

## Overcoming impediments in establishing Australian bioindustries

### Introduction

- 3.1** The reader is referred to Figure 1.1 which shows the stages that lead to the establishment of bioindustries from bioprospecting. The committee has used this framework to guide the organisation of this chapter. In this chapter, the committee discusses the impediments that stand in the way of Australia capitalising on its biological potential, and how these impediments might be overcome.
- 3.2** The committee noted at the outset of the inquiry that some of the impediments to establishing bioindustries in Australia, were similar to those it had identified in two of its previous inquiries:
- the inquiry into infrastructure and the development of Australia's regional areas;<sup>1</sup> and
  - the inquiry into primary producer access to gene technology.<sup>2</sup>

Between them, these two reports covered such issues as telecommunications infrastructure, the protection of IP, government support for R&D and its commercialisation, and public awareness of the issues raised by the use of biotechnology. These matters were discussed in

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1 House of Representatives Standing Committee on Primary Industries and Regional Services, *Time Running Out: Shaping Regional Australia's Future*, February 2000.

2 House of Representatives Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with Caution: Primary Producer Access to Gene Technology*, June 2000.

detail and recommendations directed to the government about how they might be better addressed.

**3.3** The committee does not propose to consider these topics again in detail. This does not reflect any judgement by the committee that these topics are unimportant. It is an acknowledgment of the fact that more will be gained for industries based on bioprospecting by concentrating in this report on new issues that have been raised with the committee for the first time.

**3.4** The committee has identified the following as issues that deserve special attention:

- the information available about Australia's biological resources;
- getting access to these resources and sharing the benefits from the discoveries derived from bioprospecting; and
- biodiscovery, bioprocessing and bioindustries.

A significant part of this chapter is taken up by access and benefit sharing issues, including uncertainties about the ownership of resources, establishing a nationally consistent regime, exclusive contracts to use resources, indigenous rights, and the export of Australian biota.

## **The knowledge base**

**3.5** Anyone wanting to undertake bioprospecting starts by reviewing what is known about the biota. This is possible only if the information has been collected, and is accessible.

**3.6** There are many ecosystems in Australia that are not well known, and will not be until detailed surveys have been carried out.<sup>3</sup> This is particularly true of Australia's vast marine areas. Accumulating knowledge about Australia's biological resources is fundamental to Australia's capacity to build industries based on our native biota. It requires investment at early stages of bioprospecting.<sup>4</sup>

**3.7** Information about Australia's biological resources is held in collections in herbaria, museums, public research institutions and businesses such as BioProspect and Cerylid Biosciences. The collections include DNA, plants, seeds, microorganisms, and marine animals, among others, as well as extracts from these organisms. In addition to the physical samples held in

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3 Royal Society of Western Australia Inc., Submission no. 8, p. 1.

4 Australian Institute of Marine Science, Exhibit no. 2.

these collections is information about where and when they were collected and their identity, if known. Further information, such as their ecology and chemistry, may also be available.

- 3.8** Several deficiencies in Australia's information base were brought to the committee's attention. The information base is not comprehensive,<sup>5</sup> and much of the Australian biota is poorly known. Tens of thousands of species have still to be described, particularly among the microorganisms.<sup>6</sup> Yet relatively little taxonomic work is being carried out and there is a shortage of taxonomists in the country.<sup>7</sup>
- 3.9** Australia's collections need to be more adequately funded if they are to be better sources of information for bioprospectors,<sup>8</sup> as well for the managers who are charged with the conservation of biological resources. With more information available, there are greater prospects of success in identifying useful leads and conserving the ecosystems from which they come.<sup>9</sup> The information is also needed to enable further collection of the same source material, and to confirm the origin and ownership of any IP developed from the lead. Some of these points are illustrated in Box 3.1.
- 3.10** Scientists are using ecology driven bioprospecting based on two closely related ideas from evolutionary biology and ecology.

The first is that specific molecules such as antimicrobials have evolved repeatedly and are deployed in a wide variety of ecological situations. ... Second, although we are in the era of combinatorial chemistry, it is reasonable to suggest that evolution by natural selection is a natural analogue of this process that has been operating for hundreds of millions of years. ... this suggests that the first phase of discovery is likely to be enhanced by the use of evolutionary and ecological modes of thought, employing the vast databases of natural history.<sup>10</sup>

Knowing what is in those 'vast databases of natural history' is obviously critical to success in bioprospecting.

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5 For example, Environment Australia, Submission no. 29, p. 48.

6 ExGenix Operations Pty Ltd (Cerylid Biosciences Ltd), Submission no. 13, p. 1; The Australian Society for Microbiology, Transcript of evidence, 25 June 2001, p. 88.

7 Northern Territory government, Submission no. 4, p. 6; Australian Academy of Science, Submission no. 19, p. 2; Royal Society of Western Australia Inc., Submission no. 8, p. 1.

8 Australian Academy of Science, Submission no. 19, p. 5.

9 Australian Institute of Marine Science, Submission no. 27, pp. 7, 17.

10 Professor A J Beattie, Submission no. 5, p. 1.

**Box 3.1 Better information produces greater bioprospecting success**

AIMS scientists told the committee that understanding marine chemical ecology and taxonomy can improve the odds of obtaining positive leads by 50-60 per cent. A similar situation exists with the clever use of knowledge about the ecology of tropical forests. Relying on this knowledge has given Ecobiotics a bioactivity hit rate in more than 67 per cent of samples, compared with less than eight per cent from 'traditional', non targeted bioprospecting.

By contrast, insufficient knowledge can hamper bioprospecting and biodiscovery. The committee was told of a 10 year delay in the development of the anti tumour drug, Bryostatin I, because of poor initial studies of the bryozoan from which it was sourced. Researchers failed to distinguish between different subspecies of bryozoan when the original collection was made, and they subsequently recollected and attempted further work on the wrong one.

Sources: Australian Institute of Marine Science, Committee briefing, 3 May 2001; Submission no. 27, pp. 13-14; EcoBiotics, Submission no. 18, p. 5.

- 3.11** Funding for making and maintaining collections has traditionally come from government. However, agreements are now being struck between public agencies and businesses involved in bioprospecting and biodiscovery, in which the businesses contribute to the work of the collecting institutions, or maintain their own collections. For example, specimens may be maintained in local herbaria which will allow the identity of new material to be verified.<sup>11</sup> Alternatively (or in addition), payments of the kind described in Chapter 2 may be made.
- 3.12** While payments for samples can contribute to the effort of public collecting institutions, the payments are often inadequate to build good collections.<sup>12</sup> Public funding is essential. Yet the committee received evidence of declining government support for bioprospecting and biodiscovery in Commonwealth institutions. For example, since the imposition of the efficiency dividend, AIMS has lost \$1-1.5 million from its budget, and has been unable to hire new staff for at least five years. The committee also heard about the urgent need for additional funding for a national collection of microorganisms (Box 3.2).

11 Environment Australia, Submission no. 29, p. 25.

12 Australian Institute of Marine Science, Submission no. 27, pp. 3, 13.

**Box 3.2 Collections of microorganisms**

Microorganisms are the major source of antimicrobial agents, as well as producing other important pharmaceutical and therapeutic compounds. Products derived from microorganisms net US\$35-50 billion annually in sales. Attention has turned in recent years to extremophiles (microorganisms from very hot, cold, acid, alkaline, salty or arid environments) as sources of novel substances and processes. Microbial collections are therefore a 'real biotechnological resource'.

An example of such a collection is the Australian Collection of Antarctic Microorganisms, which is dedicated to strains isolated from the Antarctic continent, subantarctic islands and the Southern Ocean. It currently holds about 5,000 Antarctic microorganisms, which exhibit a high degree of endemism and represent adaptations to extreme environments. They have already yielded leads to pharmaceuticals and polyunsaturated fatty acid production.

Another valuable culture collection is held by the Dairy Research and Development Corporation's Australian Starter Culture Research Centre, which very cost effectively supplies most of the Australian dairy industry's needs for cheese and yoghurt. Other special purpose collections are also maintained in other industries, and by state and territory governments for agricultural, medical and veterinary purposes.

In total, Australia has about 50 collections, which in 1998 maintained 65,000 cultures. It does not, however, have a national collection of microorganisms, nor adequate, accessible databases of information about the contents of the existing collections. In this, Australia differs from most developed and a few developing countries.

Australia's largest collection is at UQ, although, according to the Australian Society for Microbiology (ASM), 'that collection is now just about moribund'. As public funds have been withdrawn, its staffing has fallen from two to 0.5 and it now operates on the basis of full cost recovery. Overseas collections are substantially better staffed and 'recover around 25 per cent of their operational costs from sales and the balance is provided by government as an essential infrastructure requirement of science and industry'.

The curator of the UQ collection suggested that Australia needed 'a properly funded national collection to coordinate culture needs for science and industry in Australia and provide [a] range of services ... underpinned by a network of specialists research collections'. ASM also recommended the creation of 'a national repository of organisms for biotechnological opportunities that allows us to protect the investment that has been made in collecting and preserving those organisms and to maintain their potential'. ASM estimated that the collection would require annual funding of one million dollars from public and private sources. An alternative model would involve a central coordinating centre for several physically distinct collections.

Source: Australian Society for Microbiology, Submission no. 10, pp. 2-4; Transcript of evidence, 25 June 2001, pp. 94-6; L I Sly, 'Australian microbial resources', *Microbiology Australia*, vol. 19(1), 27-35, 1998; Submission no. 37, p. 1.

**3.13** Moves are under way to link scattered collections around the country. A virtual herbarium is being established by the state, territory and Commonwealth herbaria,<sup>13</sup> and links between other databases are mooted. For example, the committee was told of a proposal to set up a novel type of centre to serve biodiscovery and biodiversity conservation based on links between collections and databases. The proposed Australian Biodiversity and Biodiscovery Resource Centre (ABBRC) is described in Box 3.3. It was recently unsuccessful in a bid for funding from the Commonwealth government's Major National Research Facilities (MNRF) Program.

