6

Intellectual property

Introduction

6.1 The protection of IP is fundamental to the commercial development of gene technology. A strong IP system allows local organisations to protect their property and negotiate effectively with the large multinational companies. It also stimulates further innovation and encourages overseas owners of IP useful to Australian producers to make their IP available here.

6.2 There was general support among submissions to the inquiry for the system of IP protection in Australia.[1] A strong IP regime was seen as critical for farmers' access to gene technology.[2] Others suggested it should be strengthened.[3]

6.3 IP protection for GMOs in Australia relies largely on patent law and plant breeders' rights (PBRs). Other forms of protection exist, such as trade secrets, private know how agreements, and technologies that restrict the use of the GMOs to which they have been applied, like hybridisation and terminator and verminator technologies.[4]

6.4 Australia's IP regime is consistent with the international agreements to which we are party, notably the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and the International Convention for the Protection of New

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1 For example, Avcare, Submission no. 61, p. 7.

2 Agrifood Alliance Australia, Submission no. 37, p. 4; National Farmers' Federation, Submission no. 36, p. 15.

3 Australian Biotechnology Association, Submission no. 39, p. 7.

4 Terminator technology produces sterile seeds and verminator technology ensures that growers have to use particular proprietary chemicals.

Varieties of Plants. Under TRIPS, Australia is obliged to provide certain minimum IP rights, covering matters such as:

- the scope of patentable subject matter;
- exceptions to patents rights, including compulsory licensing;
- the protection of undisclosed information, including regulatory test data; and
- measures to control anti competitive licensing.

Within this general framework, there is scope for individual countries to fashion their regimes to meet local requirements.[5]

6.5 Australia's IP protection regime is similar to those of our trading partners.[6] Not only is it broadly compatible with the regimes of most other countries, its enforcement practices are 'at least on par with most advanced economies'.[7]

> … if Australian protection regimes were to be significantly out of step with our major trading partners, it would likely make us a less desirable market for innovation than our overseas competitors. Without protection, Australian innovators will not develop and manufacture the latest innovations for the domestic and export markets.[8]

6.6 The challenge for governments is to establish arrangements which on the one hand provide sufficient incentive for innovators to develop new products, but on the other hand avoid promoting monopolies which restrict innovation and extract 'above normal' returns.[9] **Getting the right balance between these two requirements is critical to the commercial development of gene technology.**

Patents

6.7 Patents are designed to encourage innovation by providing the innovator with the exclusive right to commercialise his or her invention for a set period of time, usually 20 years. In return, the patent holder makes

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5 Department of Foreign Affairs and Trade, Submission no. 70, pp. 4, 5; IP Australia, Submission no. 35, pp. 1, 2.

6 IP Australia, Submission no. 35, p. 1.

7 Intellectual Property & Competition Review Committee, *Issues Paper*, September, 1999, p. 7.

8 IP Australia, Submission no. 35, p. 3.

9 New South Wales government, Submission no. 72, p. 9.

available the details of the patented invention for publication, thereby increasing public knowledge and encouraging further innovation.[10]

The Australian patent system

6.8 Under the *Patents Law 1990,* all technologies may be patented with the exception of 'human beings and the biological processes for their generation' and 'an invention the use of which would be contrary to law'. IP Australia's submission listed the range of patentable inventions involving genetic manipulation found in Australian patent applications. They include:

- synthetic genes or DNA sequences;
- mutant forms and fragments of gene sequences;
- the DNA coding sequence for a gene (in either the isolated or recombinant form);
- the protein expressed by the gene;
- vectors (such as plasmids or bacteriophage vectors or viruses) containing the gene;
- methods of transformation using the gene;
- host cells carrying the gene;
- higher plants / animals carrying the gene; and
- organisms for expression of the gene (making the protein from the DNA) which may be bacterial, yeast, viral; plant or animal cell cultures; or higher plants or animals *per se*.[11]

Stimulating commercialisation

6.9 AFFA commented that extending patentability to biotechnology had stimulated greater private sector involvement than previously because it improved investors' ability to capture the benefits of their investment. The patent owner of a gene, for example, can control not only which species the gene is inserted into, but also the countries to which the end product is exported. Through the issue of licences, patent holders can divide up the world market. The flurry of mergers and take over activity attests to the commercial gains possible from IP in biotechnology.[12]

10 IP Australia, Submission no. 35, p. 1.

11 IP Australia, Submission no. 35, pp. 1-2.

12 Agriculture, Fisheries and Forestry Australia, Submission no. 77, pp. 18, 20.

6.10 Patented IP can thus be indispensable in attracting commercial investment.[13] Because of the long pathway to commercial release, patent protection is vital if investors are to recover their costs. The status and strength of patent protection are some of the first elements that bankers, venture capitalists, financial analysts and potential large partners will investigate when considering investing in a biotechnology project.[14]

6.11 Agricultural industries that have been identified as particularly likely to be assisted by a strong patent system for protecting their biotechnology IP include wine, cheese, cotton and wildflowers. Many others also stand to gain from it in the longer term.[15]

Limiting access to technologies

6.12 While stimulating innovation and commercialisation, patenting has limited the dissemination of information, access to material, and cooperation among researchers as IP owners release technologies only where it fits in with their global strategies. The owners also control tightly the commercial release of technologies (as discussed in Chapter 5).[16] BA suggested that this was likely to be a particular problem for Australian agriculture.[17] Examples of Australian interests being denied access to needed technologies are given in Box 6.1. The owners of patents on seeds can also interfere with traditional farm saving of seed.[18]

13 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 26.

14 V Santer, 'Intellectual property and patent issues', in *Australian Biotechnology Report 1999*, Ernst & Young, p. 33.

15 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 45.

16 P French, *Biotechnology in Australia*, Federation of Australian Scientific and Technological Societies, Occasional Paper Series, No 1, January 1999, section 6; Cotton Seed Distributors Ltd, Transcript of evidence, 18 October 1999, p. 240.

