

final report

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Prepared by: Kathryn Adams
Griffith University
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Scoping study of the application of
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Abstract

Genetic markers, DNA related diagnostic tests and processes for identifying desirable breeding traits in animals and plants are dependent on the use of techniques that have become standard practice in Australia and overseas. The granting of patents over these technologies and over specific markers and sequences potentially reduces the ability of the animal and plant industries to develop and use these techniques on which they are currently basing their future productivity development.

This study has identified a number of the issues that are relevant to Meat & Livestock Australia (MLA) both as a user of other people's patented material and as an owner of patents. In assessing its response to the issues below, MLA needs to analyse the impact on a case by case basis from the user and producer perspectives. Changes that may operate to the advantage of users of patents may limit commercial viability for a patent owner. Most of the issues identified by the study for further consideration should benefit both users and producers, as they relate to more effective operation of the patent system to ensure that it is meeting policy objectives of encouraging innovations, making them available sooner for the benefit of the community, while providing a commercial return for the inventor.

Executive summary

Meat & Livestock Australia invests significantly in plant and animal breeding programs which are based on using genetic technologies to improve the quality of red meat through a range of areas including improved pastures, better understanding of production characteristics and increasing ability to predict progeny traits. This area of biotechnology is growing rapidly. Inventions in the field are being patented at a growing rate and the future direction of the industries is based on these breeding programs. Projects in which MLA invests are both users of patented technology and producers of new patents.

The question of whether or not gene sequences and genetic material are, or should be, patentable subject matter has been debated strongly over the years. Currently in Australia there is a Senate Inquiry into gene patenting, focussing on human genes, and there have been similar inquiries in recent years.

Australia's current position is consistent with Europe, USA and Japan in that genetic material, including gene sequences, is patentable subject matter when the invention is outside the body. For example, a gene sequence is patentable subject matter when isolated and purified in vitro, even if it is the same as the sequence occurring in nature. However, to be granted a patent it must meet the other patent criteria of novelty, inventive step and usefulness. In addition, the description must be sufficient for a person skilled in the art to reproduce the invention.

The issue facing MLA and other like organisations involved in agricultural research and development in Australia is how to work within this system and ensure that they are able to utilise the best technologies available for the benefit of the Australian industries. For this to occur, it is important that the patent system is operating to a high standard, that MLA and its scientists understand both the scope of patents that are being granted and relevant aspects of the law, and that they are using the provisions of the patent system to their best advantage.

This project is a first step in understanding the current position in relation to gene patents and its implications for MLA. It provides a brief scoping review of existing patents and identifies issues that may impact on MLA. The study has:

- Identified a sample of patents that have been accepted or granted in Australia in the plant and animal genetic area to identify any issues being raised with regard to the criteria for patent validity, particularly in relation to novelty and non-obviousness.
- Reviewed judgements in relevant tribunal and court cases to ascertain the judicial position in relation to these matters generally and in relation to animal and plant genetics in particular.
- Assessed the submissions to the current gene patenting Senate Inquiry and extracted issues relevant to animal and plant gene patents.

This study has identified a number of the issues that are relevant to MLA, both as a user of other people's patented material and as an owner of patents. In assessing its response to the issues below, MLA needs to analyse the impact on a case by case basis from the user and producer perspectives. Changes that may operate to the advantage of users of patents may limit commercial viability for a patent owner. Most of the issues below should benefit both users and producers, as they relate to more effective operation of the patent system to ensure that it is meeting policy

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objectives of encouraging innovation and making them available sooner for the benefit of the community, while providing a commercial return for the inventor.

The key issues that have been identified are:

- 1 The patentability of plant and animal genetic material and whether there are any public interest issues that would warrant special treatment for plant and animal genes
- 2 Determining freedom to operate in relation to projects in which MLA invests
- 3 The operation of the Australian patent system to ensure that the criteria are being properly applied
- 4 The compatibility of the Australian patent system with foreign patent systems
- 5 Possible amendments to the *Patents Act 1990* (Cth) in relation to:
 - a. An experimental use exemption
 - b. Crown Use provisions
 - c. Compulsory licence provisions
 - d. Greater certainty in relation to ownership of intellectual property.
- 6 Other potential changes include
 - a. Patent pools
 - b. 'as-of-right' licences.
- 7 Policy issues relating to patenting of plant and animal genes, including whether or not there are any public interest issues that would warrant special consideration.