**Box 3.3 A proposed Australian Biodiversity and Biodiscovery Resource Centre**

The proposed ABBRC would comprise a complete library of research material from Australia's terrestrial and marine flora. It would act as a one stop shop for bioinformation, DNA and extract materials for commercial and non commercial research. As such, it would contribute to the conservation of the native flora, and drive the identification and development of the flora's commercial potential. ABBRC's establishment would also help to eliminate duplication of resources.

ABBRC would be based at Cellulose Valley, adjacent to SCU, which has centres for phytochemistry and plant genetic conservation. These centres are establishing plant DNA and plant extract banks. ABBRC would link SCU with:

- the Queensland Herbarium;
- JCU, which has expertise with biological databases;
- AIMS, which has the largest collection of marine extracts in the southern hemisphere, curated specifically for bioprospecting;
- the companies, BioProspect and its subsidiary, Australian Phytochemicals Ltd, which collect flora and supply extracts under agreements with state and territory governments; and
- other parties in the future, such as other Australian herbaria.

It is anticipated that ABBRC would require public funding for the first five years, but would then be self funded from access fees and royalties. It would be expanded in the future to cover the Australasian fauna as well as significant agricultural and horticultural species.

Source: Southern Cross University and Bioprospect Pty Ltd, Committee briefing, 6 July 2001.

**3.14** CSIRO also stressed the importance of building linkages between databases. It referred to the Global Biodiversity Information Facility (GBIF), which will provide electronic access to information held in separate collections, and pointed out:

The ability to datamine biodiversity information across separate databases through GBIF for the first time will be a very powerful tool to source new information about where valuable traits can be found.<sup>14</sup>

Progress in biodiversity informatics will enhance its predictive power and value of biodiversity knowledge to bioindustries.<sup>15</sup>

Others also made this point to the committee.<sup>16</sup>

**3.15** The committee believes that it is important for Australia to have a well resourced, well coordinated system in place for **building its national collections and associated databases, with support from sufficient skilled personnel and appropriate infrastructure**. Ensuring that funding for such a system is available is the responsibility of government. Better government funding, with coinvestment by the private sector, is needed to give the basic support for bioprospecting that good information provides.<sup>17</sup> Government funds should be supplemented by the private sector as part of any permit issued for access to resources.

## Recommendation 1

**3.16** The committee recommends that the Commonwealth government:

- **increase funding for baseline studies of the Australian biota;**
- **target additional funds for collecting activities in bioactive hot spots;**
- **fund a larger volume of taxonomic work than at present and ensure sufficient young taxonomists are being trained to undertake this work;**

14 CSIRO, Submission no. 14, p. 12.

15 CSIRO, Submission no. 14, p. 20.

16 Australian Institute of Marine Science, Exhibit no. 2; Southern Cross University and BioProspect Pty Ltd, Committee briefing, 6 July 2001.

17 AstraZeneca R&D Griffith University, Submission no. 33, p. 2.

- **provide more funding to maintain and expand existing collections so that they provide a comprehensive coverage of Australia's biota, including microorganisms; and**
- **ensure that commercial users contribute in kind or financially, through benefit sharing arrangements, to growing and maintaining collections and databases.**

**3.17** The committee is also concerned that the information available about Australia's biological resources be as accessible as possible. It recognises the efforts that are being made to coordinate and network national databases, but notes CSIRO's comment that 'the capacity to digitise and verify the information currently held in paper records' is a limiting factor.<sup>18</sup>

## **Recommendation 2**

**3.18** **The committee recommends that the Commonwealth government provide additional funding for digitising and networking information about all of Australia's biological resources.**

**3.19** CSIRO reported to the committee that 'in the area of *biodiversity informatics*, Australian science is at the forefront' and 'technologically ... in a good position to keep up with advances in this area'. For example, Australia is chairing the group that is establishing GBIF in Denmark.<sup>19</sup>

**3.20** However, CSIRO also sounded some notes of caution in relation to Australia's capacity to undertake bioinformatics. (Bioinformatics involves the use of powerful computational and statistical techniques to process a wealth of biological information for particular research purposes. For a fuller definition see the glossary.) This is a serious issue affecting the national capacity to provide platform technologies for biotechnology.

- There is a 'critical shortage of people with the prerequisite skills and capabilities' in bioinformatics. Although steps are being taken to address the shortage of skilled people, CSIRO suggested that more needed to be done.

<sup>18</sup> CSIRO, Submission no. 14, p. 20.

<sup>19</sup> CSIRO, Submission no. 14, pp. 12, 20, 29.

- Attempts to bring together all those with an interest in bioinformatics have failed so far. CSIRO described how each of the states is independently developing a capacity in biotechnology when sharing core capacities would be more effective. Such sharing could be achieved with funding from the Commonwealth government. In such a situation, competitive funding models may not be the most effective way of providing national capabilities.<sup>20</sup>

CSIRO recommended 'the development of a national strategy for bioinformatics to deliver core skills and data access to Australian R&D organisations'.<sup>21</sup>

### Recommendation 3

**3.21 The committee recommends that the Commonwealth government, in consultation with state and territory governments, industry and the research community:**

- **develop a national strategy for bioinformatics; and**
- **assist in funding its implementation so that the necessary infrastructure and skills are available to provide efficient access to information about Australia's biota.**

**3.22** While Australia is relatively well placed in relation to biodiversity informatics, the same is not true of molecular informatics. (Molecular informatics is a branch of bioinformatics that deals with complex datasets in molecular biology and genetics to discover how specific genes express desired traits.) CSIRO drew attention to the fact that molecular bioinformatics are largely in private hands overseas. Australians need to be able to gain access to these data on favourable terms, and 'the bargaining chip that would be most effective would be collaborative arrangements in which we contribute to these databases with annotations relevant to our own biodiversity' from our own databases.<sup>22</sup>

20 CSIRO, Submission no. 14, pp. 12, 20; Transcript of evidence, 4 April 2001, pp. 40-41, 45.

21 CSIRO, Submission no. 14, p. 29.

22 CSIRO, Submission no. 14, pp. 4, 12, 20.

## Getting access to biological resources

- 3.23** It is critical that all involved in the bioproduct development chain have confidence that access to biological resources can be gained swiftly, in such a way that the resources are used sustainably and the right to use them is absolutely secure. This is not currently the case in Australia, but needs to be.
- 3.24** The committee notes that large businesses, such as pharmaceutical companies, are increasingly requiring evidence of legality and certainty of title before investing large sums in developing products.<sup>23</sup> If this evidence is not available, or accessing resources is very time consuming and complex, overseas companies will go elsewhere and Australian companies, especially small ones, will be deterred.<sup>24</sup>
- 3.25** Difficulties in getting access to biological resources are a critical issue, and one of the most obvious and immediate impediments to bioprospecting in Australia.<sup>25</sup> The difficulties arise for a number of reasons.
- The ownership of the resources is complex and unclear.
  - Different jurisdictions have different rules.
  - The legislation governing access has often been developed for purposes other than bioprospecting; as a result, it does not immediately address bioprospectors' needs.<sup>26</sup> In addition, responsibilities for issuing the permits required by bioprospectors are often split between several agencies.<sup>27</sup>
- 3.26** As a result of the factors listed above, obtaining a permit to access resources may mean making many applications in different jurisdictions or to several agencies within one jurisdiction. Very long delays in granting permits have also been encountered, for example, two years to collect Antarctic microorganisms.<sup>28</sup> EA commented that:

Obtaining permits is time consuming and complicated by the number of separate jurisdictions that control access. The different

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23 J Voumard, *Access to Biological Resources in Commonwealth Areas*, Commonwealth of Australia, July 2000, p. 134.

24 Original Oceanz, Smart Ventures Industry Group, Committee briefing by 4 May 2001; Environment Australia, Transcript of evidence, 4 June 2001, p. 60.

25 Australian Institute of Marine Science, Submission no. 27, p. 13.

26 Environment Australia, Transcript of evidence, 4 June 2001, pp. 59-60.

27 Australian Institute of Marine Science, Committee briefing, 3 May 2001.

28 The Australian Society for Microbiology, Submission no. 10, p. 5.

conditions that each jurisdiction and their agencies apply to permits further complicate the administration of what may be done with material after it has been collected. There is also a lack of uniformity of terms and conditions of permits (and material transfer agreements) across state and territory boundaries.<sup>29</sup>

**3.27** These features of the access regimes currently in place were generally seen as a deterrent to businesses, particularly to smaller companies. In addition, the lack of uniformity between jurisdictions does not serve the national interest in that it may encourage bioprospectors to shop around for the best deal.

**3.28** The cumbersome nature of current access regimes also fails to promote the conservation of resources as EA pointed out:

The current system encourages fraudulent practices and collection without a permit, especially within national parks, and unless a particular taxon is endemic to one of these administrative units, enforcement is impossible.<sup>30</sup>

**3.29** In light of the consensus in the evidence received by the committee, it was surprising to find AFFA contesting the view that access regimes can significantly affect the ease with which bioprospecting can be undertaken.

Claims are made that access to the natural environment to search for and collect suitable material to assay is problematic, and that lack of clear title to the natural resources involved contributes to uncertainty and is a disincentive to undertaking bioprospecting activities. However, their potential impact is largely untested in the overall understanding of the broad range of factors affecting bioprospecting in Australia.<sup>31</sup>

**3.30** The committee acknowledges the point made by the Great Barrier Reef Marine Park Authority that part of the delay in its issuing of access permits (two months to several years) is the time it takes to undertake a rigorous assessment. (Statutory waiting periods as specified in native title legislation also contribute to delays.) A rigorous environmental assessment is obviously important.<sup>32</sup>

**3.31** The committee also noted that the two year delay referred to above in relation to Antarctic resources was due to the application for access being the first of its kind.

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29 Environment Australia, Submission no. 29, p. 50.

