Regulating Access to Biological Resources: The Market Failure for Biodiversity Conservation

1. Introduction

The favoured approach in Australia to regulating the access and benefit sharing objective of the United Nations *Convention on Biodiversity* (CBD) (Art 1) is a private contract model consistent with the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization* (UNEP/CBD/COP/6/20, 60-62 and 253-269), with the contract setting out the terms of the benefit sharing arrangements (Department of the Environment and Heritage 2002a, 6-8; see also UNEP/CBD/WG-ABS/3/INF/1/Add.1, 2-8; Lawson 2005, 144-152). The principal policy documents articulating the Commonwealth, State and Territory approaches to this CBD objective so far have been the 1996 *National Strategy for the Conservation of Australia's Biological Diversity* (Department of the Environment, Sport and Territories 1996a), and more recently, the 2002 *Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* (Department of the Environment and Heritage 2002a).

This private contract model essentially leaves the resource holder to negotiate with the bio-prospector and hopes that any commercial or market value from the accessed resources will be reasonable and adequate, and sufficient as an incentive for biological diversity conservation (Department of the Environment, Sport and Territories 1996a, 23; see also Department of the Environment and Heritage 2002a, 2-3).

As a generalisation, market based economies like Australia have addressed biological diversity conservation as a market failure (Department of the Environment and Heritage 2002b, 2; see also Secretariat of the Convention on Biological Diversity 2006, 13-19 and 39; Organisation of Economic Co-operation and Development 1999). Most of these economies have sought to deal with the market failure, at least in part, by establishing a property regime controlling access to the biological diversity and then imposing obligations on the subsequent users of any accessed biological resources to share the benefits (see Productivity Commission 2004, 189-197; Productivity Commission 2001b, 5-7; see generally Organisation for Economic Co-

operation and Development 2004a, 15-47 and the references therein; UNEP/CBD/WG-ABS/3/INF/1/Add.1).

This approach reflects the theory that the benefits of biological diversity conservation accrue to society and cannot be sufficiently captured by those likely to undertake the conservation – the marginal private returns from conservation activities do not correspond with their marginal social returns favouring biological diversity destruction and decline (for an overview of the issues see, for examples, Swanson and Goeschl 2000, 76-77; Janssen 1999, 315-318 and the references therein; see also Rausser and Small 2000; Stone 1995; Organisation of Economic Co-operation and Development 1994). Establishing exclusive property rights over the biological resources appropriates part of the social value for individual economic activities thus compensating those likely to undertake the conservation activity, and providing an incentive to undertake future conservation activities (for an overview of the issues see Swanson 1994; Stone 1995; see also Productivity Commission 2001c). Essentially:

> Exclusive property rights will induce economic agents, who are interested in the utilisation of genetic resources, to pay for the access to genetic resources. This entrance fee will compensate those agents who bear the cost of conserving and providing genetic resources, and hence create real economic incentives for engaging in protection and provision of diverse genetic resources (Janssen 1999, 316).

The objective of controlling access and benefit sharing is therefore to establish a market for biological diversity conservation that internalises into a market transaction all the costs of the impacts of biological diversity destruction and decline (see generally Organisation for Economic Co-operation and Development 2004a, 24-29; Department of the Environment and Heritage 2002b, 2; see also UNEP/CBD/COP/7/21, 286-296; UNEP/CBD/COP/6/20, 179-185; Organisation for Economic Co-operation and Development 2002, 23).

The recently enacted *Environment Protection and Biodiversity Conservation Amendment Regulations 2005 (No 2)* (Cth) (EPBC Amendment Regulations) formalises the private contract model for access and benefit sharing over some Commonwealth controlled biological resources consistent with the *Bonn Guidelines*

on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (UNEP/CBD/COP/6/20, 60-62 and 253-269). The EPBC Amendment Regulations attempt to create a market for the biological resources by clarifying property and use rights and minimising transaction costs (and other barriers to trading) (see Department of the Environment and Heritage 2005a, 9). The market value of the biological resources that acts as the economic incentive for biodiversity conservation is addressed, at least in part, through the delivered benefits negotiated as binding terms in the benefit sharing agreement between the resource holder and the bio-prospector.