17 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 26.

18 National Genetic Awareness Alliance, Submission no. 54, p. 4.

Box 6.1 Examples of technologies to which Australian companies were refused access

Two gene cotton

To achieve better pest control, and to reduce the risk of resistance building in cotton pests, scientists advocate the rapid development of two gene technology. The two gene variety P2 has been tested recently in Australia, and has been found by CSIRO to be more effective against *Helicoverpa spp.* than the single gene Ingard® cotton. Growers were expecting this variety to be released commercially in the next two years, but in June 1999, Monsanto decided against releasing it, arguing that the P2 gene depressed cotton yields.

Monsanto will concentrate on developing another series of two gene Bt cottons which will delay the introduction of these varieties by a further two or three years. Monsanto argues that, because P2 depresses cotton yields, it is a faulty product and commercialisation poses a significant corporate risk.

The Australian Cotton Growers Research Association stated that the industry fought hard to introduce the two gene technology, and was prepared to accept the yield losses because of the technology's importance to the future sustainability of the industry. CSIRO expressed disappointment that the product was withdrawn, arguing that Australian breeders had nearly overcome reduced yield through regular breeding.

> We – the industry, the cotton seed distributors company and CSIRO – have all looked into whether or not we could have the Monsanto company completely indemnified against damage, and our lawyers say that that is possible.

Herbicide tolerant lupin

CLIMA has developed a herbicide tolerant lupin for use in Australian farming systems. A gene was used in its development that was the property of AgrEvo (now known as Aventis). The work was completed with the knowledge and support of AgrEvo. In November 1998, CLIMA submitted an application to GMAC for the general release of the variety, and renewed negotiations with AgrEvo for commercial access to the use of the gene in the lupin. At present, CLIMA has been unable to secure commercial rights for the gene.

Source: Centre for Legumes in Mediterranean Agriculture, http://www.clima.uwa.edu.au/research/nes06.html, accessed 5 May 2000; New South Wales government, Submission no. 72, p. 13; Private meeting in Perth with local stakeholders, 27 July 1999; Stakeholders in the cotton industry, Transcript of evidence, 18 October 1999, pp. 204-5, 221-2, 238, 240.

6.13 Furthermore, as IP Australia pointed out:

> It is important not to think of patents as a "monopoly" in the everyday meaning of conferring absolute market dominance since there are normally alternative substitutes. … Rather, it is a "temporary exclusive right" to only part of the commercialisation process … [19]

6.14 Others have suggested, however, that markets are not contestable in the long run, if the original innovator can perpetuate the market advantage beyond the initial property right. This may be the case with the market for transgenic seeds where a small number of big companies own key patents for the basic enabling techniques for the genetic manipulation of organisms.[20] Asker and Stoeckel pointed out that:

> It is difficult for the patents owned by these firms to be challenged, as they are large players in the market with considerable resources. These large resources mean that they are willing to defend and pursue legal challenges. Anecdotal evidence suggests that these firms cross-license technology so that, within this group of large players, there is little incentive to challenge property rights.

In addition:

> By limiting access to enabling technologies, large firms guarantee that they will have ownership of the next stage in the development of enabling technology since they are in a position to control existing research.[21]

6.15 Asker and Stoeckel concluded that:

- only time will tell if these monopolies will persist; and
- it is better to characterise markets as contestable in the long term because there are few examples of perpetuating monopolies, other than those operated with government assistance.[22]

The Department of Foreign Affairs and Trade acknowledged that 'there is considerable international debate about the role of IP rights in promoting and limiting access to the benefits of gene technology'.[23]

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19 IP Australia, Submission no. 35, p. 4.

20 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, pp. 16-17.

21 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 17.

22 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 19.

6.16 The committee is concerned that the stimulus that a strong patent system can give to innovation may be threatened by the power of monopolies to perpetuate their market positions beyond the patent period. In addition to damaging innovation, monopolies obviously are also economically damaging to other industries. The committee is aware that two major reviews of competition law are proceeding, which will identify changes that are needed to it.[24]

Cost and complexity

6.17 According to AFFA, it can cost $500,000 to gain full patent protection for a discovery, and double that per year to protect the patent from illegal use or challenge.[25] BA's discussion paper estimated that less than half this amount would be required to obtain and protect patents in an appropriate range of countries.[26] Much smaller amounts were also quoted as typical in private meetings that the committee held with people involved in businesses using GMOs.

6.18 The costs incurred in enforcing patents include legal fees, lost time assembling information, the chance of having to meet the other party's costs, stress and bad publicity. Litigation is extremely expensive in part because of the need to employ specialised lawyers.[27] By international standards, however, relatively few Australian biotechnology firms were engaged in litigation in 1999.[28]

6.19 A general problem facing any business interested in enforcing its IP rights was identified by the Advisory Council on Industrial Property. The committee reported 'substantial uncertainty' facing businesses that were considering whether to enforce their IP rights. Not only were cost and time issues of concern, so were uncertainty in legal proceedings, questions about the validity of patents and fear of abuse of the system by large players to the detriment of smaller players.[29] One view of the international scene was that 'no part of the tale is straightforward, and no one's rights

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23 Department of Foreign Affairs and Trade, Submission no. 70, pp. 5-6.

24 The reviews are by the Intellectual Property and Competition Committee and the National Competition Council. The latter is examining sections 51(2) and 51(3) of the *Trade Practices Act 1974*.

25 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p 18.

26 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 26.

27 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 27.