30 Environment Australia, Submission no. 29, p. 51.

31 Department of Agriculture, Fisheries and Forestry - Australia, Submission no. 24, p. 2.

32 Great Barrier Reef Marine Park Authority, Committee briefing, 4 May 2001.

As a result of Australia's international commitments, it took about two years to arrive at a decision which would allow us to collect the samples and for those samples to be passed on to [a commercial organisation]. The major difficulty was the notion of exclusivity and the fact that Antarctica, under the Madrid protocol, is a world resource and no-one is supposed to have exclusivity of the resources from Antarctica.

ASM told the committee that eventual advice from the Department of Foreign Affairs and Trade and the Attorney-General's Department was that:

... the actual soil or water samples that we took from Antarctica could not be given exclusively to a commercial organisation. But if we used our skills, our expertise, to isolate micro-organisms from those samples, then that was not infringing the Madrid protocol and those micro-organisms that we isolated from the samples could in fact be given to a commercial organisation.<sup>33</sup>

## Ownership

**3.32** Several submissions to the inquiry claimed that the ownership of biological resources is unclear, and urged that it be resolved.<sup>34</sup> Others commented on its complexity.<sup>35</sup> The ownership of microorganisms and marine and Antarctic resources were mentioned as presenting particular challenges, as was the question of indigenous rights.<sup>36</sup>

**3.33** Similar observations were made to the Voumard inquiry into access to biological resources in Commonwealth areas, which reported in July 2000.<sup>37</sup> The report commented on 'a lack of understanding about who owns the resources'. It provided advice on 'the legal status of the elements of the terrestrial and marine biota affected by differing forms [of] land tenures and sovereignty in Commonwealth areas'.

The effect of the advice is that in all Commonwealth areas, it is possible to determine either a legal owner of biological resources

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33 The Australian Society for Microbiology, Transcript of evidence, 25 June 2001, p. 91.

34 EcoBiotics Pty Ltd, Submission no. 18, p. 1; ExGenix Operations Pty Ltd (Cerylid Biosciences Ltd), Submission no. 13, p. 2.

35 Australian Institute of Marine Science, Committee briefing, 4 May 2001.

36 Northern Territory government, Submission no. 4, p. 4; The Australian Society for Microbiology, Submission no. 10, p. 5.

37 In 1999 Senator Hill, Minister for the Environment asked John Voumard to carry out an inquiry into access to biological resources in Commonwealth areas which reported the following year (see footnote 23, this chapter).

or a holder of the sovereign authority to control access and derive benefits from the biological resources.<sup>38</sup>

- 3.34** The committee believes that the advice provided in the Voumard report should be widely available. It is important that the perception of uncertainty and complexity is dispelled as far as possible as both are deterrents to making agreements about bioprospecting, and investing in it and the industries derived from it.
- 3.35** The Voumard report dealt only with areas under Commonwealth control. However, the lack of clarity about ownership applies to areas under state and territory jurisdiction as well. In addition, the legislative details vary from state to state. The committee notes that BA, as the manager of the NBS, has as one of its goals, resolving the legal issues surrounding the ownership of Australian biological resources.<sup>39</sup> The committee believes that BA should work with the Attorney-General's Department to ensure that information about ownership of biological resources in both public and private possession throughout Australia is compiled. This information should be available from a single, easily accessible source.

#### **Recommendation 4**

- 3.36** **The committee recommends that Biotechnology Australia and the Attorney-General's Department, in conjunction with the state and territory governments, ensure that information about the ownership of biological resources is compiled, and made publicly available as a single, easily accessible source.**
- 3.37** The Australian Property Institute (API) pointed out that ill defined rights in biota already reside with private landowners. It suggested that these should be recognised as 'property rights ... constructed in such a way that they have features common to other more traditional property'. The API preferred the creation of privately held biota property rights to the option of government ownership of flora and fauna and licensing their use.<sup>40</sup> A South Australian government discussion paper on access to biological resources considered vesting the state's indigenous flora and fauna in the

38 J Voumard, p. 41.

39 Biotechnology Australia, Submission no. 25, p. 21.

40 Australian Property Institute, Submission no. 20, p. 8.

Crown, using mining legislation as a template.<sup>41</sup> The paper rejected this option.

- 3.38** The committee is not in a position on the basis of input to the inquiry to come to any conclusions about the need for changes to property right regimes in relation to bioprospecting. The committee is aware that economic growth can be facilitated by well defined property rights and the creation of new ones, particularly if they are nationally consistent. Changes to the existing regime of property rights might very effectively encourage the development of biobased industries in Australia, and position the country well in a bioindustrially dominated future.
- 3.39** The committee recognises, however, that any change to property rights is a complex matter and needs full and careful consideration. It believes that this matter should be researched and a report prepared by the Australian Law Reform Commission. This report could serve as the basis for discussion between the Commonwealth, state and territory governments and public consultation.

## **Recommendation 5**

- 3.40** **The committee recommends that the Attorney-General ask the Australian Law Reform Commission:**
- **to inquire into the impact on the use of native biota of the different property rights regimes across Australia; and**
  - **to recommend on a nationally consistent regime that would facilitate this use, with due consideration of the wider ramifications of any changes.**

## **A nationally consistent access regime**

- 3.41** The committee was told repeatedly of the need to establish a nationally consistent access regime for Australia's biological resources.<sup>42</sup> EA, for example, claimed that:

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41 *Access to Biological Resources in South Australia: A Discussion Paper for Public Comment*, Department for Environment and Heritage, Government of South Australia, 2000, p. iii.

42 For example, CSIRO, Submission no. 14, pp. 13-14; ExGenix Operations Pty Ltd (Cerylid Biosciences Ltd), Submission no. 13, p. 2.

... if bioprospecting is to be facilitated in Australia, with the aim of developing high technology knowledge industries based on it, there is an urgent need for a nationally consistent approach to access and benefit sharing at the Commonwealth, State and Territory levels. The need for clear rules regarding access to Australia's biological resources is widely recognised.<sup>43</sup>

**3.42** CSIRO commented that:

... national consistency in the various State and Commonwealth permit schemes regulating access to biological resources must be achieved as a matter of urgency. This is particularly relevant to bioprospecting, as there are at present significant variations in both policy objectives and administrative systems between all jurisdictions. As a result, there is a real risk of international bioprospectors "shopping" between the various jurisdictions to suit their own needs.<sup>44</sup>

**3.43** The need for a nationally consistent approach was recognised more than five years ago but progress in establishing it has been slow.<sup>45</sup> The South Australian government refers to the frustratingly long time taken to establish policy and the jurisdictional and legislative framework. Incidents of biopiracy demonstrate 'the need for an internationally/universal and national legislative and operating framework'.<sup>46</sup>

**3.44** The committee notes that, under the NBS, renewed moves are under way to harmonise state, territory and Commonwealth arrangements. One element of these moves is the development of an access regime for Commonwealth areas which will be 'broadly compatible with existing and possible future State and Territory regimes'.<sup>47</sup>

**3.45** The Voumard inquiry made recommendations about the nature of the regulations to be made under the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act) for access to Commonwealth biological resources. The inquiry consulted widely, including with state and territory governments, before developing its recommendations for the access

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43 Environment Australia, Submission no. 29, p. 5.

44 CSIRO, Submission no. 14, p. 21.

45 J Voumard, pp. 27-31. Following Australia's signature of the CBD, papers on access to biological resources were prepared by the Australian and New Zealand Environment and Conservation Council and the Chief Scientist. They were followed in 1994 by the setting up of a Commonwealth-state working group to consider the matter further. This group reported in 1996, its report was released in 1998, and submissions called for, but little further action had been taken by the time the Voumard inquiry was set up in December 1999.

46 South Australian government, Submission no. 28, p. 5.

47 J Voumard, p. 3.

framework. A wide ranging consultative process is also planned for the draft Commonwealth regulations once they are released. The committee believes that this is a useful approach to facilitating the development of nationally consistent arrangements.

- 3.46** As part of the harmonisation of arrangements, the committee believes that it is important to have a single point of information about the arrangements for applying for access permits anywhere in Australia. As Cerylid Biosciences commented, 'what would be helpful would be to make it easier to know who are the bodies that you need to talk to'.<sup>48</sup> It is also important that the permit system be streamlined, for example, with a single permit application acceptable to all jurisdictions and agencies.<sup>49</sup>

## Recommendation 6

- 3.47** The committee recommends that Environment Australia, in consultation with state and territory agencies:
- **develop an electronic gateway to information about access arrangements in all jurisdictions; and**
  - **take a lead in coordinating the development of a simplified, streamlined system of applying for permits.**

## Benefit sharing

- 3.48** One of the factors that has complicated and slowed the granting of access to biological resources has been uncertainty on the part of those granting access permits about the benefits that should be required from bioprospectors, should commercialisable discoveries result. The emphasis on benefit sharing is relatively new and flows from the Convention on Biological Diversity (CBD).
- 3.49** The CBD, to which Australia is a signatory, came into force in 1993. With its introduction, the view that the world's genetic resources are the common heritage of mankind changed. Now, 'the conservation of biological diversity is a common concern of mankind'. This conceptual

48 Cerylid Biosciences, Transcript of evidence, 25 June 2001, p. 83.

49 Australian Institute of Marine Science, Committee briefing, 3 May 2001; Australian Academy of Science, Submission no. 19, p. 2.

shift led to the need to affirm national sovereignty over genetic resources, and the Convention provides the framework in international law under which national policies and legislation on access and benefit sharing are developed.<sup>50</sup>

- 3.50** EA pointed out that, while legislation exists in Commonwealth areas to control access to resources, 'there is generally less or no provision for benefit sharing arising from the use of these resources'.<sup>51</sup> A similar situation exists in South Australia.<sup>52</sup>
- 3.51** Uncertainty about, or overblown expectations of, the benefits that might be expected from the resources under their control has led some agencies in the past to delay the issue of access permits.<sup>53</sup> In some cases reported to the committee, the delays caused have amounted to many years.<sup>54</sup> In other cases, they have led prospective bioprospectors to work on material sourced from other countries. In both situations, Australia has failed to benefit from potential leads, and both in Australia and overseas, a perception has formed that Australia is a difficult place to bioprospect.<sup>55</sup>
- 3.52** Experience is now being gained in the development of benefit sharing arrangements. A number of them are listed in several submissions to the inquiry.<sup>56</sup> Notable among the agreements that have been concluded is that between AIMS and the Queensland government, which has been taken as a model for use internationally. The key element, from AIMS' point of view, was the separation of granting permits (on the basis of environmental considerations) from negotiating the benefit sharing arrangements with the owner (the Queensland government).<sup>57</sup>
- 3.53** The Voumard report made recommendations about an access and benefit sharing scheme for use in Commonwealth areas and as a possible model for other jurisdictions, where needed. The scheme provides that a person seeking access to Commonwealth areas would apply to EA for a permit.