The purpose of this submission is to examine the EPBC Amendment Regulations in the context of addressing the market failure for biodiversity conservation in Australia. This scheme has been subjected to some other analysis and criticism in its proposed form (see, for examples, Sherman 2003; Lawson and Downing 2002; Lawson and Pickering 1998). In particular, this submission examines the Australian Government's claim for the EPBC Amendment Regulations that: '[t]he regulatory framework is consistent with a number of Australia's policies and Acts including … *National Competition Policy*' (Department of the Environment and Heritage 2005a, 5; Au/NR/03, 171; Commonwealth of Australia 2000a, 29; see also UNEP/CBD/WG-ABS/3/INF/1/Add.1, 6). Part 1 outlines the EPBC Amendment Regulations. Part 2 outlines the role of the *National Competition Policy* (NCP), and in particular the requirements of the *Competition Principles Agreement* (CPA) (see National Competition Council 1997), showing that the failure to comply with this process leaves open to speculation the configured values in the decision making process and the most efficient and effective means of achieving the CBD's objectives that justify the EPBC Amendment Regulations. Part 3 speculates that the focus of the EPBC Amendment Regulations is in promoting investment in biological resource-based product research and development rather than the CBD's objectives for biodiversity conservation and sustainable use. Part 4 speculates that the assumption that the current *Patents Act 1990* (Cth) patent settings are necessarily appropriate for promoting biodiversity conservation may not reflect biodiversity conservation values and may not be able to be tailored to biodiversity conservation objectives. Part 5 sets out the conclusions that the price setting under the EPBC Amendment Regulations is necessary so that the 'low price' for access to biological resources will match the

'high price' of other uses of the land and water promoting biodiversity conservation in favour of those other uses.

2. Outline of the Regulations

The EPBC Amendment Regulations amended the *Environment Protection and Biodiversity Conservation Regulations 2000* (Cth) (EPBC Regulations) made under the *Environment Protection and Biodiversity Conservation Act 1999* (Cth) (EPBC Act) ss 301(1) and 520(1) that provides for regulations to be made about controlling access to 'biological resources'[1] and benefit sharing in 'Commonwealth areas'.[2] These regulations commenced on 1 December 2005 (EPBC Amendment Regulations r 2) so that, in summary, an access permit is required together with a benefit sharing agreement between the parties based on 'terms mutually agreed', 'adequate benefit sharing arrangements including, that if practicable, some benefits would be used for biodiversity conservation in the area from which the resource was obtained' and 'prior informed consent of any Indigenous owners' (Minister for the Environment and Heritage 2005, 1).

The articulated purpose of enacting regulations to control access and benefit sharing is:

> (a) promoting the conservation of biological resources in those Commonwealth areas, including the ecologically sustainable use of those biological resources; and
> (b) ensuring the equitable sharing of the benefits arising from the use of biological resources in those Commonwealth areas; and
> (c) recognising the special knowledge held by indigenous persons about biological resources; and
> (d) establishing an access regime designed to provide certainty, and minimise administrative cost, for people seeking access to biological resources; and
> (e) seeking to ensure that the social, economic and environmental benefits arising from the use of biological resources in those Commonwealth areas accrue to Australia; and
> (f) contributing to a nationally consistent approach to access to Australia's biological resources (EPBC Regulations r 8A.01).

The regulations were also asserted to be giving effect to the Commonwealth's responsibility under the CBD and the *National Strategy for the Conservation of Australia's Biological Diversity* (Department of the Environment, Sport and

Territories 1996a), and commitments made in the *Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* (Department of the Environment and Heritage 2002a) and the *Australian Biotechnology: A National Strategy* (Commonwealth of Australia 2000b; see Minister for the Environment and Heritage 2005, 2).