The research undertaken in this project forms a report '*Scoping study of the application of patenting requirements to plant and animal genetic material and processes in Australia*' (see full Report at Appendix 1) which includes:

- A scoping study on the extent of patenting of plant and animal genetic material in Australia.
- The identification of key issues being raised by industry and scientists in the field and any further validation that is needed to clarify the impact of patenting plant and animal genetic material on future industry development.
- The highlighting of any areas where further investigation would be needed to reach a conclusive position.
- The identification of potential generic impacts on MLA's R&D and implementation interests in genetic improvement.
- The provision of suggestions for potential legal and/or policy response which MLA could undertake in order to mitigate unfavourable impacts.

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1 Background

Genetic markers, DNA related diagnostic tests and processes for identifying desirable breeding traits in animals and plants are dependent on the use of techniques that have become standard practice in Australia and overseas. The granting of patents over these technologies and over specific markers and sequences potentially reduces the ability of the animal and plant industries to develop and use these techniques on which they are currently basing their future productivity development. It also greatly increases the need for education and training for MLA staff, Board Members, research managers, relevant members of Industry Organisations, and other interested parties about intellectual property. This project identified some of the issues being raised as to whether patent law is appropriate in the area of genetics for plants and animals, particularly in the areas of manner of manufacture, novelty and non-obviousness. The project also scoped some of the issues in relation to the impact of patents on both research and implementation in genetic improvement in plants and animals.

2 Project objectives

The objectives of the project were to:

- Identify a sample of patents that have been granted in Australia in relation to plant and animal genetic material and identify issues being raised about adherence to patent criteria, particularly in relation to novelty and non-obviousness. This project did an initial screen of these patents to see which key ones were applicable and whether there was any value in doing a more detailed study to support any claims in relation to patentability criteria.
- Review the scope and applicability of exceptions to patent infringement.
- Review recent court decisions regarding the validity of patents over genes and methods of diagnosis.
- Assess the submissions to the gene patenting Senate Inquiry and extract issues relevant to animal and plant gene patents.
- Provide background research to inform future submissions to the government either directly or through relevant Inquiries.
- Provide generic guidance and recommendations regarding potential impacts under each item on MLA R&D and implementation in genetic (including genomics) improvement, including potential legal and policy development responses that MLA could consider to mitigate any such impacts.

3 Methodology

This project looked at three key aspects of current practice in patenting animal and plant genetics, with particular regard to current and potential impact on MLA investment in research and development, and/or implementation in the area of genetic improvement (including genomics research and implementation):

- 1 Identify a sample of patents that have been accepted or granted in Australia in the plant and animal genetic area to identify any issues being raised with regard to the criteria for patent validity, particularly in relation to novelty and non-obviousness. This project did an initial screen of these patents to see which ones were applicable and whether there was any value in doing a more detailed study to support claims of non-obviousness, lack of novelty and/or other areas where patent criteria may not appear to meet the required standard.
- 2 Review judgments in relevant tribunal and court cases to ascertain the judicial position in relation to these matters generally and in relation to animal and plant genetics in particular.
- 3 Assess the submissions to the current gene patenting Senate Inquiry and extract issues relevant to animal and plant gene patents.

In each area, the project addressed potential generic implications for MLA, and possible responses to such implications.

4 Results and discussion

4.1 Summary

- MLA invests in research and development (R&D) to benefit the red meat industry in Australia. MLA has an initiative to conduct R&D on the selection and management of livestock to improve the yield, eating quality and nutritional content of red meat. In addition to direct investment in R&D, MLA is also a participant or project partner in a number of Cooperative Research Centres (eg Beef, Sheep, Dairy Futures) which are involved in animal and plant genetic research aimed at improving genetic traits of red meat and improving pastures to better suit changing consumer demands and climatic variations. MLA is both a user of and investor in patented technology in plant and animal genomic breeding programs. It is therefore important to examine both the beneficial and adverse impacts of the patent system for MLA.
- From the information provided in the ‘Scoping Study’ Report (Appendix 1), it is clear that the patent system in Australia and internationally, in the absence of any superior court or policy decisions to the contrary, will continue to consider genetic material, including isolated gene sequences as patentable subject matter to be treated in the same way as any other field of technology.

4.2 Key issues for MLA

The ‘Scoping Study’ Report (Appendix 1) has identified a number of areas in relation to patenting plant and animal genetic material that has impact on MLA and its research/breeding programs for the meat and livestock industry in Australia. These issues are summarised below and dealt with in more detail in Appendix 1.