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50 Environment Australia, Submission no. 29, p. 8.

51 Environment Australia, Submission no. 29, p. 19.

52 *Access to Biological Resources in South Australia A Discussion Paper for Public Comment*, Department for Environment and Heritage, Government of South Australia, 2000, p. 7.

53 Committee briefing by Original Oceanz, Smart Ventures Industry Group, 4 May 2001.

54 Australian Institute of Marine Science, Submission no. 27, p. 7.

55 Australian Institute of Marine Science, Committee briefing, 3 May 2001; Original Oceanz, Smart Ventures Industry Group, Committee briefing, 4 May 2001.

56 Northern Territory government, Submission no. 4, p. 4; Environment Australia, Submission no. 29, pp. 20-6; AstraZeneca R&D Griffith University, Submission no. 33, p. 2; BioProspect Limited, Submission no. 12, pp. 1-2.

57 Australian Institute of Marine Science, Committee briefing, 3 May 2001; Submission no. 27, p. 1.

He/she would negotiate a benefit sharing arrangement with the resource owner while waiting for the access permit to be issued. Before issuing the permit, the Minister must be satisfied, among other things, that there is a benefit sharing contract.<sup>58</sup>

**3.54** A model benefit sharing contract is being developed by EA:

- to promote parties' understanding of the issues;
- to facilitate negotiations and agreement between them; and
- to promote certainty for industry by ensuring that agreements are based on prior informed consent, mutually agreed terms and adequate benefit-sharing arrangements, which will in turn provide an agreed set of standards against which industry's performance can be judged.<sup>59</sup>

The model contract will also help to reduce transaction costs and times.<sup>60</sup> EA saw such contracts as being of particular use to smaller companies that may not have many resources to devote to contract negotiations.

**3.55** The benefits flowing from benefit sharing agreements may be monetary or non monetary. Some of the benefits most frequently demanded in evidence to the committee were the lodging and maintenance of specimens of bioprospected material in state institutions.<sup>61</sup> AZGU suggested that collecting should be restricted to professional agencies that can house specimens and undertake taxonomic work. Such an arrangement is used by several companies, including AZGU.<sup>62</sup> Additional information, derived as a result of bioprospecting, should also be made publicly available, subject to it not being commercial in confidence.<sup>63</sup>

**3.56** Another demand was for royalties or up front payments by bioprospectors to be dedicated to conservation and research activities, or returned to the region of origin of the material. Agreements may also specify that downstream development from bioprospecting be carried out locally.<sup>64</sup>

**3.57** The committee understands that the model benefit sharing contract will allow for flexibility in negotiations between resource owner and bioprospector. A menu of possible matters to consider for inclusion might

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58 Environment Australia, Submission no. 29, pp. 39-40.

59 J Voumard, p. 103. More detailed information about the scheme is available in Appendix E.

60 Environment Australia, Transcript of evidence, 4 June 2001, pp. 60, 63.

61 For example, Royal Society of Western Australia Inc., Submission no. 8, p. 1; Royal Botanic Gardens Sydney, no. 1, p. 1.

62 AstraZeneca R&D Griffith University, Submission no. 33, p. 2.

63 Victorian government, Submission no. 34, p. 2.

64 BioProspect Limited, Submission no. 12, p. 3.

be made available for guidance.<sup>65</sup> The nature of a company's obligations under a contract will be influenced by the resource owners' IP and other contributions to discovery, as well as the owners' particular interests in each case. Different conditions will be imposed depending on whether the highest priority is, for example, conservation, regional development, or monetary returns.<sup>66</sup>

**3.58** The committee noted that BioProspect has finalised access and benefit sharing contracts with the Western Australia and Queensland governments and is negotiating similar ones with the governments of the other states and the Northern Territory. Among the benefits that flow to the states under the agreements with BioProspect are:

- the collection of samples under strict protocols and state control which ensure the conditions of the CBD are met;
- payment to the states of 10 per cent of BioProspect's gross receipts from royalty and milestone payments made by the businesses to which BioProspect licenses extracts;
- the vesting of any IP patented in the name of the state of origin of the material, while giving BioProspect and its licensees exclusive rights to develop patents;
- undertaking as much further development of any biodiscoveries in the state of origin; and
- meeting performance criteria for screening and commercialisation activity.<sup>67</sup>

### **Criticism of the proposed access and benefit sharing scheme**

**3.59** The committee is aware that industry and some in the research community would not normally enter into serious benefit sharing negotiations until a biologically active molecule is found. For these organisations, the scheme recommended by Voumard would undoubtedly add to the bureaucratic processes with which they would have to deal. It might also adversely affect the way in which Commonwealth collections or collections sourced from Commonwealth areas are managed and any research activities using these collections, including plant breeding.

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65 Environment Australia, Transcript of evidence, 4 June 2001, pp. 66-9, 74.

66 Australian Institute of Marine Science, Submission to the Voumard inquiry, p. 7; Committee briefing, 3 May 2001.

67 BioProspect Ltd, Submission no. 17, p. 1-3; Committee briefing, 6 July 2001.

**3.60** AFFA raised with the committee some concerns about the access and benefit sharing regime recommended by the Voumard report. AFFA was concerned that the proposed regime:

- might alter existing property rights and interfere with IP rights (or least give that appearance);
- might jeopardise Australia's ability to access genetic material from overseas for crop improvement; and
- was too onerous.<sup>68</sup>

**3.61** At present, the FAO International Understanding on Plant Genetic Resources (IUPGR) is a non binding agreement that provides for unrestricted access to plant genetic resources. It is in the final stages of being revised to bring it into line with the CBD.

The draft revised Undertaking attempts to maintain relatively unrestricted access to biological material under the control of governments in the public domain while securing reasonable benefits, particularly for developing countries which provide significant sources of agricultural biological material for development and research in developed countries.

If adopted, the Undertaking would be a binding agreement that would stipulate the payment of benefits into an international account by recipients who commercialise research based on material covered by the Undertaking. Material in public *ex situ* collections is expected to be free of charge.<sup>69</sup>

**3.62** AFFA claimed that:

... while such international developments do not preclude the application of an access and benefit sharing system in Australia, the need to reconcile any domestic system with such international developments is highly important to avoid having two systems of access and benefit sharing operating in Australia.<sup>70</sup>

**3.63** Furthermore, Australia is 'a significant net beneficiary' from the current and likely future multilateral system for the exchange of plant genetic

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68 Department of Agriculture, Fisheries and Forestry – Australia, Supplementary submission, no. 36, pp. 11, 12.

69 Department of Agriculture, Fisheries and Forestry – Australia, Supplementary submission, no. 36, pp. 6-7.

70 Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 7.

resource.<sup>71</sup> 'If Australia were to charge for access to public biological material we should not be surprised if other countries were to do the same to us.'<sup>72</sup>

**3.64** AFFA listed 'elements of the Voumard recommendations that if adopted could prove onerous and a disincentive to commercial bioprospecting':

- every interested person registered under s266A of the Act must be invited to make written submissions about whether a permit should be issued (on environmental grounds) and that these should be taken into account by the Minister in making his decision;
- the 'precautionary principle' must be applied, 'where appropriate';
- any variations to the model contract must be 'acceptable';
- a maximum of three years would be set for the validity of an access permit; and
- the permit may be transferred only with the approval of the Minister.<sup>73</sup>

**3.65** AFFA suggested that:

... a less onerous system than that proposed in the Voumard recommendations would achieve the benefits of consistency, certainty and a return to the community, while being more conducive to the further development of industries based on bioprospecting.<sup>74</sup>

**3.66** AFFA described the scheme that it would prefer. The key elements of this scheme are:

- a model material transfer agreement (MTA) for access to *in situ* material (and *ex situ* material in some cases) under Commonwealth ownership or control;
- inclusion in the MTA of a flexible benefit sharing agreement contingent on the material being commercialised, for example, a percentage of the gross profits over the first five years of commercialisation;

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71 Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 11.

72 Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 8.

73 Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 11, quoting the Voumard report, pp. 17-18.

74 Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 3.

- exemptions for benefit sharing considered if the recipient company or institution is prepared to make the developed material publicly available for further research;
- access to, and benefit sharing of, biological resources on freehold property subject to private negotiation (although the model MTA for Commonwealth areas may serve as a model for the private sector); and
- encouragement extended to states and territories to adopt the Commonwealth approach as a basis to achieve a nationally consistent framework.

According to AFFA, a flexible approach to benefit sharing is vital so that the individual circumstances of particular projects and applicants are taken into account.<sup>75</sup>

**3.67** AFFA stressed that, whatever approach the Commonwealth government eventually adopts:

... it will be important that a detailed Regulatory Impact Statement examines the practical impact of any regulations on government, business and other users. Such cost benefit analyses would need to give due recognition to differential impacts within agriculture, fisheries and forestry sectors.<sup>76</sup>

**3.68** The committee notes that EA responded to some points raised by AFFA. EA disputed that the scheme proposed by the Voumard report would replace common law with new property rights or interfere with IP protection.<sup>77</sup> EA also stressed that the proposed benefit sharing arrangements would allow for considerable flexibility in what should be included in contracts.<sup>78</sup>

**3.69** With respect to the need to accommodate existing international obligations such as the IUPGR, the Voumard report recommended that material which is the subject of such agreements be excluded from the ambit of the regulations.<sup>79</sup> AFFA, however, took the view that this

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<sup>75</sup> Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, pp. 8-9.