The EPBC Amendment Regulations require a person accessing biological resources (a bioprospector) (r 8A.03) to have a permit issued by the Minister (rr 8A.06(1) and 17.01(ab)). Before issuing a permit for access for commercial purposes or potential commercial purposes there must be a benefit sharing agreement entered into between the access provider(s) (r 8A.04) and the bio-prospector (rr 8A.07(1) and 17.03A(6)(a)(i)), and the Minister 'must take into account the extent to which the requirements of [the relevant regulation] have been met by the benefit sharing agreement' (r 8A.15(2)(a)). The Minister 'may issue a permit only if' (r 17.03(2)) 'the Minister believes, on reasonable grounds, that some of the benefits of access to the biological resources will, if practicable, be used for biodiversity conservation in the area from where the resources were taken' (r 17.03A(6)(c)). A benefit sharing agreement 'must provide for reasonable benefit sharing arrangements', and according to the relevant regulation, include the following:

> (i) a statement regarding benefits to be provided …;
> …
> (k) the details of any proposals of the applicant to benefit biodiversity conservation in the area if access is granted;
> (l) details of the benefits that the access provider will receive for having granted access (EPBC Regulations r 8A.08).

A further 'requirement' is that the issue of the permit be 'consistent with the conservation of Australia's biological diversity' (r 17.03A(6)(f)).

The *National Strategy for the Conservation of Australia's Biological Diversity* (Department of the Environment, Sport and Territories 1996a) objective for access to biological resources is to '[e]nsure that the social and economic benefits of the use of genetic material and products derived from Australia's biological diversity accrue to

Australia' (Department of the Environment, Sport and Territories 1996a, 23). The 'actions' include sharing benefits:

> Through effective controls, legislation and incentives (including secure property rights) ensure that Australia participates in research into and development of, and shares the benefits from, any commercial opportunities, including the development of biotechnologies that are based on genetic resources collected from areas within Australia's jurisdiction (Department of the Environment, Sport and Territories 1996a, 24).

The EPBC Amendment Regulations further provide that the Minister may publish in the *Gazette* a model benefit sharing agreement as a guide for permit applicants (r 8A.07(4)), although this will have no mandatory obligation, and instead 'aim to provide assistance and incorporate best practice examples from similar agreements world wide' (Department of the Environment and Heritage 2005a, 15). Other key concerns appear to be to limit transaction costs (Department of the Environment and Heritage 2005a, 9) and accepting that the benefits from accessed biological resources may be monetary and non-monetary (Department of the Environment and Heritage 2005a, 9). The kinds of intellectual property related benefits are suggested to be royalties, joint ownership of relevant intellectual property, joint ventures and sharing research and development results (Department of the Environment and Heritage 2005a, 10).

3. The role of the National Competition Policy in new regulations

The Australian Government expressly asserts that the EPBC Amendment Regulations are 'consistent' with the NCP (Department of the Environment and Heritage 2005a, 5; Au/NR/03, 171; see also UNEP/CBD/WG-ABS/3/INF/1/Add.1, 6). The *Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* was also formulated on the basis that the 'framework' for access and use of Australia's biological resources would be based on a number of principles, and in particular, 'be consistent with … *National Competition Policy*' (Department of the Environment and Heritage 2002a, 5). Presumably, in both instances, this means 'consistent' with the content and substance of the NCP, as opposed to 'consistent' with the NCP through reliance on an exception to any

requirement to comply with the NCP, and in particular the CPA (Office or Regulation Review 1998, A3).

The NCP reflects the concern about the high social costs from restrictions on competition, together with the inefficiencies in the market from less than optimal allocation of resources. As a consequence the Commonwealth, State and Territories have undertaken an extensive review of their regulations and government actions to remove anti-competitive arrangements that cannot be justified to achieve an identifiable benefit or 'public interest' (Independent Committee of Inquiry into Competition Policy in Australia 1993). In the first steps along this path, there was a broad ranging policy review of the restrictions on competition in Australia and a number of reforms were directed to removing barriers to competition with the aim of benefiting consumers, promoting business competition, fostering innovation and making the Australian economy more flexible, thereby 'improving its capacity to respond to external shocks and changing market opportunities' (Independent Committee of Inquiry into Competition Policy in Australia 1993, xvi).