28 V Santer, 'Intellectual property and patent issues', in *Australian Biotechnology Report 1999*, Ernst & Young, p. 35.

29 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights*, quoted by the Intellectual Property & Review Committee, *Issues Paper*, September, 1999, p. 27.

are clearly defined in the shifting nexus of international legal protection, fast-paced technological developments, and changing business alliances'.[30]

6.20 Those wishing to use other's technologies can also face considerable expense and complexity. From its experience of licensing-in GM traits for commercial use, CSD singled out two aspects for comment. One related to the difficulty of identifying 'whom do we licence from and what do we licence?'[31] The difficulty arises from the fact that there are frequently many patents involved in a single technology, and the ownership of each must be discovered and addressed. In addition, ownership of particular patents may be under dispute.

> … really a lot of people do not know who owns what. In the middle of last year, there were 42 patent cases going on in corn. There was an estimate of $US100 million to $US150 million being spent on legal fees and the clarification of who had freedom to operate commercially with corn. Some of those have probably been sold, but there would probably be in excess of 30 patent issues currently being fought globally in corn.[32]

6.21 A second factor that contributes to the high cost and complexity of accessing gene technology is the need to deal with other legal systems.

> … the governing law of an agreement … is often not Australian law, which then predisposes you to know everything about New York law or Delaware law, and this adds to the cost, complexity and representation.[33]

6.22 Much of the cost and complexity discussed in this section reflects the way in which the patent system operates internationally. Actions that the Australian government can take to ameliorate this situation are therefore somewhat limited. However, a more uniform system of patents in different countries would simplify their use and help to reduce costs and complexity; Australia can support international moves in this direction, as discussed later in the chapter. Another way in which the Australian government can assist is by providing training in the use of patents so that the complexity inherent in the system is more easily dealt with. This issue is also covered in more detail later.

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30 S Shulman, *Owning the Future*, Houghton Mifflin Company, New York, 1999, p. 92.

31 Cotton Seed Distributors Ltd, Transcript of evidence, 18 October 1999, p. 235.

32 Cotton Seed Distributors Ltd, Transcript of evidence, 18 October 1999, p. 238.

33 Cotton Seed Distributors Ltd, Transcript of evidence, 18 October 1999, p. 235.

Practices in issuing patents

6.23 Patents are issued for inventions that are new, non obvious and useful. A more detailed definition of a patent, with particular relevance to GMOs is given by IP Australia.

> A patent is granted for an invention that is an innovative idea which provides a practical solution to a technological problem. In this context, a patent would only be granted for subject matter which meets all the following tests:
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> - involves the technical intervention of a technologist applying their inventive ingenuity to produce something distinguishable from the natural source material. (A patent cannot be granted for a mere discovery of biological material);
> - is new in the sense of not previously being publicly available. That is, a patent cannot be granted for materials in their naturally occurring state or for materials which have previously been made publicly available [in Australia or overseas];
> - has been fully described in the sense that sufficient information is provided to allow the technologist to make the product or perform the process without having to resort to invention;
> - has a demonstrated industrial use. The use to which the invention is to be put, for example, for the treatment of human diseases such as cancer or multiple sclerosis, must also be fully described. This means that there must be an actual use for an invention rather than speculation as to future uses.

A further criterion exists for biological inventions; they must be repeatable.[34]

6.24 How these criteria have been interpreted in issuing patents for biotechnology in Australia has been the subject of comment in several recent papers, as well as in some of the input to the committee's inquiry. For example, Dr Charles Lawson suggested that:

- the hurdle for inventiveness, non obviousness and novelty and the grant of a patent has been set too low; and
- the breadth of coverage of patents is too wide, leaving very little room for further invention.[35]

6.25 Others have also commented on the problems caused by broad patents. Combined with the similarity of commercially important genes across many species, broad patents have contributed to the dominance of the

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34 IP Australia, 'Australian patents for: Microorganisms; Cell lines; Hybridomas; Related biological materials and their use; & Genetically manipulated organisms', November 1998, pp. 2, 3-4.

35 Dr Charles Lawson, Submission no. 19, p. 1.

owners of these patents. This may be a situation that needs to be remedied.[36] Uniquest drew attention to the drawbacks of broad patents.

- They are more likely to be challenged which raises the cost of enforcing them.
- Potentially valuable lines of research or applications may be abandoned because of the risk of infringement.
- Additional expense is incurred if a user needs to seek clarification from the patent owner, and must pay licence fees which ought not to have been required had the patent been properly granted.
- Potential patentees decide the rigour of the system is too low to justify seeking protection in Australia.[37]

However, it has been suggested that the broadness of the patents is 'transitory, reflecting the immaturity of those technologies currently being developed'.[38]

6.26 The rigour of examination of patent applications was called into question in private meetings that the committee held with gene technology businesses. Participants in these meetings claimed that Australian patent examination is weak by comparison with that carried out in the USA and European countries. They told the committee that:

- a patent was issued by IP Australia after one day's examination when it took four years for US authorities to issue a patent and longer in Europe; and
- in another case, inadequate examination was carried out by IP Australia and a broader patent issued than in the USA. As a result of the limitations imposed on the patent in the USA, researchers in that country will be able to design around the patent and innovate while Australian researchers will not.

Others referred to weakness in the Australian patent system as well.[39]

6.27 The Intellectual Property and Competition Review Committee (IPCRC) was set up to assist with the implementation of the National Competition Policy in relation to IP protection. In an interim report, the IPCRC examined a number of matters concerning the issuing of patents, and

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36 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, pp. 26, 27.

37 Uniquest, Submission no. 29 to the Intellectual Property & Competition Review, p. 6.

38 Department of Industry, Science and Resources, Submission no. 34 to the Intellectual Property & Competition Review, p. 23.

39 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, p. 50.

some of its observations reinforce the evidence received by the committee. The IPCRC's conclusions and proposals, based on the submissions which it received, have been put forward for further public discussion and are summarised here.