4.2.1 Patentability of plant and animal genetic material

The key issue identified is the patentability of plant and animal genetic material and whether there are any public interest issues that would warrant special treatment for plant and animal genes:

- Assuming, as is likely, that these materials are considered to be patentable subject matter, MLA should consider the positive and negative aspects.
- In relation to positive aspects, inventions developed through MLA projects can be protected with patents, giving MLA the potential (as a co-owner) to control the terms and conditions of use by others and to have as an asset for negotiation in relation to use of patents owned by others.
- On the negative side, MLA will need to be particularly diligent when using new techniques and processes to ensure that they have freedom to operate and that patent applications have not been filed in Australia or overseas:
- When negotiating licence agreements to use patents owned by others MLA will also need to ensure that the end commercial use can be included at a reasonable price.

4.2.2 Determining freedom to operate

- Ensuring that no-one else has a patent in an area of research where MLA wishes to invest is key to enable unfettered commercial use of the innovations arising. This will be one of the more difficult issues that MLA will need to deal with as it is not always immediately apparent that a patent has been applied for by someone else, particularly if provisional patents are involved.
- In addition, in Australia the threshold for patentability appears to be lower than in other countries (see Part 3 of Appendix 1).
- Some reviews have recommended that IP Australia improve accessibility to its databases. IP Australia has indicated that it is working on this.

4.2.3 Providing evidence of prior art

- One of the key difficulties is providing a paper trail of prior publication or prior use of a technology by those skilled in the art. These need to precisely document activity in the terms of the patent claim if an objection is to be successful on the grounds of lack of novelty or obviousness.
- As outlined in Part 3 of Appendix 1 the test for 'prior art' is not always straight forward.

4.2.4 Operation of the Patent system to ensure criteria are being properly applied

- From the MLA perspective the key areas in relation to ensuring that others are not obtaining patents that do not meet the proper standards are novelty, inventive step, usefulness and ensuring that the description is sufficient that a person skilled in the art could reproduce the invention.
- In addition, MLA is impacted adversely by the need to be able to trace the prior art to determine whether an invention was obvious at the time of filing.
- IP Australia has indicated in its submission to the Senate Inquiry into Gene Patenting that it is looking to strengthen the standards in relation to these matters through:
 - Stricter requirements to prove an invention's usefulness at examination and require experimental results showing that the patented invention has utility.

- Raising the inventive step threshold to expand the prior art considered when assessing inventive step and raising examination standards for inventive step.
 - Raising the threshold for disclosure requirements to require that patent specifications describe inventions in sufficient detail to enable the invention to be performed across the full scope of the claims.
 - Improving the balance between rights and obligations and increase certainty in relation to Freedom to Operate and the scope of the right.
 - Changes to legislative timeframes and patentability criteria (including those proposed by ALRC Report 2004).
 - Raising the level of proof with respect to all patentability criteria from the current mix of 'balance of probabilities' and 'benefit of the doubt' to a 'balance of probabilities' evidentiary standard.
- At this point there does not appear to be a time frame on these changes. In addition, there does not appear to be demonstrated action to ensure that the Patent Examiners are able to keep up to date with the rapid changes in technology so that they can properly operate at the higher standards that will be required.

4.2.5 The compatibility of the Australian Patent System with foreign patent systems

- From MLA's perspective it is important that Australia maintain compatibility with international market countries in relation to patenting genetic material so that patents arising from MLA investment can also be protected overseas and so that any technology MLA wants to use that has been developed and protected overseas can be similarly protected in Australia so that the owner is likely to provide MLA with a licence to use the technology.
- The review of court decisions in the UK, USA and Europe, it appears that there are some differences in the law and its interpretation in Australia and overseas. Part 3 of Appendix 1 provides more detail.