One of the recommendations arising from this process was that '[a] mechanism to promote reform of regulation that unjustifiably restricts competition form a central plank of a national competition policy' (Independent Committee of Inquiry into Competition Policy in Australia 1993, 211) so that '[t]here should be no regulatory restrictions on competition unless clearly demonstrated to be in the public interest' (Independent Committee of Inquiry into Competition Policy in Australia 1993, 212). Further:

> Proposals for new regulation that have the potential to restrict competition should include evidence that the competitive effects of the regulation have been considered; that the benefits of the proposed restriction outweigh the likely costs; and that the restriction is no more restrictive than necessary in the public interest (Independent Committee of Inquiry into Competition Policy in Australia 1993, 212).

Finally, '[a]ll existing regulation that imposes a significant restriction on competition should be subject to regular review to determine that the restriction on competition is

'clearly demonstrated' to be in the "public interest"' (Independent Committee of Inquiry into Competition Policy in Australia 1993, 212).

Following this process, a number of measures were implemented as part of a NCP, including the CPA (National Competition Council 1997; Deighton-Smith 2001). A significant part of the CPA was that governments around Australia review the anti-competitive effects of their existing legislation (CPA cl 5(3)), and ensure those proposals for new legislation that restricts competition be consistent with the 'guiding principle' (CPA cl 5(5)):

> … that legislation (including Acts, enactments, Ordinances or regulations) should not restrict competition unless it can be demonstrated that:
> (a) the benefits of the restriction to the community as a whole outweigh the costs; and
> (b) the objectives of the legislation can only be achieved by restricting competition (CPA cl 5(1)).

The approach adopted by the Australian Government when proposing new legislation is to undertake public consultation with those affected (*Legislative Instruments Act 2003* (Cth) s 17(1)), assess the possible restrictions on competition (*Legislative Instruments Act 2003* (Cth) s 39), and where an 'explanatory statement' is lodged with the legislative instrument (*Legislative Instruments Act 2003* (Cth) s 39) then that statement must 'contain[] a description of the nature of that consultation' about restricting competition or 'explain[] why no such consultation was undertaken' (*Legislative Instruments Act 2003* (Cth) s 4(1)).

A further obligation is the preparation of Regulatory Impact Statements (RIS) for new regulations (see House of Representatives Standing Committee on Financial Institutions and Public Administration 2002, 16). The key objective of the RIS is:

> Preparation of a [RIS] is a critical feature of the regulation making process, primarily because doing so formalises and evidences the steps that should be taken in policy formulation. It helps to ensure that options to address a perceived policy problem are canvassed in a systematic, objective and transparent manner, with options ranked according to their net economic and social benefits. The RIS embodies this analytical process (Office of Regulation Review 1998, A1).

The benefits of RISs are to document the relevant information, explicitly and transparently set out the decision-making process, and identify the most efficient and effective means for achieving a relevant policy objective (Office of Regulation Review 1998, A1-A2). The key elements of a RIS are:

- the problem or issues which give rise to the need for action;
- the desired objective(s);
- the options (regulatory and/or non-regulatory) that may constitute viable means for achieving the desired objective(s);
- an assessment of the impact (costs and benefits) on consumers, business, government and the community of each option;
- a consultation statement;
- a recommended option; and
- a strategy to implement and review the preferred option (Office of Regulation Review 1998, A2).

The CPA does provide some insight into the 'public interest' that may be relevant in applying the 'guiding principle' (CPA cl 5(5)) and determining the threshold or standard necessary for the benefit to outweigh the costs (see CPA cl 5(9); Productivity Commission 2001a, 78-79):

> Without limiting the matters that may be taken into account, where this Agreement calls:
> (a) for the benefits of a particular policy or course of action to be balanced against the costs of the policy or course of action; or
> (b) for the merits or appropriateness of a particular policy or course of actions to be determined; or
> (c) for an assessment of the most effective means of achieving a policy objective;
> the following matters shall, where relevant, be taken into account:
> (d) government legislation and policies relating to ecologically sustainable development;
> (e) social welfare and equity considerations, including community service obligations;
> (f) government legislation and policies relating to matters such as occupational health and safety, industrial relations and access and equity;
> (g) economic and regional development, including employment and investment growth;
> (h) the interests of consumers generally or of a class of consumers;
> (i) the competitiveness of Australian businesses; and
> (j) the efficient allocation of resources (CPA cl 1(3)).