<sup>76</sup> Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 10.

<sup>77</sup> Environment Australia, Transcript of evidence, 4 June 2001, p. 61.

<sup>78</sup> Environment Australia, Transcript of evidence, 4 June 2001, pp. 74-5.

<sup>79</sup> J Voumard, p. 131; Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 11.

approach would introduce complexity because it would establish 'multiple systems covering different biological material'.<sup>80</sup>

### **Additional issues of concern in access and benefit sharing arrangements**

- 3.70** Several submissions to the inquiry listed issues of particular concern in relation to access and benefit sharing arrangements. They included:
- ensuring that arrangements made with commercial operators do not restrict non commercial research activities and do allow reasonable access to other commercial operators;
  - accommodating indigenous rights;
  - finalising benefit sharing arrangements with multiple parties;
  - clarifying the conditions for accessing biological collections;
  - the export of Australian material; and
  - monitoring the performance of permit holders and contracting parties.
- 3.71** These issues are discussed in more detail below.

### **Exclusivity in accessing biological resources**

- 3.72** Access and benefit sharing arrangements contain a degree of exclusivity. This concerned the Royal Botanic Gardens Sydney, which feared that its non commercial research activities might be restricted by contracts between resource owners and commercial operations.<sup>81</sup> This exclusivity also hampers other commercial operators as AIMS pointed out:

A common scenario is for bioprospecting contracts to be arranged on an exclusive basis with a company where sample access by others is severely limited (samples are deemed to be exclusive property of the contracting company). This can prohibit the use of the biodiversity for many different research activities that would maximise the possibility of finding commercially promising chemicals.<sup>82</sup>

- 3.73** EA provided the committee with an example of such a contract: the Victorian government and a bioprospecting business 'signed an exclusive

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80 Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 11.

81 Royal Botanic Gardens Sydney, Submission no. 1, p. 1.

82 Australian Institute of Marine Science, Submission no. 27, p. 3.

contract for access to any plant, any vascular or non-vascular plant on publicly owned land, anywhere in Victoria for the purpose of pharmaceutical screening'. A less exclusive contract would have diminished the level of benefit sharing that the Victorian government could demand.<sup>83</sup>

- 3.74** There was also a perception among some witnesses to the inquiry that the Western Australian government's agreement with BioProspect was tying up biological resources, and making it difficult for others to access them.<sup>84</sup> However, BioProspect's agreements do not prevent others from applying for permits to collect.<sup>85</sup> Similarly, in the case of the Victorian contract described in the last paragraph, bioprospectors would be able to collect from private land.<sup>86</sup>
- 3.75** Exclusivity of access is also reduced if conditions are attached to permits. Access is restricted, for example, if there are limits on how long the permit is current, what organisms or species may be taken, which areas visited, or the type of biodiscovery that may be carried out on the material collected.<sup>87</sup> As the ASM pointed out, it is important not 'to tie up everything in one hit with one company'.<sup>88</sup> AIMS suggested that companies could be required to make samples available to others once they have decided which ones are of no further value to them.

Such a scenario maximises information, opportunity for science/ community benefit (particularly through a knowledge base for better resource management ...) and maximises opportunity for any one sample to be screened many times thereby enhancing the likelihood of a commercial success.<sup>89</sup>

- 3.76** The committee was concerned that the conditions attached to some access permits may also give such wide rights to the accessor, that all other bioprospectors are excluded and further research activity is excluded. The committee believes that care must be taken when setting the permit conditions and making benefit sharing arrangements to ensure that reasonable opportunities are available to all wishing to access a particular

83 Environment Australia, Transcript of evidence, 4 June 2001, p. 67.

84 Cerylid Biosciences, Transcript of evidence, 25 June 2001, pp. 82, 83-4; The Australian Society for Microbiology, Transcript of evidence, 25 June 2001, p. 91.

85 BioProspect, Committee briefing, 6 July 2001; The Hon Cheryl Edwardes, Western Australian Minister for the Environment, Media release, 9 November 1999.

86 Environment Australia, Transcript of evidence, 4 June 2001, p. 74.

87 Environment Australia, Transcript of evidence 4 June 2001, pp. 66, 68, 69.

The Australian Society for Microbiology, Transcript of evidence, 25 June 2001, p. 92;

88 The Australian Society for Microbiology, Transcript of evidence, 25 June 2001, p. 93.

89 Australian Institute of Marine Science, Submission no. 27, p. 3.

area. It is important that the right balance is found, such that access conditions grant sufficient exclusivity to encourage a bioprospector to make full use of resources, but not so exclusive a deal that activity by others is discouraged.

## Indigenous rights

**3.77** There are two elements to indigenous involvement in bioprospecting: one is the result of indigenous ownership of the land and the other comes from knowledge of the uses to which native plants and animals can be put.

**3.78** In some parts of Australia, significant areas are owned by Aboriginal groups. This allows control of access to those lands and heightens the possibilities for controlling the use of traditional knowledge. For example, 42 per cent of Northern Territory land is under Aboriginal ownership and a further 11 per cent is under claim; 27 per cent of South Australia is Aboriginal owned.<sup>90</sup>

**3.79** The EPBC Act does not recognise IP indigenous rights, as the Northern Territory government pointed out.<sup>91</sup> However, the Voumard report recommended that regulations under the act should specify that there must be a contract between the parties. The contract should include prior informed consent, mutually agreed terms, and adequate benefit sharing that protects and values traditional knowledge. The report also recommended that:

- decisions by indigenous communities to deny access to bioprospectors should not be reviewable; and
- advice be provided to indigenous communities on how to get the best deals possible with bioprospectors.<sup>92</sup>

Such an arrangement might help to resolve some of the 'complex matters [that] need to be addressed in respect of ensuring Indigenous interests are not compromised through individual agreements with entrepreneurs'.<sup>93</sup>

**3.80** Traditional knowledge is a source of information that can help focus bioprospecting activities. Such information is available from indigenous Australians and in written records, although some of this knowledge will

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90 Northern Territory government, Submission no. 4, p. 4; South Australian government, Submission no. 28, p. 7.

91 Northern Territory government, Submission no. 4, p. 7.

92 J Voumard, pp. 83, 90-1.

93 South Australian government, Submission no. 28, p. 7.

disappear as older people die and their languages are lost.<sup>94</sup> While several submissions to the inquiry called for rewards to flow to indigenous groups from biodiscoveries that arise from traditional knowledge,<sup>95</sup> others were interested only in collecting species from indigenous land.

- 3.81** A requirement to respect traditional knowledge stems from Commonwealth obligations under international agreements such as the CBD. Article 8(j) of the CBD recognises that indigenous people should be involved in approving the use and application of their traditional knowledge and should share equitably in benefits from its application. The National Strategy for Ecologically Sustainable Development and the National Strategy for the Conservation of Australia's Biological Diversity reflect these requirements.<sup>96</sup>
- 3.82** There has been some criticism and dispute in the past about the unacknowledged use of traditional knowledge in Australia. An example is provided in Box 3.4.
- 3.83** Further criticism of Western Australian practices came from the Royal Society of Western Australia. It related to the contract between the state government and the firm, BioProspect, which the society claimed appears not to allow for the recognition of indigenous knowledge.<sup>97</sup> However, a national trust fund, such as BioProspect has proposed (see later in this chapter), would address this problem. Furthermore, BioProspect does not rely on traditional knowledge to guide its bioprospecting. It prefers to use high throughput screening associated with knowledge about an area's biodiversity; this strategy is more effective in discovering bioactive materials than using traditional knowledge.<sup>98</sup>
- 3.84** The committee gained the impression that most bioprospectors place relatively little, if any, reliance on indigenous knowledge. This appeared to be in part the result of difficulties in benefit sharing and the lack of IP protection for traditional knowledge.

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94 Royal Society of Western Australia Inc., Submission no. 8, p. 2; Australian Institute of Marine Science, Committee briefing, 3 May 2001.

95 Mr Shane Bawden, Submission no. 11, p. 3; South Australian government, Submission no. 28, p. 7.

96 H Fourmile, 'Indigenous interests in biological resources in Commonwealth areas - synthesis of submissions and related information', Appendix 10 to Voumard report, p. 200.

97 Royal Society of Western Australia Inc., Submission no. 8, p. 2.

98 BioProspect, Committee briefing, 6 July 2001.

**Box 3.4 Modern use of a traditional cure: the case of the Western Australian smokebush**

'The Smokebush [*Conospermum*] grows in the coastal areas between Geraldton and Esperance in Western Australia. Indigenous people from this region have traditionally used Smokebush for healing. ... in the 1960s, the Western Australian Government granted the US National Cancer Institute a licence to collect plants for screening purposes. In 1981, specimens of the Smokebush plant were sent to the National Cancer Institute to test for the presence of cancer-fighting properties.

'The specimens were found to be ineffective, but were held in storage until the late 1980s when they were tested again in the quest to find a cure for AIDS. Out of 7,000 plants screened from around the world, the Smokebush was one of only four plants found to contain the active property Conocurovone, which laboratory tests showed could destroy the HIV virus in low concentrations. This 'discovery' was subsequently patented. The US National Cancer Institute has since awarded Amrad, a Victorian pharmaceutical company, an exclusive world wide licence to develop the patent.

'Under amendments to the Conservation and Land Management Act 1984 (WA) in 1985 and the National Parks and Wildlife Act (WA), the Western Australian Minister of the Environment has the power to grant exclusive rights to Western Australian flora and forest species for research purposes. In the early 1990s, the Western Australian Government also awarded Amrad the rights to the Smokebush species, to develop an anti-AIDS drug ... Amrad paid \$1.5 million to the WA government to secure access to Smokebush and related species ... if *Conocurovone* is successfully commercialised, the WA government will recoup royalties of \$100 million per year by 2002.