4.2.6 Possible amendments to the *Patents Act 1990* (Cth)

As noted in Parts 4 and 5 of the 'Scoping Study' Report, a number of recommendations have been made in other reviews to amend the *Patents Act 1990* (Cth) in a number of areas. Most of these would be of benefit to MLA as a user of other people's patents, but not so much if it (or its collaborators) is the one seeking a patent:

- An experimental use provision. This would allow MLA projects to operate without the need for a licence from the patent owner. This would be particularly beneficial to MLA where project technology did not proceed to commercial use. However, for those that do go all the way to the market, MLA would need to ensure that it did not reduce its vigilance in terms of Freedom to Operate at an early stage as the earlier a licence agreement can be negotiated the more beneficial the terms might be as the technology is further from market.
- More clarity in the Crown Use provision. This section of the Act, if amended could have some benefit for MLA, particularly if any amendment made agricultural research and development a 'State purpose'. The issues raised in relation to commercialisation would still be an issue except possibly in cases where the patented material was needed for pest and disease management, where this may also be a State purpose.

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- More clarity in relation to Compulsory Licences. This would be of use to MLA if it needed access to someone else's technology and they were not prepared to negotiate on reasonable terms or were acting in an anti-competitive way.

As noted above, all these provisions could act adversely for MLA when it wishes to have research patented. In those cases, MLA would be the one having to allow experimental use of the invention by others (and how would you know), having to allow Crown Use and having to give the compulsory licence (although in both the latter cases there is provision for reasonable royalties). It may be that MLA only wants the invention to be used by its own members, but the above provisions may make it available to others, depending on the case at hand.

4.2.7 Other areas being explored

IP Australia in a supplementary submission to the Senate Inquiry into Gene Patents summarised some of the other areas that could be explored to strengthen the patent system for genetic materials. These included:

- Patent pools
- As of right licences:
 - In the UK a patent can be issued with a tag that indicates that anyone can obtain a licence provided they agree to the terms and conditions of use. This means that the patentee will not withhold.

4.2.8 Policy issues

- In the human gene area a number of other policy avenues were identified to help mitigate against the royalty cost and access issues associated with patents on genetic material. These included coverage of some of the costs through Medicare and the Pharmaceutical Benefits Scheme as well as possible compulsory licences for public health facilities.
- The animal and plant genetic area may not warrant such special treatment at this point, although if there becomes food or climate crisis there may be policy incentive to be pursued to mitigate against inability to access the best available technology for further development. At the moment this is probably most likely if research is directed towards pest and disease management and bio-security risk mitigation.

4.3 Previous reviews

Previous reviews examined in Part 5 of the 'Scoping Study' Report (at Appendix 1), which were predominantly dealing with human genes, have taken into account diverse views on all the issues raised in submissions and have still recommended that human genes should be patentable subject matter other than when they fall into the category already excluded under the *Patents Act 1990* (Cth), namely section 18(2): *Human beings, and the biological processes for their generation, are not patentable inventions.*

The research has not found anything that would support plant and animal genes having any special consideration over human genes and therefore it could be assumed that recommendations which retain human genes as patentable subject matter will continue to apply to plants and animals.

MLA should therefore use that as a starting point and then examine the other issues in Parts 3, 4 and 5 of the ‘Scoping Study’ Report to assess the impact (beneficial and adverse) on its activities.

4.4 Internal MLA policies

One of the highest risk areas for MLA appears to be in relation to freedom to operate. MLA should have strict internal policies in this area to ensure that not only the Commercial section of the organisation is searching but also the scientists as they are not the ones most likely to know who is doing what in the world. There needs to be formal processes and regular sign-offs to ensure that these searches are done regularly and thoroughly.

4.5 Cooperative action

The actions recommended for MLA would apply equally to other RDCs and CRCs working in the plant and animal genetics field and it might be advantageous for actions to be taken collectively.

5 Success in achieving objectives

All of the stated objectives for this project have been achieved.

5.1 Identify a sample of patents

A review of patents in Australia was undertaken and discussions were held with some key scientists. The outcomes and the conclusion of this objective are reported in Part 1 of the ‘Scoping Study’ Report (Appendix 1).

5.2 Review the scope and applicability of exceptions to patent infringement

A review of the scope and applicability of exceptions to patent infringement, in particular the prior use right, is addressed in Parts 1, 2, 3, 4 and 5 of the ‘Scoping Study’ Report (Appendix 1).

5.3 Review recent court decisions

A summary of findings of Australian and overseas case law has been provided in Part 3 of the ‘Scoping Study’ Report (Appendix 1).

5.4 Assess submissions to the current gene patenting Senate Inquiry

An assessment of the submissions to the current gene patenting Senate Inquiry was made and issues relevant to animal and plant gene patents were extracted. For a full report on this objective refer to ‘Part 4: *Scan of submissions to the Senate Gene Patenting Inquiry for issues relevant to animal and plant gene patents*’ of the ‘Scoping Study’ Report (Appendix 1).

