private sector investment in agricultural R&D in Australia demonstrates the plant science industry's commitment to supporting sustainable agriculture and the extent necessary to bring technological innovation to the market.

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.

In Australia, GM crops have two main types of IP protection – patents on genetic constructs and plant breeder rights.

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.

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 existing patent protection were to be weakened or removed, 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 found that Australia's biotechnology industry would be threatened if patents on genetic material were weakened or banned. The report stated[13]:

> "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."

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11 James, Clive (2014) *Global Status of Commercialised Biotech/GM Crops 2014*, ISAAA

12 Phillips McDougall, 2011, 'The cost and time involved in the discovery, development and authorisation of a new plant biotechnology derived trait'. A consultancy study for CropLife International, September 2011.

13 ALRC (2004) *Op. cit*

This opinion was shared by the ACIP in December 2010 when it stated[14]:

> "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."

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[15]. 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 per cent and 25 per cent 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.

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 per cent more food by 2050[16] if there is to be sufficient food for everyone.

The cutting-edge nature of the research required to meet these challenges reflects the large investments made by both industry and governments into agricultural biotechnology. If the Australian patent system were to be weakened in any way, it would threaten the significant investment potential in this space and industry would refuse to risk their IP by releasing it in this country without adequate protection and safeguards.

Weakening Australia's current robust IP arrangements would undermine hundreds of millions of dollars in private and public investment in agricultural research and would have major implications on how Australia is viewed globally. In addition, the competitiveness of Australian agriculture would be greatly reduced if we were to lose access to the latest agricultural innovations.

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14 ACIP (2010) *Op. cit*

15 Agrifood Skills Australia (2010) *Environmental Scan of the Agrifood Industries – A perfect storm of shortages*, Industry Skills Council.

16 Reuters (September 3, 2009) *World food output must rise 70 per cent by 2050 - FAO*

6. THE IMPORTANCE OF INTELLECTUAL PROPERTY PROTECTION FOR CROP PROTECTION PRODUCTS

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

The use of crop protection products 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 crop protection products, but reach the great majority of people across the world. The general public often take the use of crop protection products for granted, but without access to these tools, farmers may potentially lose as much as 50 per cent of their annual production to pests, weeds and diseases. These products also enable other land and environment managers, such as parks and wildlife authorities, to protect Australia's native flora and fauna from noxious weeds and invasive pests. According to a Deloitte Access Economics report released in 2013, '*Economic activity attributable to crop protection products',* it is estimated that up to $17.6 billion of Australian agricultural output (or 68 per cent of the total value of crop production) is attributable to the use of crop protection products.

Crop protection products are subjected to extensive regulation by the Federal and state governments in Australia. Before crop protection products can be sold in Australia, they 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.

Crop protection products are subjected to a rigorous scientific risk assessment process before they can be approved and registered by the APVMA for sale in Australia. Applicants seeking registration of crop protection products must develop and 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.

This extensive assessment means that a large investment is required to bring a new product to market. On average, globally it takes 10 years and costs $250 million to bring a single agricultural chemical to market with over half of those costs representing regulatory costs in terms of data generation and costs of assessments[17].

It is vitally important to the agricultural industry that robust IP protection is maintained for crop protection products in Australia. Currently, patent protection can be granted for the active ingredient, subject to the normal tests for patentability. Any weakening of Australian patent laws could 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 resistance management and modern agricultural practices such as integrated pest management. The benefits of integrated pest management include a reduction in environmental pressures from farming and the increased sustainability of crop protection chemistries.

Any weakening in the current robust IP protection for agricultural chemicals 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 these agricultural impacts need to be fully considered as part of the inquiry into Australia's IP arrangements.

[17] Phillips McDougall (2010) *The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000 and 2005-8*, A Consultancy Study for Crop Life America and the European Crop Protection Association.

7. DATA PROTECTION

The Issues Paper developed for the current Inquiry specifically refers to data protection (page 18) in the context of regulatory approval of agricultural products. Australia has had a data protection scheme in place since 1995 whereby new active ingredients and associated products get data protection from the date of submission of the data, and 10 years exclusive protection from the date of regulatory decision by the APVMA.

New registrations of associated products and new uses for already registered products get the remaining period of protection until the 10 years runs out with a minimum of 5 years regardless of the protection afforded by the active ingredient. For example, if the active ingredient protection has expired a new registration gets 5 years. If there is still 6 years protection on the active ingredient the new registration will get 6 years. This is the same for new uses. Published data, or proprietary data not used to make the decision are not protected.

Active ingredients and products that are subject to reconsideration get data protection from the date of submission and 8 years mandatory compensation protection from the date of decision. Published data, or proprietary data not used to make the decision are not protected.

The draft text of the Trans-Pacific Partnership (TPP) Agreement included a clause for at least 10 years data protection for new agricultural chemical products. This means that the countries in the agreement, aside from the US and Australia who already have that data protection for new agricultural chemical products, namely Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam, will now provide the same data protection when products are exported into those markets. Countries will be given certain transitional periods to comply with these requirements.

8. AREAS WHERE REFORM IS REQUIRED – PATENT EXTENSIONS AND SPRING-BOARDING APPLICATIONS

The 2010–2012 *Raising the Bar* reforms of Australia's IP arrangements amended the *Patents Act* 1990 to introduce an exemption from patent infringement for activities undertaken for the purpose of obtaining information required for regulatory approval of non-pharmaceutical products. This practice, commonly called 'spring-boarding', permits generic manufacturers to obtain regulatory approval during the term of the patent so they can compete with the patentee as soon as the term expires.

In recognition of both the importance and impact of the regulatory approval process, and the need for a return on the substantial investments of money and time expended on the generation of new pharmaceuticals, many countries have introduced a system of patent term extensions in relation to patents that protect regulated pharmaceutical products. In Australia, s70 of the *Patents Act 1990* provides for patent term extensions for pharmaceutical products of up to 5 years in appropriate circumstances.

Like the pharmaceutical industry, the agricultural chemical and crop biotechnology industries are subject to mandatory pre-market regulatory assessment and approval before a product can be brought to market.

Despite also being subject to a mandatory regulatory process, innovative agricultural chemical and crop biotechnology product developers do not have access to the same patent term extension as pharmaceutical companies, and yet face the prospect at the expiration of the patent that competitive generic manufacturers can spring-board their own products as soon as the patent term expires.

Reform to the patent system is needed to equitably deal with product spring-boarding. Mechanisms, such as patent extensions, need to be put into place to recognise the loss of patent protection value that occurs when agricultural chemical or crop biotechnology products are undergoing mandatory regulatory assessment.

While spring-boarding new products may have benefits (as it can reduce the cost of products to users) innovative companies must be treated equitably with their generic competitors. CropLife recommends that amendments be made to Australia's IP arrangements to compensate patent owners for the real loss of the value of their patents as a result of the inability to get a commercial return during the assessment period imposed by the mandatory registration process. This should have happened as part of the *Raising the Bar* reforms, and to not address this issue fundamentally weakens the efficacy and robustness of Australia's IP arrangements for agricultural chemcials.