In applying the CPA and achieving the policy objectives of the NCP, the threshold or standard necessary for the benefit to outweigh the costs is significant, as the matters prescribed by the CPA are not comprehensive (CPA cl 1(4)). The words of the CPA provide little guidance as to how the threshold or standard is to be methodologically determined or the boundaries within which it should be assessed. Unfortunately, the Commonwealth, States and Territories have very different views about the appropriate methodology for determining the relevant costs and benefits of any restrictions on competition (see, for examples, House of Representatives Standing Committee on Financial Institutions and Public Administration 2002; Senate Select Committee on Socio-economic Consequences of the National Competition Policy 2000; Senate Select Committee on Socio-economic Consequences of the National Competition Policy 1999 and the submissions to these inquiries) and how the 'public interest' test should be applied (see Senate Select Committee on Socio-economic Consequences of the National Competition Policy 1999, 101).

A definitive statement of the 'public interest' test remains elusive (see Council of Australian Governments 2006a, att B; Council of Australian Governments 2006b, 8 and 36-37; Productivity Commission 2005, 134-147). However, the framing of the 'public interest' test has changed in recent articulations, favouring process over substance:

> While greater specification and guidance on matters to be considered in applying the test may be helpful, there is only so much that can be achieved via this route. This in turn puts a premium on ensuring that mechanisms are in place to promote the quality of the review process … Processes which systematically review the rationales for regulatory and other restrictions on competition, and the merits of different options for better meeting underlying objectives, are critical to informed decision making by governments. They can also play a useful role in promoting public awareness of the issues and trade-offs associated with different policy approaches. Effective monitoring and assessment of procedural arrangements is also important for promoting good outcomes. (Productivity Commission 2005, 140).

Despite these uncertainties, guidelines have been prepared identifying legislative restrictions and many of the relevant factors to take into account (Office of Regulation Review 1998). These guidelines do not assist in finally determining the threshold or standard of benefit to outweigh the costs and 'public interest' that warrants or justifies

restrictions on competition, although regulation that imposes charges, compliance costs and other regulatory barriers are within the scope of the CPA (Office of Regulation Review 1998, A3). Further, 'the Government has decided by administrative decision that preparation of a RIS is mandatory for all reviews of existing regulation, proposed new or amended regulation and proposed treaties involving regulation which will directly affect business, have a significant indirect effect on business, or restrict competition', subject to some exceptions (Office of Regulation Review 1998, A2-A3; see also Council of Australian Governments 2006b, 36-38).

There seems little doubt that the EPBC Amendment Regulations required a RIS either because it restricts competition or affects business (see Office of Regulation Review 1998, A3). The regulations require a permit that will involve compliance costs (see EPBC Regulations r 17.03A(6)(c)), imposes a fee (EPBC Regulations r 18.01) and restricts bio-prospecting without a permit that might otherwise have been lawful (see EPBC Regulations rr 8A.06(1) and 17.01(ab)). The RIS might therefore be expected to provide *some* insight into the configured values in the EPBC Amendment Regulations and how access and benefit sharing arrangements contribute to addressing the market failure for biodiversity conservation.

Unfortunately, the documents accompanying the EPBC Amendment Regulations do not address the NCP (or CPA) and a RIS has not been released or disclosed (see Minister for the Environment and Heritage 2005). This means that the role, place and significance of biodiversity conservation in the EPBC Amendment Regulations is unclear as well as what considerations were taken into account, and how the various considerations that were taken into account, were balanced. In the spirit of the NCP, the RIS process was not transparent and independent (see Productivity Commission 2005, 255-259). In sum, the CPA assessment did not reveal the configured values leaving open to speculation the considerations and preferences in adopting the EPBC Amendment Regulations approach, and finally, whether the outcome will necessarily promote biodiversity conservation. The following parts speculate that in effect the EPBC Amendment Regulations most probably do not address the market failure for biodiversity conservation, but instead prefer short term interests that encourage investment in biological resource-based product research and development.