- The threshold for the issue of a standard patent should be 'no less than the highest threshold set by any of the countries with which we conduct substantial technology trade';[40]
- In relation to the threshold tests for granting patents:
  - ⇒ The current basis for assessing the industrial or technical nature of patents applied for is flexible and adapts well to new and rapidly evolving technologies. It serves the purpose of the patent system better than any firm definition of what constitutes a patentable invention.[41]
  - ⇒ Mere discoveries, such as identifying a gene sequence, should continue to be excluded from patentable subject matter. Only the applications of these discoveries should be patentable. Guidelines may be needed to assist in making this distinction.[42]
  - ⇒ The test for inventiveness used in Australia appears to be more lenient than those used in some other countries; the threshold for inventiveness should be raised.[43]
  - ⇒ It is possible that there would be a better balance between the interests of IP owners and users if the objectives of the Patent Act emphasised that the long term interests of end users should be the predominant consideration in granting patents. Such a requirement would serve to balance the greater lobbying power possessed by IP owners compared with that of end users.[44]
- With respect to the administration of the patent system:
  - ⇒ Rigorous screening of patent applications is needed to ensure that those that are granted are 'strong, certain and enforceable'.[45]
  - ⇒ A more stringent test for granting patents is suggested which will improve their certainty and validity.[46]

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40 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, p. 38.

41 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, pp. 40-1.

42 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, pp. 43-4.

43 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, p. 46. See also: J Revesz, *Trade-Related Aspects of Intellectual Property Rights*, Productivity Commission Staff Research Paper, AGPS, Canberra, 1999, p. 29.

44 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, pp. 47-8.

45 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, p. 50.

46 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, p. 52.

⇒ A small office like IP Australia cannot hope to have the level of expertise that much larger overseas offices have. The quality of patent examination in Australia might be improved through more use of, and cooperation with, overseas patent offices. The work of patent examiners might also be assisted by requiring applicants to provide a wider range of relevant information than they do at present.[47]

6.28 The committee believes that a strong patent system that issues clear, valid patents to biotechnological inventions will benefit Australian agriculture. From the small amount of evidence it received and the findings of other reviews, the committee recognises that there are a number of improvements needed.

6.29 The committee favours narrower, more stringently examined patents issued over higher thresholds than at present. It believes that changing the Patent Act's objectives to emphasise more firmly the long term interests of end users would help to inhibit the emergence of persistent monopolies. The monopoly power of the multinational life science, agrichemical companies was a recurring theme of the inquiry. The committee wishes to ensure that the highest level of protection is provided to Australian IP.

Recommendation 24

6.30 **The committee recommends that IP Australia:**

- **avoid issuing broad patents;**
- **raise the thresholds for granting patents so that they are equivalent to the highest set by overseas countries; and**
- **screen patent applications more rigorously.**

47 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, pp. 52-3.

Recommendation 25

6.31 **The committee recommends that the *Patent Act 1990* be amended:**

- **to give effect to the changes proposed in Recommendation 24; and**
- **to clarify that the long term interests of end users are as important as the rights of intellectual property owners to benefit from their investment in that intellectual property.**

6.32 The committee also believes that IP Australia's staff must be assisted to carry out their work as efficiently and effectively as possible. The suggestion that IP Australia might share skills with overseas patent offices seems to be one that is worth pursuing. It also appears logical to the committee to require maximum assistance from patent applicants by way of providing relevant information to IP Australia.

Recommendation 26

6.33 **The committee recommends that IP Australia develop and implement mechanisms for sharing skills with other patent offices.**

6.34 One of the issues brought to the committee's attention concerned the ongoing debate about whether gene sequences should be regarded as scientific discoveries, which are not patentable, or technological innovations, which are.[48] The committee is aware that there are those who argue that gene sequences should be patentable. For example, in a submission to the IPCRC, Uniquest argued that gene sequences and the proteins they encode are no different from the patentable biologically active chemical entities used in crop protection as pesticides and herbicides. Failure to patent genetic sequences might inhibit biotechnological innovation.[49] Avcare mounted a similar argument,[50] but this view has been challenged.[51]

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48 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, pp. 42-3; Revesz, *Trade-Related Aspects of Intellectual Property Rights*, Productivity Commission Staff Research Paper, AGPS, Canberra, 1999, p. 12.

49 Uniquest, Submission no. 29 to the Intellectual Property & Competition Review, p. 4.

6.35 On the other hand, others object to the patenting of all genetic material, particularly food plants, on a number of grounds. Their objections are summarised below.[52]

- There are moral and spiritual objections to treating life as a commodity. It is inappropriate to draw on precedents developed to serve other industries.
- Food plants are not owned by one group of people but are part of our human heritage from the past.
- If they belong to anyone, it is to their traditional owners, whose rights have been ignored when plants such as the Neem tree and Basmati rice have been patented. This is biopiracy.
- Patents on the genetic material of food plants put these plants under the control of private corporations. When private firms gain exclusive control over the IP needed to grow the food on which we rely for survival, they will effectively own the future, determining the direction and shape of agricultural development and the types of food available.

6.36 The committee believes that the current practice in Australia of regarding the identification of genetic sequences as mere discoveries meets some of the objections of those opposing patents on living organisms, while still encouraging innovation. The committee is aware the IPCRC reached a similar conclusion in its interim report, and is seeking to more clearly define the distinction between discovery and invention.[53]

Time limits on patents

6.37 The term of patents on agricultural biotechnology is 20 years, in keeping with the minimum requirement imposed by TRIPS. It is possible that a longer patent period is needed to make sure that the cost of bringing GMOs to the market can be recouped. There is often only eight to ten years left on patents after commercial release.[54]

6.38 Pharmaceutical patents can be extended to 25 years, in recognition of the delays that regulatory requirements may impose on commercialisation. A similar case can be made for lengthening the patent period for

50 Avcare, Submission no. 42 to the Intellectual Property & Competition Review, p. 26.

51 Dr Charles Lawson, Submission no. 19, p. 2.

52 Australian GeneEthics Network, Submission no. 71, p. 11; National Genetic Awareness Alliance, Submission no. 54, p. 4; S Shulman, *Owning the Future*, Houghton Mifflin Company, New York, 1999, pp. 87, 99-100.