'Indigenous people are concerned that they have not received any acknowledgment, financial or otherwise, for their role in having first discovered the healing properties of Smokebush.

'The current legislation disregards the potential intellectual property rights that Indigenous peoples in WA have in flora on their lands. Furthermore, multinational drug companies could be sold exclusive rights to entire species of flora, preventing anyone from using these species for any other purpose without the consent of the companies.

'Indigenous peoples in WA face the possibility of being prevented from using any of the flora which is the subject of an exclusive agreement.'

The argument developed above has been rebutted by those that claim that Aboriginal knowledge related only to the general curative properties of smokebush and not to its potential to cure specific diseases like cancer and AIDS.

Source: Quoted from an ATSIC commissioned report, *Our Culture, Our Future: Report on Australian Indigenous Cultural and Intellectual Property Rights*, 1998, pp. 24-5.

- 3.85** Australia's IP regime does not currently protect traditional knowledge. Nor do the IP regimes of foreign countries. They fail to recognise collective rights and provide protection for only limited periods of time. Furthermore, traditional knowledge would not generally be regarded as patentable because it lacks the requisite newness.<sup>99</sup>
- 3.86** What may therefore be needed is a new category of rights that protects traditional knowledge from unauthorised use, recognises its origin, and provides just compensation. *Sui generis* methods of IP protection, such as those used for plant varieties, have been recommended in this context, for example, in an ATSIC commissioned report on indigenous cultural and IP.<sup>100</sup>
- 3.87** The committee noted that a recent report by the House of Representatives Standing Committee on Legal and Constitutional Affairs recommended that it be given a reference to inquire into mechanisms for protecting indigenous cultural and IP.<sup>101</sup> How to protect traditional knowledge in a rigorous fashion is also under discussion in international forums, such as the World Intellectual Property Organization (WIPO).
- 3.88** Two major concerns have been articulated by WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.
- Those who hold traditional knowledge should be able to protect it.
  - Parties other than the traditional knowledge holders should not be able to protect unmodified traditional knowledge based innovations.<sup>102</sup>
- 3.89** Work is under way to identify how far traditional knowledge can be protected by existing IP systems. IP Australia reports that:
- ... although there are at present no clear, specific international IP standards for protecting such knowledge, there are a growing number of instances where individuals and organisations are resorting to existing patent ... systems to protect their knowledge.<sup>103</sup>

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99 S Farquhar, IP Australia, 'Traditional knowledge, herbal medicines and IPRs protection', paper given to the International Symposium on Intellectual Property and International Trade in the New Millennium, Bangkok, 29-30 November 1999.

100 T Janke, *Our Culture, Our Future: Report on Australian Indigenous Cultural and Intellectual Property Rights*, 1998, pp. xxx-xxxi.

101 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Cracking Down on Copycats: Enforcement of Copyright in Australia*, November 2000, p. xv.

102 IP Australia, Supplementary submission no. 39, p. 1.

103 IP Australia, Supplementary submission no. 39, p. 2.

In addition, market research is being conducted to establish what information is needed by traditional knowledge holders in Australia to increase their awareness and use of IP protection.

- 3.90** Other work by the intergovernmental committee includes examining the feasibility of how far traditional knowledge can be considered as 'prior art'. Prior art is the information that a patent is compared against to determine whether the invention is novel and inventive. IP Australia reports that:

The existence of traditional knowledge that may deprive an invention of its novelty or inventiveness generally is not readily available to the examiners. Therefore WIPO is looking at the possible options for establishing a database to record this information and thereby make it available to patent examiners.<sup>104</sup>

- 3.91** The committee supports IP Australia's work in promoting the use of existing IP protection among Australia's indigenous people, and assisting WIPO's efforts to provide a more comprehensive system for protecting traditional knowledge.

### Accommodating the interests of multiple parties

- 3.92** Benefit sharing arrangements may involve a number of parties, as Cerylid reported to the committee:

... in the Northern Territory we have an agreement to collect samples on the Tiwi Islands, so that involves the Tiwi Islands Land Council, Parks and Wildlife Commission in the Northern Territory, Northern Land Council and any other people who either have ownership or would claim to have ownership of those resources. Quite often there are a number of parties that are signatories to the collecting agreements.<sup>105</sup>

- 3.93** BioProspect pointed out that benefit sharing in these circumstances is complex, and proposed that a national trust fund be established that would channel payments to those with claims to the original resource. BioProspect outlined:

... a model whereby the sovereign states share of royalty income derived from bioprospecting resides, wholly or partly, in a suitable independently managed fund or pool from where this resource is distributed to further protect the diversity of the nation's biota and

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104 IP Australia, Supplementary submission no. 39, p. 2.

105 Cerylid Biosciences, Transcript of evidence, 25 June 2001, p. 81.

to directly reward the use of indigenous knowledge in the sustainable development of that biota. ...

Advantages of such a model would include an easily implemented equitable mechanism for fair recognition of input from several sources regarding the same material. This is perhaps the biggest hurdle in private enterprise's attempt to fairly reward similar input from several diverse parties. A Commonwealth sponsored model would clearly overcome this difficulty.<sup>106</sup>

- 3.94** It is not clear to the committee how extensive a problem this matter may be, nor that a trust would be the most appropriate solution to it. However, the committee believes that this issue should be tracked.

### **Access to biological collections**

- 3.95** There are some difficulties in applying an access and benefit sharing scheme, such as that recommended in the Voumard report, to the contents of public collections. This is because the ownership of some parts of some collections is hard to establish. The committee noted that 'Principles on access to genetic resources and benefit-sharing for participating institutions' have been drawn up by an international group of botanical institutions to guide their dealings.<sup>107</sup> The World Federation of Culture Collections is examining how to address the requirements of the CBD in relation to the conditions under which access to collections of microorganisms is allowed.
- 3.96** The Voumard report recommended that, as far as possible, Commonwealth collections of native species be covered by regulations under the EPBC Act.<sup>108</sup> The committee understands that work is continuing to find mechanisms whereby the regulations will allow access and address benefit sharing in situations where ownership is unclear. As noted above, there are concerns that plant breeding research and the management of collections might be adversely affected were the Voumard scheme to be implemented.

### **Export of biological material**

- 3.97** One of the means by which access to biological resources by overseas interests can be limited is through export controls. The committee recognises that, with the small amounts of material needed for
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106 BioProspect Ltd, Submission no. 12, p. 3.

107 Royal Botanic Gardens Sydney, Submission no. 1, pp. 1-2.

108 J Voumard, pp. 128-132.

biodiscovery, it is very easy for the determined person to remove it from the country. Although biopiracy of this kind cannot be prevented, it is no excuse for not ensuring that the controls are as comprehensive as possible.

- 3.98** The export of plants and animals is currently controlled by the *Wildlife Protection (Regulation of Exports and Imports) Act 1982*. This Act will be repealed on 11 January 2002 when amendments to the EPBC Act come into effect. These amendments have the effect of incorporating the provisions of the Wildlife Protection Act into the EPBC Act.
- 3.99** The Voumard report drew attention to the fact that the export of biological resources is only partially controlled. Microorganisms can be exported without a permit. As a consequence, there is no opportunity to require a share for Australia in any commercial success derived from them. Furthermore, as microorganisms can be fairly readily cultured, the exporter may never need to refer back to Australia for further supplies, and control of those organisms will be lost by Australia. The report recommended that export controls be extended to microorganisms.<sup>109</sup> The committee supports this recommendation, particularly in view of concerns about the export of genetic material expressed to it in submissions to the inquiry.<sup>110</sup> The committee makes a recommendation on the export of genetic material later in this chapter.

## Conclusions about access and benefit sharing

- 3.100** The committee supports the moves that are being made to put a nationally consistent access and benefit sharing scheme in place. It is unfortunate that the regulations to s301 of the EPBC Act have not yet been issued for comment. The committee would have welcomed the opportunity to test them against the evidence received during the inquiry and to comment on them.
- 3.101** The committee supports the concept of sharing the benefits derived from bioprospecting with the owner of the resource and regional communities. It appreciates the simplicity of the model proposed by the Voumard report and the attempt made to accommodate the concerns of interest groups, such as indigenous owners and the curators of *ex situ* collections.
- 3.102** The committee was concerned, however, by AFFA's claims that the system proposed in the Voumard report is too onerous, and does not adequately address the impact it could have on Australians' access under the IUPGR

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109 J Voumard, pp. 132-4.

110 For example, Australian Institute of Marine Science, Submission no. 27, pp. 14, 17; Submission no. 18, pp. 4-5.

to plant genetic resources from overseas. These are serious claims and deserve careful investigation. Although AFFA did not raise these concerns with the committee until the final stages of the inquiry, the committee wishes to highlight them.

- 3.103** Drawing on the discussion earlier in this chapter and the last two paragraphs, the committee recommends some of the considerations that should guide finalisation of the regulation. In doing so, the committee is concerned to maximise the opportunities offered by bioprospecting. The committee recognises that the regulations recommended by the Voumard Report break new ground. It believes that it is imperative that the new approach to access and benefit sharing does not have any undesirable consequences. The regulations must not impede the development of the bioprospecting opportunities.

#### **Recommendation 7**

- 3.104** The committee recommends that the regulations governing access and benefit sharing under section 301 of the *Environment Protection and Biodiversity Conservation Act 1999* be subject to review after 12 months to ensure that they are not impeding the development of opportunities arising from bioprospecting.