3. Speculations about configured values

The only concession to environmental considerations ('[e]nvironmental issues') in the EPBC Amendment Regulations appears to be about lodging information about collected specimens and environmental impact statements to minimise the impact of collection activities (Department the Environment and Heritage 2005a, 12). The pursuit of promoting investment in the biological resource-based product research and development industries (see, for example, Department of the Environment and Heritage 2005a, 1) is a much more likely explanation for the configured values reflected in the EPBC Amendment Regulations. Contrasting the *National Strategy for the Conservation of Australia's Biological Diversity* (Department of the Environment, Sport and Territories 1996a) and the *Australian Biotechnology: A National Strategy* (Commonwealth of Australia 2000b) illustrates this contention.

The *National Strategy for the Conservation of Australia's Biological Diversity* was a commitment by Australian Commonwealth, State and Territory governments 'to bridge the gap between current activities and the effective identification, conservation and management of Australia's biological diversity', with a further commitment to 'implement this Strategy as a matter of urgency' (Department of the Environment, Sport and Territories 1996a, iii). In particular, the Strategy 'recognised' that '[t]here is a pressing need to strengthen current activities and improve policies, practices and attitudes to achieve conservation and sustainable use of biological diversity' (Department of the Environment, Sport and Territories 1996a, 5). These conservation ideals may be reflected in the EPBC Amendment Regulations requiring a permit that is based, at least in part, on the identification to the satisfaction of the Minister (EPBC Regulations rr 8A.06(1) and 17.01(ab)) of 'reasonable benefit sharing arrangements' (EPBC Regulations r 8A.08). Taking into account the need to address the market failure for biodiversity conservation and the structure of the EPBC Amendment Regulations, the Minister might be expected in granting the permit to determine the price of the benefit so that the marginal private returns from conservation activities are sufficient to at least correspond with their marginal social returns. In setting the price the Minister would need to balance the price of access against the other uses of the land and water, and take into account the other private values captured by the conservator so that overall the private values are at least equivalent to the social

values. As other price setting arrangements have found, this is an extremely complex task (see, for example, Council of Australian Governments 2006b, 18-20), although in finding a solution to market failure a price *can* be identified and set (see, for example, Council of Australian Governments 2006b, 28-32).

This is likely to have been a controversial and difficult issue in the CPA assessment and might have been expected to have involved some indication about how a Minister might set an appropriate price (see Productivity Commission 2005, 295; see also Organisation for Economic Co-operation and Development 2003a). This, however, seems unlikely to have been addressed as the *only* price setting appears to be the administration and management fees (the administration fee is presently set at AUD$50 and the assessment and management fees at 'nil': EPBC Regulations sch 11), and no price setting policy (or intention to develop such a policy) has been articulated in any of the publicly available materials accompanying the EPBC Amendment Regulations (see, for examples, Department of the Environment and Heritage 2005a; Minister for the Environment and Heritage 2005). Further, there does not appear to have been an assessment of the CPA's requirement for competitive neutrality that necessitates an examination of whether governmental price setting (including no price) potentially undervalues government controlled biological resources. This was necessary as a 'too low' price (including no price) would be likely to undermine the private sector market for biodiversity conservation on State, Territory and privately held lands and water (see Productivity Commission 2001b, 5-7; CPA cl 3(5); see also Council of Australian Governments 2006b, 26-28).