5.5 Provide background research

The ‘Scoping Study’ Report (Appendix 1) in its entirety, provides a significant level of background research to assist MLA both in its management of intellectual property issues and in preparing submissions to government on relevant issues.

5.6 Provide generic guidance and recommendations

Guidance and recommendations are provided in Part 6 of the ‘Scoping Study’ Report (Appendix 1).

6 Impact on meat and livestock industry – Now and in five years time

Genetic markers, DNA related diagnostic tests and processes for identifying desirable breeding traits in both animals and plants are dependent on the use of techniques that have become standard practice in Australia and overseas. Granting of patents over these technologies and over specific markers and sequences is being claimed by some to reduce the animal and plant industries’ ability to develop and use these techniques on which they are currently basing their future productivity development. This project has identified some of the key issues in relation to patent law for innovations in plant and animal genetics and some of the issues being raised in relation to patent criteria, particularly in areas of novelty and non-obviousness. As a result MLA will be better able to identify potential intellectual property issues when making investment decisions and to inform government of the implications of operation of the patent laws and their impact on R&D in the meat and livestock sector both now and in the future.

7 Conclusions and recommendations

7.1 Summary of some actions for MLA

MLA invests in Research and Development to benefit the red meat industry in Australia and is also a participant or project partner in a number of Cooperative Research Centres (eg Beef, Sheep, Dairy Futures) which are involved in animal and plant genetic research aimed at improving genetic traits of red meat and improving pastures to better suit changing consumer demands and climatic variations. MLA is both a user of and an investor in patented technology in plant and animal genomic breeding programs. It is therefore important to examine both the beneficial and adverse impacts of the patent system for MLA.

Reviews of the use of the patent system for genetic innovations were examined in Sections 4 and 5 of the ‘Scoping Study’ which is provided in full at Appendix 1. The reviews dealt predominantly with human genetic innovations and took into account widespread views on all the issues raised. They have still recommended that human genes should be patentable subject matter except when they fall into the category already excluded under Section 18(2) of the *Patents Act 1990: Human beings, and the biological processes for their generation*, are not patentable inventions.

This research has not found anything to support plant and animal genes having any special consideration over human genes and therefore it can be assumed that recommendations which

retain human genes as patentable subject matter will continue to apply to plants and animals as well.

In addition, Part 3 of the ‘Scoping Study’ Report (Appendix 1) examined the laws and their interpretation by the courts in Australia and overseas and highlighted some of the technicalities that can be used to either obtain a patent when *prima facie* it does not meet the criteria, or conversely can be used to reject a patent application. This part also highlighted some variances in the law and how it is applied in different countries, so that a patent application can be successful in one jurisdiction but not in another.

The key issues that have been identified for further consideration by MLA are listed in Part 4 ‘Results and discussion’ of this Final Report and in Part 6 of the ‘Scoping Study’ Report (Appendix 1). They are listed here with relevant recommendations for possible action by MLA.

Key issues identified in this report

- from the information provided in the ‘Scoping Study’ Report (Appendix 1), in the absence of any superior court or policy decisions to the contrary, it is clear that the patent system in Australia and internationally, will continue to consider genetic material, including isolated gene sequences as patentable subject matter to be treated in the same way as any other field of technology
- the patentability of plant and animal genetic material and the matter of whether there are any public interest issues that would warrant special treatment for plant and animal genes
- determining freedom to operate in relation to projects in which MLA invests
- providing evidence of prior art
- the operation of the Australian patent system to ensure that the criteria are being properly applied
- the compatibility of the Australian patent system with international patent systems
- possible amendments to the *Patents Act 1990* in relation to:
 - an experimental use exemption
 - Crown Use provisions
 - compulsory licence provisions
- other potential changes being explored such as:
 - patent pools
 - ‘as-of-right’ licences
- policy issues relating to patenting of plant and animal genes, including whether or not there are any public interest issues that would warrant special consideration, eg in the Senate Inquiry into [human] Gene Patents, some submissions noted that lessons could be learnt from the Pharmaceutical system where there is a public contribution to the cost of medicines.

7.2 Recommendations

As part of this research, ACIPA was asked to make recommendations to MLA on actions it could take to better understand and manage issues relating to patents on plant and animal genetic material and make submissions to reviews and government if appropriate. In relation to some of the key issues listed above, ACIPA has made recommendations which should be viewed as a starting point rather than a definitive list.