53 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, pp. 43-4.

54 Dr Brian Booth, Submission no. 7, p. 2.

biotechnology innovations.[55] However, the committee is aware that others believe that there is insufficient evidence to justify either a shortening or lengthening of the patent term.[56]

6.39 The New South Wales government asked:

> … whether the time limit applying to patent protection should be standardised in terms of years, or should relate to the period of time required for innovators to derive a 'normal' return on their investment.[57]

It appears to the committee that the latter course would introduce an extra degree of complexity to the patent system that is not justified.

Impact of patents on agricultural biotechnology R&D

6.40 As discussed in Chapter 5, much of Australia's agricultural R&D is carried out by publicly funded bodies with obligations to make their IP widely available. By contrast, the R&D carried out by private firms is unambiguously owned by them and used for their own financial benefit. Consequently, they are more likely to be responsive to the innovation incentive provided by patent protection than are publicly funded R&D bodies.

6.41 If the international IP regime is strengthened, as some anticipate it will be (see below), the property rights that attach to intellectual endeavour will become more widely acknowledged. Under these circumstances, the incentive effects of the patent system are likely to increase. Asker and Stoeckel predicted that the impact of this on Australian R&D will depend on the relative mix of 'private' and 'public' R&D in the country. They pointed out that:

> … the high proportion of public R&D in agriculture tends to suggest that agricultural industry is unlikely to be in a position to be able to extract the maximum benefit from the rewards and incentives offered by a patent system.[58]

The committee received confirmation that this is happening, as detailed in Chapter 5.

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55 Avcare, Submission no. 42 to the Intellectual Property & Competition Review, p. 25; Department of Industry, Science and Resources, Submission no. 34 to the Intellectual Property & Competition Review, p. 24.

56 Dr Charles Lawson, Submission no. 19, p. 3; J Revesz, *Trade-Related Aspects of Intellectual Property Rights*, Productivity Commission Staff Research Paper, AGPS, Canberra, 1999, p. 26.

57 New South Wales government, Submission no. 72, p. 9.

58 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, pp. 38-9.

6.42 Asker and Stoeckel described the dilemmas facing publicly funded R&D organisations in relation to how they manage their IP.

> Who should the returns of R&D, which can be realised through the patent, be distributed to? If the organisation keeps the funds, this suggests there is less need for external funding, but which funding body should reduce its contribution? If the returns are transferred to industry, how is it done? If the organisation is giving returns to industry, why is the taxpayer, in effect, subsidising a virtually private firm?
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> In this instance, the solution seems to be to set up the organisation according to the normal model of corporate governance with industry and the government having the same position as shareholders. However, this begs the question why is the government involved in what is now a private organisation?[59]

6.43 Because the commercial exploitation of IP by an R&D organisation may not be consistent with its mission and purpose, it raises complex issues, which Asker and Stoeckel described thus:

> A public R&D organisation, typically in agriculture, operates to benefit a collection of small producers. The organisation conducts research that is intended to benefit all producers. To reap the rewards afforded by the property rights IP law gives, the public R&D organisation should sell its IP to the very firms that the IP was created to benefit. This does not seem a problem except where the purpose of the R&D organisation is to give an R&D subsidy to the industry. The price involved in selling the R&D may offset the subsidy intended to be created.
>
> The R&D organisation is also bound by the fact that it cannot just give away its IP to the industry that it is trying to benefit. If it does this, the members of the industry may sell the IP to others. In this way, the organisation may get next to no benefit from owning IP. This would mean obtaining a patent would be too costly when compared with the benefit.[60]

6.44 The committee considered user views of the dilemmas facing publicly funded R&D organisations in Chapter 5. It recommended a review of the arrangements used by these organisations to make their output available to others. It suggested that best practice be identified and information disseminated.

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59 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 40.

60 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 40.

6.45 A further factor that might inhibit innovation in public institutions is that their researchers are less likely to receive rewards for their innovations than their counterparts in the private sector. The committee was told in private meetings that this was a problem that needs to be addressed. The committee agrees.

6.46 The committee believes that acknowledging and rewarding researchers when their innovations lead to commercial success is important in stimulating a commercial focus for research. Rewards also help to retain Australian researchers in this country and attract skilled people from overseas.

Recommendation 27

6.47 **The committee recommends that research institutions that receive Commonwealth funding and do not at present acknowledge and reward their researchers for innovative output that leads to commercial success, be required to do so as a condition of receiving public funding.**

Plant breeders' rights

6.48 The *Plant Breeders' Rights Act 1994* permits developers of plant varieties to benefit commercially from their work in developing those varieties. At the same time, it allows access to new plant varieties for public and private uses, such as further improving them. PBRs do not extend to genes and the processes for manipulating them, but they do cover GM varieties. PBRs represent a reasonably easy and inexpensive method to protect all new varieties, and are potentially available to the breeders of all varieties, regardless of size. Further information about PBRs is provided in Appendix C.

6.49 There remain unresolved issues relating to the current framework for protecting PBRs. Three problems were identified:

- farm saving of seed which is prevalent, for example, in the grains industry;
- the difficulty experienced by owners of variety rights in recouping their financial outlays; and

- the absence of benefit to the owners of rights to varieties that are subsequently genetically modified.