#### **Recommendation 8**

- 3.105** The committee recommends that, when finalising the regulations under section 301 of the *Environment Protection and Biodiversity Conservation Act 1999*, the Commonwealth government:
- ensure that the regulations do not create new property rights;
  - obtain a detailed regulatory impact statement; and
  - examine fully the implications of the regulations for Australia's access to overseas plant genetic material.
- 3.106** The committee regrets that AFFA did not raise its reservations about the scheme recommended in the Voumard report when it made its first submissions to the inquiry and during its two appearances before the committee. The committee is concerned by the time that it took AFFA to

address access and benefit sharing issues when these are such significant issues. AFFA's first submission to the inquiry made no reference to access and benefit sharing. The second submission did not clearly address the issues and made only two passing references to the Voumard report and recommendations. Yet the latter are the major input to the draft regulations to the EPBC Act. It was only when the committee requested responses to specific questions in order to gain AFFA's views, that their concerns were raised.

- 3.107** Given AFFA's role, along with other government departments, in finalising the regulations, the committee believes that AFFA should have been better informed and raised its concerns with the committee at the first opportunity.

### **Recommendation 9**

- 3.108** The committee recommends that Environment Australia and the Department of Agriculture, Fisheries and Forestry - Australia give a high priority to:

- **finalising the regulations on access to biological resources and the sharing of benefits from them, under section 301 of the *Environment Protection and Biodiversity Conservation Act 1999*; and**
- **working with state and territory governments to establish nationally consistent arrangements.**

- 3.109** The committee also makes a number of more specific recommendations. The first two spell out important principles which the committee believes should underpin a nationally consistent access and benefit sharing regime. They relate to ensuring that a balance is found between competing objectives in the best interests of all concerned. It is important to get the mix of exclusive rights versus open access to use resources that will promote bioprospecting effectively. On a similar note, a balance must be struck between encouraging industry to bioprospect and benefiting the owners of biological resources. The committee believes that an important part of any benefit sharing arrangement must be a requirement for information and specimens derived from bioprospecting to be publicly accessible, provided commercial in confidence is not involved.

### Recommendation 10

**3.110** The committee recommends that, when granting access to biological resources, the Commonwealth government:

- ensure access for non commercial activities; and
- with commercial activities, ensure a balance between open competitive access and restricting access by granting exclusive use.

Exclusivity should be restricted by permit conditions such as duration, area or species collected, and uses to be explored.

### Recommendation 11

**3.111** The committee recommends that, when finalising benefit sharing arrangements, the Commonwealth government ensure that commercial activity is not discouraged by the benefits bioprospectors are required to provide.

When negotiating non monetary benefits, emphasis should be placed on providing support for regional development and the lodging of information and specimens in publicly accessible databases and collections (see recommendation 1).

### Recommendation 12

**3.112** The committee recommends that the *Environment Protection and Biodiversity Conservation Act 1999* be amended to extend export controls to all elements of Australia's non human, native biota, with particular reference to microorganisms.

## Finding and using bioactive substances

**3.113** The previous sections of this chapter have dealt with topics that impinge on accessing biological material. In this and the following sections, the later stages in the chain of industry development are considered.

## Biodiscovery

- 3.114** The term, biodiscovery is used here to refer to the extraction and testing of molecules for biological activity, identification of compounds with promise for further development, and research on the molecular basis for the biological activity. Significant value adding is often possible at the biodiscovery stage. The perception that value adding occurs only with commercialisation and production is wrong.<sup>111</sup> Value adding can, in fact, be ongoing as samples are repeatedly screened for new clients and targets, and as new circumstances arise. Value increases both in terms of the financial returns from research as well as adding to knowledge about the resource.<sup>112</sup>
- 3.115** Furthermore, as AIMS pointed out, 'if funding is available at early phases of the bioprospecting/biodiscovery process, then IP is also captured early'.<sup>113</sup> As Figure 3.1 shows, Australian research organisations can exercise strategic leverage as products are developed through the IP positions they hold. A tenfold increase in value can be expected from the biodiscovery stage to final product development, as the figure also indicates.<sup>114</sup>
- 3.116** Value adding to bioprospected material was mentioned as being very important in many submissions, discussions and hearings during the inquiry.<sup>115</sup> So too was maintaining control over the uses to which discoveries from Australian material are put. Even if further development of promising leads goes overseas, biodiscovery will provide much greater, lasting returns to Australia than the sale of samples and extracts, particularly if discoveries can be taken as far as patenting. The further value adding can be taken along the bioproduct development chain, the greater the return to Australia.<sup>116</sup>

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111 ExGenix Operations Pty Ltd (Cerylid Biosciences Ltd), Submission no. 13, p. 1.

112 Australian Institute of Marine Science, Submission no. 27, pp. 4-5.

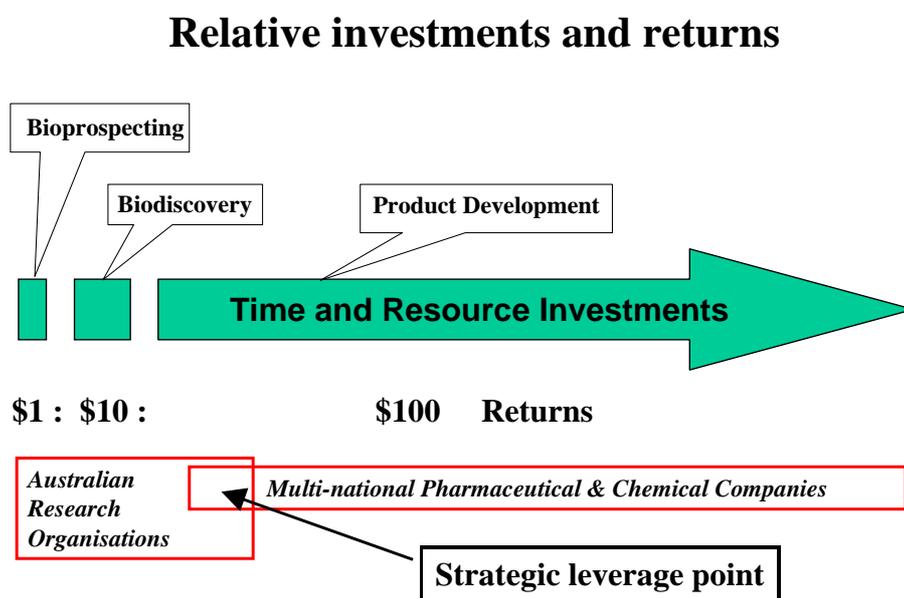
113 Australian Institute of Marine Science, Submission no. 27, p. 16.

114 CSIRO, Submission no. 14, p. 17.

115 For example, Original Oceanz, Smart Ventures Industry Group, Committee briefing, 4 May 2001.

116 Environment Australia, Submission no. 29, p. 30; AstraZeneca R&D Griffith University, Submission no. 33, p. 1; Australian Institute of Marine Science, Submission no. 27, p. 1.

Figure 3.1 The relative investment in lead time and expenditures (size of the arrow) and the relative returns at each step.



**Note:** Whilst the down-stream operators are often multinational companies, Australian research organisations can exercise strategic leverage through the overlap in activities and IP positions.

**Source:** CSIRO, Submission no. 14, p. 17.

**3.117** The committee was told, however, that there are frequently insufficient funds to carry research far enough to obtain IP protection, and then to meet the costs of obtaining patents. According to Professor Palmer, Vice Chancellor of JCU, universities are not well enough funded to patent IP (and have a very conservative attitude to IP management), so they licence overseas and the IP is lost to Australia.<sup>117</sup> AIMS agreed that research grants do not cover the costs of obtaining IP protection.<sup>118</sup> According to BA, however, some assistance is now available to assist with these costs.<sup>119</sup> Commercial partners in joint ventures with public sector research institutions have also sometimes met the costs of patenting.<sup>120</sup>

117 James Cook University, Committee briefing, 3 May 2001.

118 Australian Institute of Marine Science, Submission no. 27, p. 15.

119 Biotechnology Australia, Transcript of evidence, 2 April 2001, p. 15.

120 Australian Institute of Marine Science, Committee briefing, 3 May 2001.

- 3.118** The potential of plant breeders rights (PBR) for protecting biodiscovery was also brought to the committee's attention. According to AFFA, 12 per cent of the applications received by the PBR Office relate to native species. AFFA suggested that considerable growth would occur in the selective breeding of native species, but reported poor understanding of PBR among those carrying out this work.<sup>121</sup>
- 3.119** Biodiscovery requires equipment and skills, but 'there are classic signs of stress on infrastructure, skill development and retention, and competition between national centres'.<sup>122</sup> The committee noted the view that Australia lacks the financial capacity to support an approach to biodiscovery that relies heavily on high throughput random screening.<sup>123</sup> Nonetheless, as the Western Australian government pointed out:
- ... the establishment of a small number of international standard screening and extraction facilities and the development of world class researchers ... would increase Australia's capacity to generate commercialisable IP and exert meaningful controls over access to Australia's biological resources.<sup>124</sup>
- 3.120** CSIRO recommended more collaborative research between public and private sectors be sought so that expertise and facilities could be pooled and bioactive molecules developed further along the product development pipeline.<sup>125</sup>
- 3.121** According to CSIRO, biodiscovery is dominated by the global R&D system more than any other stage in the development of bioindustries.<sup>126</sup> In this context:
- Australia cannot hope to be a world leader across all major biotechnology areas, but must carefully select the most appropriate niches and then be smart in the way that Australian intellectual property (IP) positions are used to exercise leverage over multinational companies.<sup>127</sup>
- Nationally, it is critical to clearly identify the market niches for *biodiscovery* projects that are of strategic importance to Australia.
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121 Department of Agriculture, Fisheries and Forestry - Australia, Transcript of evidence, 2 April 2001, pp. 31, 34.

122 CSIRO, Submission no. 14, p. 22.

123 Faculty of Biological and Chemical Sciences, The University of Queensland, Submission no. 26, p. 2.

124 Western Australian government, Submission no. 32, p. 4.

125 CSIRO, Submission no. 14, pp. 30, 34.

126 CSIRO, Submission no. 14, p. 21.

127 CSIRO, Submission no. 14, p. 3.

Furthermore, international collaborative ventures are important ... to ensure Australia retains a seat at the negotiating table when dealing with multinational companies that are active in this area.<sup>128</sup>

CSIRO called for 'strong, national leadership directed into areas and niches where our global contribution makes a significant difference'.<sup>129</sup>

**3.122** This section has identified a number of issues that require attention if the most is to be made for Australia from biodiscovery. These issues include:

- the need for screening and extraction facilities of an international standard;
- the cost of obtaining and maintaining patents;
- the lack of public understanding about the potential of PBRs to protect IP;
- the selection of market niches; and
- the need for greater collaboration among researchers.