On the contrary, the low administration and management fees (EPBC Regulations r 18.01) suggest that the intention was to impose as low a cost as possible on the bioprospector (see Department of the Environment and Heritage 2005a, 9) and avoiding any mention of Ministerial price setting (see Department of the Environment and Heritage 2005a; Minister for the Environment and Heritage 2005). An alternative explanation is a focus on legal provenance and promoting investment in biological resource-based product research and development that is more consistent with the Commonwealth's other commitments made in the *Australian Biotechnology: A National Strategy* (see Minister for the Environment and Heritage 2005, 2; see also House of Representatives Standing Committee on Primary Industries and Regional

Services 2001, 51-52). The objective was ‘to enhance access to Australian biological resources’ through ‘clear and transparent terms of access and conditions for the use of Australia’s marine and terrestrial biological resources’ (Commonwealth of Australia 2000b, 26; see also Prime Minister’s Science Engineering and Innovation Council 2005, 28). The strategies included ‘[r]esolv[ing] legal issues on the ownership of Australian biological resources’ and ‘[w]ork[ing] with sectoral interests to identify their resource needs in biotechnology, including in the utilisation of Australian endemic and exotic biological resources’ (Commonwealth of Australia 2000b, 26).

While the vision, objectives and strategies of the *Australian Biotechnology: A National Strategy* are undoubtedly worthy, they do not specifically address the market failure for biodiversity conservation and the appropriate price of access (or benefit sharing). They mention ‘conserving genetic and biological resources’ in the same ‘vision’ as ‘productive investment in biotechnology research and development’ and ‘secure access to genetic and biological resources’ (Commonwealth of Australia 2000b, 7). Importantly, however, the *Australian Biotechnology: A National Strategy* ‘objective’ to ‘[w]ork with the States and Territories to achieve nationally consistent regimes on access’ resulted in the *Nationally Consistent Approach for Access to and the Utilisation of Australia’s Native Genetic and Biochemical Resources* that expressly divorces the CBD objective of conservation from the objective of the fair and equitable sharing of the benefits from using biological resources (Department of the Environment and Heritage 2002a, 2-3; see also Biotechnology Liaison Committee 2005, 53).[3] The outcome has been to address the concerns of biodiversity conservation in other governmental programs (see, for example, Environment Australia 2001; see generally Au/NR/03), and use the EPBC Amendment Regulations as a forum to address the concerns of legal provenance and promoting investment (see also Department of the Environment and Heritage 2005a, 9). For example:

> The absence of consistent legislative frameworks across Australia for access and use of the genetic and biochemical makeup of our native biodiversity creates legal uncertainty. Where the burden of uncertainty, over-regulation and high transaction costs impact directly on the resources of parties willing to participate in biodiscovery, the process is slowed or stopped and competitive advantage lost. Legal uncertainty arises from the intersection of Commonwealth and State Laws including jurisdictional and territorial accommodations … For Australia to attract the investment to support its biotechnology industry in biodiscovery it needs to accelerate the introduction of legislation for

> legal certainty. Delay will see Australia losing investment to other jurisdictions (Prime Minister's Science Engineering and Innovation Council 2005, 22-23).

In essence, the EPBC Amendment Regulations appear most likely to configure values that focus more on legal provenance and promoting investment in biological resource-based product research and development than biodiversity conservation.

The problem with this approach is that if the purpose of the EPBC Amendment Regulations was to establish legal provenance and promote investment, then the form of regulation is central to achieving that purpose. So, for example, grants, tax concessions, indemnities, and other forms of incentive measures, might have been more appropriate, or perhaps even no regulation at all relying on the current market and existing contract laws (see, for example, House of Representatives Standing Committee on Primary Industries and Regional Services 2001, 37-38). These other forms of incentive might also have been expected to have been addressed in some detail by the CPA assessment in considering 'the options (regulatory and/or non-regulatory) that may constitute viable means for achieving the desired objective(s)' (Office of Regulation Review 1998, A2 and B3), and the preference for the chosen approach over the other possible means.

Some commentators have argued that the returns from bioprospecting are unlikely to be large enough to create any significant incentive for biodiversity conservation (see, for example, Simpson *et al* 1996; Craft and Simpson 2001). The inference from these studies is that the price of access to biological resources may effectively be ignored as that value will, at best, contribute marginally to the market for biodiversity conservation, and that other incentive measures are necessary (see Simpson and Craft 1996). It is perhaps possible that the Australian Government accepts this inference, and as a consequence, there was no need to include any assessment of the price of access into benefit sharing arrangements as they will be insignificant in the broader assessment of incentives to promote biodiversity conservation. While this inference is not universally accepted (see, for example, Rausser and Small 2000; Goeschl and Swanson 2002), the CPA assessment might have been expected to address this issue and articulate the Australian Government's particular perspective about the incentive measures and programs that have addressed the market failure for biodiversity

conservation. This expectation is not unreasonable as the Australian Government did proclaim its compliance with the NCP in formalising its commitments to the CBD (see Department of the Environment and Heritage 2005a, 5; Au/NR/03, 171; Commonwealth of Australia 2000a, 29; see also UNEP/CBD/WG-ABS/3/INF/1/Add.1, 6).