End point royalties

6.50 Producers saving seed for future sowing limit the collection of seed royalties and therefore the return to the developer of the variety. This situation can be rectified by collecting EPRs on grain produced or on processed products of the grain. The committee is aware that there are difficulties in collecting EPRs. The ABB suggested that the collection of EPRs is difficult in deregulated markets unless closed loop marketing is used. Although public breeding institutions have not favoured closed loop marketing to date, the ABB saw a place for it in the market development of a variety and giving a return to breeders.[61] The CRCA suggested that, with the withdrawal of government funds for plant breeding activities, the collection of EPRs will be essential to maintain the standard of Australia's crop varieties.[62]

6.51 EPRs have been under discussion by the grains industry. At one stage, consideration was given to the possibility that EPRs might be collected by AFFA's Levies Management Unit at cost to the owner of the variety.[63] However, EPRs are now recognised as a purely commercial arrangement between producers and breeders, supported by contract law. The basis for collecting EPRs will be clearer in the light of work being undertaken at present in relation to the PBR Act. The committee supports amendments to the act to clarify and facilitate the commercial relationship between breeders and producers.

Genetic manipulation of protected varieties

6.52 The New South Wales government expressed concerns that PBRs allow protected varieties to be used for genetic manipulation in breeding programs and research without reference to the original owner of the variety.[64] The Western Australian government also believed that the PBR Act may not adequately recognise the efforts of the first breeder of the variety. It suggested that 'advances in biotechnology are allowing rapid insertion of important genes into well established PBR varieties that may devalue the rights of the breeder of the first variety'.[65]

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61 Australian Barley Board, Submission no. 60, p. 7.

62 Cooperative Research Centres Association, Submission no. 40, p. 9.

63 For example, NSW Farmers' Association, Submission no. 38, p. 10.

64 New South Wales government, Submission no. 72, p. 10.

65 Agriculture Western Australia, Submission no. 48, p. 4.

6.53 The Australian Raw Sugar Industry illustrated the disadvantage it would suffer under the current legislation.

> Our concern is that a variety developed by the industry and paid for through the BSES [Bureau of Sugar Experiment Stations] research levy could be transformed with a single gene which adds one distinct characteristic (e.g. herbicide resistance). Under current legislation, the organisation creating this transformed variety can claim PVR [Plant Variety Rights], while the original plant breeder that provided all of the other useful genes in the variety has no further claim.[66]

The sugar industry claimed that failure to protect the IP of the original breeder is contrary to the International Convention for the Protection of New Varieties of Plants and to Australia's best interests.

> This provision would mean that large multinational companies can obtain access to PVR protected varieties, transform them, and then charge growers for using the variety even though an industry's own organisation bred the original variety.[67]

6.54 Furthermore, the holders of varieties under PBR 'stand to have their better varieties genetically modified and then patented without any royalties accruing to the original PBR holder in the longer term'.[68] The sugar industry recommended that the PBR Act be changed to take into account the rights of the initial breeder of varieties which are subsequently genetically transformed.[69]

6.55 The committee understands that the PBR Act:

- recognises the major contribution of the first variety by allowing joint control of the derived variety, where the incremental improvement produced by a subsequent breeder is minor; but
- allows the breeder of the derived variety to market the new variety without reference to the breeder of the first variety, where the improvement on the first variety is large.[70]

It appears from the arguments put to the committee that most submissions were based on the premise that genetic modification of varieties would *per se* produce 'large' improvements.

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66 Australian Raw Sugar Industry, Submission no. 64, p. 12.

67 Australian Raw Sugar Industry, Submission no. 64, p. 12.

68 NSW Farmers' Association, Submission no. 38, p. 3.

69 Australian Raw Sugar Industry, Submission no. 64, p. 12.

70 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 19.

6.56 There are attractions in the suggestion that the first breeders' rights should be strengthened, but this is likely to inhibit the production of new varieties from existing ones, as well as increase the price of new varieties to growers.[71] The committee concludes that it would not be in the interests of Australian agriculture overall to change the current arrangements.

International arrangements

6.57 Internationally consistent IP laws are to Australia's advantage.[72] They facilitate international trade and investment by eliminating official barriers to these activities and by reducing the transaction costs facing exporters and importers.[73] Support for similar, synchronised laws among nations was expressed in submissions to the inquiry, for example, by the NSW Farmers' Association.[74]

6.58 As indicated at the start of this chapter, Australia's regime for IP protection is comparable to those of its trading partners. However, Australia currently provides stronger protection for biological innovations than other countries in the world, with the possible exception of the USA and Japan. A paper by a Productivity Commission staff member suggested that Australia's IP protection 'goes much beyond' the minimum requirements imposed by TRIPS. Under these circumstances, lowering Australian standards to maximise gains to Australia might be advisable unless Australian standards are adopted globally.[75] Asker and Stoeckel, in their report on IP in agricultural trade, advocated the latter course: negotiating to strengthen TRIPS' minimum requirements to mirror Australia's domestic law.[76]

6.59 The committee is aware that globalisation is putting pressure on nations not only to strengthen their IP laws but also to harmonise them.[77] TRIPS is currently under review, and any revision of Article 27.3(B), which covers the patenting of biological material, will be relevant here. Some of the issues likely to be considered in this context are:

- clarification of the current wording of Article 27.3(B);

71 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 18.

72 Department of Foreign Affairs and Trade, Submission no. 70, p. 5.

73 Intellectual Property & Competition Review Committee, *Issues Paper*, September, 1999, p. 7.

74 NSW Farmers' Association, Submission no. 38, p. 9.

75 J Revesz, *Trade-Related Aspects of Intellectual Property Rights*, Productivity Commission Staff Research Paper, AGPS, Canberra, 1999, pp. 31-2.

76 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 35.

77 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 22.

- increased compliance with existing obligations by developing countries; and
- mandatory protection of bioengineering innovations above the microorganism level.[78]

6.60 It has been suggested that all these developments would be in Australia's interests as they would clarify the application of patent law to biotechnology, provide more uniform protection and increase compliance. Stronger IP regimes in developing countries would give greater certainty to Australian companies doing business in those countries.[79] Developing countries, concerned about such matters as farmers' rights, are likely to oppose such moves, however.[80]

6.61 The committee believes that the Commonwealth government's position in negotiations over changes to TRIPS should be to strengthen the international IP regime.