Some of these issues are relevant to a larger range of endeavours than just biodiscovery, and are discussed further in Chapter 6. The committee makes one recommendation relating specifically to biodiscovery.

### Recommendation 13

**3.123** The committee recommends that the Commonwealth government ensure that the major publicly funded research organisations are sufficiently well funded to purchase the equipment needed to meet present and future demands.

**3.124** The committee considered IP protection at some length in its report on primary producer access to gene technology. The matters brought to the committee's attention in relation to IP protection for biodiscoveries cover some of the same concerns. In its report on gene technology, the committee made two recommendations dealing with providing information about IP issues to small producers, and monitoring initiatives to improve IP skills. The committee was pleased that both

<sup>128</sup> CSIRO, Submission no. 14, p. 4.

<sup>129</sup> CSIRO, Submission no. 14, p. 9.

recommendations were supported in the Government's response to the report.<sup>130</sup>

## Bioprocessing and bioindustries

**3.125** Bioprocessing involves the development of industrial processes to manufacture new biological products on a commercially viable scale, often using fermentation or enzyme processes.<sup>131</sup> Brewing and cheese making are old technologies based on bioprocessing. An example of modern bioprocessing approaches was given to the committee by Dupont Australia (Box 3.5).

### **Box 3.5** New approaches to bacterial bioprocessing

Genes have been identified that drive the production of widely used substances, currently synthesised from petrochemical or other non renewable feedstocks. These genes have been inserted into bacteria which are housed in a bioreactor and fed on sugar. Dupont Australia reported that the first commercial plants using these bacteria will open in 2003; they will produce herbicides, plastics and nylon.

The advantage of this mode of manufacture is that it is more efficient than conventional manufacturing processes. Production is carried out under ambient conditions, compared with the high temperatures and pressures that are often required conventionally. The bacteria's biochemical pathways yield products with high specificity, and may have conversion rates as high as 98 per cent. The bioprocesses thus produce very little waste, and all the end products are biodegradable.

Biobased sources of chemicals are an attractive alternative to petrochemicals as the cost of oil rises and the pollution caused by it and industries based on it increase.

Source: Dupont Australia, Committee briefing, 6 June 2001.

**3.126** One estimate is that biobased products will be competitive in 30 per cent of the chemical market by 2010, especially in the market for fine and speciality chemicals.<sup>132</sup> With technological advances over coming years, the cost of producing other biobased products is expected to fall and

130 House of Representatives Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with Caution: Primary Producer Access to Gene Technology*, June 2000, pp. 94, 122.

131 CSIRO, Submission no. 14, pp. 15, 32.

132 R Bachmann, E Bastianelli, J Riese & W Schlenzka, 'Using plants as plants', *McKinsey Quarterly*, 22 March 2000.

become competitive with those derived from petrochemicals. A study carried out for the US National Research Council suggested that liquid fuels might follow commodity chemicals into biobased production.<sup>133</sup>

- 3.127** The committee's attention was drawn to the potential for producing liquid fuels from various types of biomass. The technology needed for this has been known for a number of years, but has been little used in Australia until recently. Small plants produce ethanol from sugar for blending with petrol but, although exempt from excise, large scale ethanol production is not cost effective. However, a scenario can be imagined in which this would change, for example, if petrol costs were to rise significantly, more efficient production processes were developed, or carbon credits acquired a greater value. Research is also being undertaken in Australia into ethanol production from other sources, such as wheat starch and woody material. Support for this research and for the establishment of biologically sourced ethanol plants is being provided by the Commonwealth government.<sup>134</sup>
- 3.128** CSIRO identified two impediments to bioprocessing in Australia. The first is the predominantly small to medium size of the enterprises involved in bioprocessing. Such enterprises do not have access to sufficient capital to undertake high risk, commercial developments.<sup>135</sup> This point was made by others as well.<sup>136</sup> Considerable R&D is needed to take bioprocessing concepts from laboratory to commercial scale. It can take as long as 10 years and consume up to 90 per cent of the overall costs of developing a new product.<sup>137</sup>
- 3.129** The second impediment is the shortage in Australia of pilot plants to research the scaling up of fermentation processes. While CSIRO has good capabilities and facilities in this area, it has only sufficient to support its own research needs. It saw:

... a need for some form of a national technology transfer centre or facility for bioprocessing R&D within the next few years to offer

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133 Committee on Biobased Industrial Products, Board on Biology, Commission on Life Sciences, National Research Council, *Biobased Industrial Products: Priorities for Research and Commercialisation*, National Academy Press, Washington DC, 2000, pp. 1-2.

134 Biotechnology Australia, Submission no. 25, pp. 11-12.

135 CSIRO, Submission no. 14, p. 22.

136 University of Queensland, Faculty of Natural Resources, Agriculture and Veterinary Science, Submission no. 31, p. 1; Western Australian government, Submission no. 32, p. 1.

137 CSIRO, Submission no. 14, p. 15.

such services to industry to commercialise research in Australia prior to the commercial manufacturing stage.<sup>138</sup>

Noting the difficulties in taking R&D to commercialisation, the committee is attracted to the idea of a national biotechnology transfer centre, incorporating a bioprocessing scale up facility.

#### **Recommendation 14**

**3.130 The committee recommends that the Commonwealth government facilitate the establishment of a national biotechnology transfer centre that should include scaling up facilities for bioprocessing.**

**3.131** Impediments to the establishment of bioindustries were also identified in the regulatory regimes maintained by the Therapeutic Goods Administration and the National Registration Authority for registering new products. The cost of their processes and the time taken to complete them were criticised at a private committee meeting at SCU.<sup>139</sup> Participants at this meeting suggested that a scheme based on the same principle as the Higher Education Contribution Scheme would be a less punitive way of recovering registration costs, particularly from small companies.

**3.132** The challenges typically faced in employing microorganisms and enzymes in bioindustries are increasing product yields, product concentrations, and processing rates.<sup>140</sup> Significant engineering challenges also exist in establishing new plants. In addition, as Dupont pointed out, bioprocessing needs to be integrated into the complex infrastructure of the chemical industry, and bioderived materials will not necessarily be 'drop in' replacements for petroleum based products.<sup>141</sup> The US National Research Council flagged the need for educational support and training for bioindustries.<sup>142</sup>

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138 CSIRO, Submission no. 14, p. 22.

139 BioProspect Ltd and Southern Cross University, Committee briefing, 6 July 2001.

140 Committee on Biobased Industrial Products, p. 10; CSIRO, Committee briefing, 27 November 2000.

141 Dupont Australia, Committee briefing, 6 June 2001.

142 Committee on Biobased Industrial Products, Board on Biology, Commission on Life Sciences, National Research Council, *Biobased Industrial Products: Priorities for Research and Commercialisation*, National Academy Press, Washington DC, 2000, pp. 11-12.

**3.133** In its report on primary producer access to gene technology, the committee flagged the need for increasing numbers of people and levels of skills in biotechnology research.<sup>143</sup> The government supported this recommendation in its response to the report. It undertook to monitor emerging skill needs in the biotechnology sector and develop appropriate responses to them.<sup>144</sup> The committee believes that skills development continues to be critically important.

### **Recommendation 15**

**3.134** The committee recommends that the Commonwealth government:

- **audit the availability of skills needed in the biotechnology sector, including those required to develop bioindustries;**
- **ensure that relevant training is available; and**
- **promote uptake of training opportunities.**

**3.135** CSIRO warned that the 'development of bioindustries may ... require attention to public concerns about biotechnology and gene technology in particular'.<sup>145</sup> While this might not be an issue with processes that depend on genetically modified microorganisms contained in fermenters, greater concern might be felt about crops or animals modified to produce new substances. CSIRO recommended that BA's public awareness program be continued.

**3.136** This is another topic covered extensively by the committee in its last report.<sup>146</sup> The committee's five recommendations that addressed the need for increased public awareness of biotechnology were all accepted by the government. It is the committee's view that this need still exists and is likely to continue to do so for some time to come. The provision of balanced, comprehensible, easily accessible information about the

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143 Committee on Biobased Industrial Products, p. 88.

144 House of Representatives Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with Caution: Primary Producer Access to Gene Technology*, June 2000, pp. 14-15.

145 CSIRO, Submission no. 14, p. 30.

146 House of Representatives Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with Caution: Primary Producer Access to Gene Technology*, June 2000, pp. 38, 42, 43, 46, 47.

scientific, economic, social and environmental implications of biotechnology should continue to be made available.

**3.137** The committee believes that bioprospecting and the development of bioindustries should be fully covered in material provided to the public by BA. This does not appear to be the case at present: the committee's impression is that the focus is largely on gene technology. It is particularly important that the bad image created by instances of biopiracy and past environmentally unsustainable activities be dispelled.<sup>147</sup>

### **Recommendation 16**

**3.138** The committee recommends that the Commonwealth government:

- **continue to provide extensive information about biotechnology in its public awareness program; and**
- **ensure that the contribution of bioprospecting and biodiscovery to economic development is covered in this program, including the benefits that bioindustries offer to the environment, medicine and agriculture.**

## **Conclusion**

**3.139** The recommendations in this chapter address some of the specific impediments associated with each of the stages in the bioproduct development chain (Figure 1.1). As foreshadowed in the last two sections, there is also a number of wider issues in the development of bioprospecting and bioindustries, which are covered in Chapter 6, along with some of the broader issues raised in the next chapter on regional matters.

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147 Dr Kirsten Benkendorff, University of Wollongong, Submission no. 38, p. 6.