Recommendation 1: Freedom to Operate

Identify areas of IP Australia's database and other areas where availability of information is limiting the effectiveness of determining freedom to operate and include this information in any submissions to government or formal inquiries.

Recommendation 2: Providing evidence of prior art

Include stringent provisions in relation to literature and patent searches before a project begins and ensure researchers keep precise laboratory notebooks as part of each project.

Operation of the patent system to ensure criteria are being properly applied

From the MLA perspective the key areas in relation to ensuring that others are not obtaining patents that do not meet the proper standards are: novelty, inventive step, usefulness and ensuring that the description is sufficient that a person skilled in the art could reproduce the invention.

In addition, MLA is impacted adversely by the need to be able to trace the prior art to determine whether an invention was obvious at the time of filing. IP Australia has indicated in its submission to the Senate Inquiry into Gene Patenting that it is looking to strengthen the standards in relation to these matters but at this point there does not appear to be a time frame on these changes.

In addition, there does not appear to be demonstrated action to ensure that the Patent Examiners are able to keep up to date with the rapid changes in technology to enable them to properly operate at the higher standards that will be required.

Recommendation 3: Operation of the patent system to ensure criteria are being properly applied

- make submissions urging the rapid implementation of the proposed changes and the implementation of measures to ensure that patent examiners are skilled enough to meet the challenge
- ensure that MLA has assessed the positive and negative impacts to its business of any proposed changes to the patents law before making submissions
- pro-actively object to any patent application that does not appear to meet the novelty, inventive, usefulness or disclosure requirements
- ensure that all MLA projects have detailed laboratory notebooks that are kept even after the project is completed so that the prior art, at least within the MLA projects, can be traced.

Compatibility of the Australian patent system with foreign patent systems

From MLA's perspective it is important that Australian law is compatible with foreign market countries in relation to patenting genetic material so that patents arising from MLA investment can also be protected overseas and any technology MLA wants to use that has been developed and protected overseas can be similarly protected in Australia, – so that the owner is likely to provide MLA with a licence to use the technology. Note the differences outlined in Part 3 of this report in relation to the different approaches taken in different countries in relation to patent law and its interpretation by the courts.

Recommendation 4: Compatibility of the Australian patent system with foreign patent systems

Include in any submission the need for Australia to maintain similar position on protection of genetic material as its trading partners, in particular in relation to the application of the patentability criteria.

Recommendation 5: Possible amendments to the *Patents Act 1990*

Make submissions recommending the changes and clarifications to the Act, but before taking such a step MLA should assess the positives and negatives for its research program. In particular assess provisions such as:

- Experimental Use
- Crown Use
- Compulsory Licences

Recommendation 6: Other areas being explored

Assess the positive and negative impact of other changes being explored and be prepared to make necessary submissions if a relevant review arises. In particular, issues relating to:

- patent pools
- ‘as of right’ licences

Recommendation 7: External Policy issues

Ensure that MLA is fully aware of potential policy issues in relation to patenting of plant and animal genetic materials and input that it can make to policy making in the future, particularly in relation to areas of national interest where access to genetic material may be hindered by patents.

Recommendation 8: Internal Policy Issues

MLA should have strict internal policies in relation to patenting genetic inventions and freedom to operate to ensure that scientists are involved in relevant searches given their expertise. Formal processes and regular sign-offs should be in place to ensure that these searches are done regularly and thoroughly and that there is a good understanding of the potential commercial use of research outputs.

Recommendation 9: Cooperative action

Engage other RDCs and CRCs working in the plant and animal genetics field and take action collectively.

Recommendation 10: Education and training

Recognise the increased need for education and training and provide courses for MLA staff, Board Members, research managers, relevant members of Industry Organisations, and other interested parties about intellectual property.

Recommendation 11: Ownership

Following the decision of *UWA v Gray*¹ it is important that MLA set in place processes to ensure that ownership of intellectual property is clear. This is particularly important where research is funded by MLA and undertaken in a public sector research institution.

¹ *University of Western Australia v Gray* [2010] HCATrans 11 (22 February 2010), from the Full Federal Court's decision in *University of Western Australia v Gray* (2009) 259 ALR 224 (*UWA v Gray*).

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9 Appendices

9.1 Appendix 1: Scoping study of the application of patenting requirements to plant and animal genetic material and processes in Australia