Recommendation 28

6.62 **The committee recommends that, in international negotiations, the Commonwealth government support the strengthening of the provisions of the Agreement on Trade Related Aspects of Intellectual Property and assist in establishing stronger intellectual property systems in developing countries in Asia.**

Alternative means of protecting intellectual property

6.63 Most submissions to the inquiry saw patents as the best way of protecting IP in biotechnology. The New South Wales government drew attention to the views of SCARM's High Level Working Group on Gene Technology; the group regarded patents as the preferred instrument for

78 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, pp. xiv, 8; J Revesz, *Trade-Related Aspects of Intellectual Property Rights*, Productivity Commission Staff Research Paper, AGPS, Canberra, 1999, p. 95.

79 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, pp. 32, 34, 37.

80 J Revesz, *Trade-Related Aspects of Intellectual Property Rights*, Productivity Commission Staff Research Paper, AGPS, Canberra, 1999, p. 94.

commercialising innovations derived from gene technology. Australian patent law provides the necessary legal and commercial protection.[81]

6.64 However, according to the Queensland government:

> The rate of innovation should be considered in determining appropriate mechanisms for protection of intellectual property. The emergence of genomics is accelerating the rate of discovery and application to an extent that may render many patents redundant. Perhaps the cost of patent filings may not be warranted in many cases, relying instead on trade secrecy — particularly for innovations directed specifically at Australian production and marketing systems.[82]

6.65 The importance of trade secrets has increased in recent years 'because the pace of incremental innovations in dynamic sectors … has rendered patent protection less relevant'. Trade secrets may be protected by contracts, but may also rely on legal injunctions and, more usually, common law remedies for breaches of confidence. They are effective in limiting the loss of commercially significant information to competitors. However, they also inhibit further innovation and the transfer of technologies because, unlike patents, no information about the secret is disclosed and no time limit applies.[83]

6.66 Biotechnological methods of protecting IP have also been proposed, most notably terminator technology. An outcry accompanied the first revelation that a patent on that terminology had been acquired. Inserting terminator genes into a variety that would render it sterile was seen as unacceptable. Terminator technology would prevent farm saving of seed, which would be particularly disadvantageous for poor farmers, and enable the genes' owners to extract monopoly rents. Monsanto subsequently gave an undertaking not to release terminator technology.

6.67 More subtle biotechnological approaches to limiting the use of GMOs are theoretically possible, however. Turning off the GM trait after the first generation while maintaining the organism's viability would be a solution to the objections raised to terminator technology.

6.68 The Queensland government proposed that alternatives to patents and PBRs should be considered in the context of a review of the appropriateness of the Australia's IP system for the innovators and users

81 New South Wales government, Submission no. 72, p. 9.

82 Queensland government, Submission no. 79, p. 5.

83 B Bailey, *New Ideas, Old Laws: Copyright, Patents, Trade Marks and Designs, and How to Avoid Plagiarism*, Department of the Parliamentary Library, Background Paper 12, 1995-96, p. 10; J Revesz, *Trade-Related Aspects of Intellectual Property Rights*, Productivity Commission Staff Research Paper, AGPS, Canberra, 1999, pp. 23-4.

of biotechnology.[84] The committee is not convinced that such an inquiry is necessary. It understands that trade secrets will be used where they benefit the IP's owner, for example, if the product using the IP cannot be easily reverse engineered or is likely to become obsolete very quickly. With other products, patents will provide more effective protection. Similarly, the committee expects that biotechnological protection of IP will be employed where appropriate.

Managing intellectual property

Intellectual property skills

6.69 IP is expected to grow in significance to Australian agriculture as global competition increases. This trend will be driven by:

- continuing falls in commodity prices as yields rise, particularly in the developing world; and
- life style and attitudinal change among consumers in favour of products of higher, more consistent quality and greater diversity.[85]

In this context:

> Product differentiation and innovation are likely to be increasingly important to agricultural industries in the future. As competition in world markets continues to intensify, the greatest advantage may accrue to those producers who use intellectual property (IP) to the greatest advantage.[86]

6.70 In this context, the committee was concerned to hear from many witnesses to the inquiry that the level of skills in, and understanding of, IP is inadequate.[87] According to BA:

> Lack of appropriate intellectual property protection and management strategies has led to the loss of commercialisation opportunities for a number of key Australian innovations. These losses can be far greater than the costs of obtaining intellectual property rights. Therefore, it is important that firms and researchers have a good understanding of how to strategically

84 Queensland government, Submission no. 79, p. 5.

85 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 1.

86 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. xi.

87 Grains Research and Development Corporation, Submission no. 47, p. 15.

> manage their intellectual property, for example, when to patent or trade mark, and in which countries, and when to rely on other strategies.[88]

6.71 In private meetings with gene technology businesses, it was stressed to the committee that IP considerations must be a part of any project from the very beginning. The nature of this relationship and the activities that need attention at each stage of the process of bringing research findings to the market are illustrated in Figure 6.1.

6.72 The first step in a project's design is to make sure that the results of any research planned are not already other people's property and therefore unavailable for commercialisation.[89] Freedom to operate must be addressed at a global level.[90] Twenty-one per cent of the 90 Australian companies surveyed by Ernst & Young in 1999 had at some time abandoned an important biotechnology project because further work was blocked by IP rights held by another organisation. This may reflect an inadequate level of due diligence before undertaking a project,[91] and indicates the need for better in house understanding of IP issues and use of specialist advice.

6.73 In addition to carrying out one's own research, it is usually necessary to license-in some of the technology needed. Because many pieces of technology are required to produce a GMO, it is highly likely that all projects will involve locating the owners of the relevant technologies and negotiating rights to use them. The GRDC reported that research priorities can shift dramatically when access to, and the costs of, any prerequisite IP are considered.[92]

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88 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 26.

89 Cooperative Centre for Tropical Plant Pathology, Submission no. 21, p. 4.

90 Avcare, Submission no. 61, p. 6.

91 V Santer, 'Intellectual property and patent issues', in *Australian Biotechnology Report 1999*, Ernst & Young, p. 35.

92 Grains Research and Development Corporation, Submission no. 47, p. 15.

Figure 6.1. Diagram to show the IP issues that need to be addressed at each stage in R & D

	research	development	commercial
R & D:	•set objectives •identify milestones •develop strategies •experiment, repeat, review	•extrapolate to other systems •verify stability of outcomes •select best prototype •optimise performance	•seek partners •negotiate agreements •establish legal framework

IP issues:	•ensure not already done •locate relevant 3rd party rights •decide whether to make or buy •protect IP as it arises	•monitor 3rd party positions •negotiate at appropriate time •formulate IP protection strategies •continue prosecution	•maintain rights •prosecute infringers •monitor competitors

Source: Dr Carol Nottenburg, Center for the Application of Molecular Biology to International Agriculture

6.74 There are alternative approaches to licensing but they involve very wise, well informed decision making. They include:

- ignoring other people's rights and risk challenges from them – this may be a risk worth taking when a patent is near the end of its term; and
- challenging the validity of a patent but this can be a very costly undertaking, US$500,000 as a minimum.

6.75 Smart implementation of IP rights is crucial to the successful use of IP. A firm's decision to enforce its IP rights is often a complicated strategic commercial decision. Mismanaged, IP is liable to impose considerable costs on an organisation and erode any benefit IP may have brought.[93]

6.76 IP cases require highly specialised lawyers, involve very complicated factual detail and are concerned with a body of law that, in relation to biotechnology, is still being developed at a rapid rate.

> Similarly, other firms may anticipate that an IP owner will not choose to enforce their IP rights. It may be apparent that the gains from enforcement do not outweigh the costs, particularly as a patent comes close to the end of its term. … The owner may have been better off licensing their IP in the early stages of the patent, and getting some profits from other firms, rather than finding themselves helpless in the face of patent violation.[94]

6.77 Several elements were identified to the committee as necessary to improve the management of IP in Australia: education, resources to assist decision making, and an environment that enables the most to be gained from Australian IP. A number of initiatives have been taken to provide training and resources.

- BA is running IP management awareness seminars, producing a CD-ROM on IP management and developing a professional training course on the same topic;[95]
- CAMBIA is establishing an informatics centre, funded by the Rockefeller Foundation, to enhance the ability of public sector and small to medium sized businesses to use biotechnology for crops. The centre will provide internet access to IP databases, as well as business and strategic advice.

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93 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, pp. 7, 27-8.

94 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 7.

95 Department of Industry, Science and Resources, Submission no. 84, p. 2.

- The establishment of the Australian Centre for Intellectual Property in Agriculture at the Australian National University was announced in March 2000. It is being set up with funding from the university, the GRDC and the Commonwealth government. Biologists and lawyers will work together to provide education and training and, through partnerships with other centres such as CAMBIA, develop a national network in IP law and policy. The centre's activities will target industry, professionals in the field, students, farmers and the public.[96]
- In recent years IP Australia has undertaken 'major marketing and awareness-raising activities … to ensure that businesses effectively use the IP rights available to them by law'.[97] With BA, it is providing information about IP protection through its web site and CDs, and training and other materials for small and medium businesses, schools and universities.

6.78 Other suggestions have also been made. From CSD came the idea that it would be useful to help those who need access to key technologies to develop relationships with the owners of these technologies.[98] It would also be useful to provide a framework for research and industry groups to network and share IP management skills with legal, commercial, and patent experts.[99]

6.79 The importance of providing resources of this kind was underlined by the Department of Industry, Science and Resources' comment in relation to doing business overseas that:

> … a number of government programs are in place to assist firms (particularly small and medium enterprises) in gaining access to information about other countries' requirements. … but there is little available information on overseas intellectual property systems. For example, Austrade can provide exporters with considerable information about the United States' food, automotive, and engineering markets, but has no comparable level of information on the United States' intellectual property system.[100]

6.80 The committee appreciates that R&D is now being commercialised in an environment where there is a much greater emphasis than before on

96 Professor John Lovett (GRDC) and Professor Michael Cooper (ANU), 'New centre for intellectual property in agriculture at ANU', Media release; Professor John Hearn, Interview on ABC radio, Canberra 2CN, 7 March 2000.

97 IP Australia, *1999 Corporate Report*, p. 29.

98 Cotton Seed Distributors Ltd, Transcript of evidence, 18 October 1999, p. 237.

99 Prime Minister's Science, Engineering and Innovation Council quoted by P French, *Biotechnology in Australia*, FASTS Occasional Paper Series, No 1, January 1999, section 6.

100 Department of Industry, Science and Resources, Submission no. 34 to the Intellectual Property & Competition Review, p. 12.

exploiting IP and extracting commercial returns from it. It recognises the need to upgrade the national skills and resources in IP protection, and supports the initiatives that are being taken to improve them. The committee believes that the success of these initiatives should be monitored so that they can be fine tuned quickly in the light of experience.

Recommendation 29

6.81 **The committee recommends that the effectiveness of the initiatives to upgrade the level and volume of intellectual property skills in Australia be monitored, reviewed, and improved when gaps in required skills are identified.**

A national intellectual property strategy

6.82 The committee was told that a national strategy to invest in agricultural biotechnology IP should be developed. Such a strategy should aim to reduce Australian growers' input costs and increase their productivity. It should also minimise Australia's exposure to overseas IP and provide Australian businesses with commercial leverage.[101]

6.83 The committee is aware that one of the issues to be addressed by the National Biotechnology Strategy is the management of IP in Australia. The committee supports this initiative, and understands that the strategy will be announced shortly.

101 National Farmers' Federation, Submission no. 36, p. 13; Western Australian government, Submission no. 48, p. 2.