Perhaps a remaining question is what configured values should a CPA assessment have included to address access and benefit sharing? In short, this is an extremely complex question that requires a broad approach to identifying the value of biological diversity (see, for example, Department of the Environment and Heritage 2005b; see also Organisation for Economic Co-operation and Development 2001, 2002 and 2003a; Adair 1997) and the kinds of incentives necessary to promote its conservation (see Department of Agriculture, Fisheries and Forestry 2004; see also Department of the Environment, Sport and Territories 1996b). The solution probably does lie, at least in part, within the existing EPBC Amendment Regulations through its requirement that the Minister set the price of access (see EPBC Regulations rr 8A.06(1) and 17.01(ab)). The early economic modelling conclusions that prices for access to biological resources are likely to be insignificant (see, for examples, Simpson *et al* 1996; Craft and Simpson 2001; and continually perpetuated by the most likely beneficiaries of this perspective: see, for example, Finston 2005) have been challenged by a more sophisticated understanding about the kinds of values of biodiversity (see, for examples, Rausser and Small 2000; Goeschl and Swanson 2002; Zohrabian *et al* 2003; Kassar and Lasserre 2004; Tvedt 2006, 198-202), measures of diversity (see, for examples, Mainwaring 2001; Weikard 2002), methods of biodiversity valuation (see, for example, Department of the Environment and Heritage 2005b) and that the institution of the CBD (and the World Trade Organisation's (WTO) *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPS)) itself may be contributing to the undervaluing of biodiversity (see, for example, Goeschl *et al* 2005). Most importantly, however, economic modelling of the private and social values of preserving biological diversity (or at least the land and water set aside for conserving biodiversity) does suggests that in almost every circumstance the private value of allocating land and water to biodiversity conservation will be less than its social value (see, for example, Goeschl and Swanson 2002; see also Organisation of Economic Co-operation and Development 2001) so that setting a

price alone will not be adequate. The Minister needs to identify values and mechanisms that deliver sufficient private value to the land and water conservators that promote biodiversity conservation, and this will include a properly assessed price of access. Many of the benefits identified by the Australian Government are undoubtedly relevant (see Department of the Environment and Heritage 2005a, 9-10), but they need to be assessed in a way that delivers the benefit to the land and water conservators, rather than broader society. This will undoubtedly require some form of governmental intervention in addition to price setting. Other important considerations in assessing the price under the EPBC Amendment Regulations will also be in promoting a private market for biodiversity conservation (competitive neutrality; see, for example, Commonwealth Competitive Neutrality Complaints Office 2001) and making any subsidies in the form of under-priced access (less than the social value) transparent (Office of Regulation Review 1998, A3).

Unfortunately, the very uncertain values and consequences of *Patents Act 1990* (Cth) patents makes the price setting task harder because, not only do they confound ownership with uses, they are also an economic policy tool directed to a different market failure – the market failure for innovation and creation, and investment in innovation and creation (see, for example, Commonwealth of Australia 2001, 18). The following part considers the role and place of *Patents Act 1990* (Cth) patents. This is an important question as the CBD expressly recognises that patents and other forms of intellectual property should support the CBD's objectives including biodiversity conservation and sustainable use (Art 16(5)), and that Australia should adopt incentive measures that promote biodiversity conservation rather than its destruction and decline (Art 11).

4. Patents and the market failure for biodiversity conservation

The key question is assessing whether the EPBC Amendment Regulations is in effect an optimal form of regulation for conserving biological diversity is whether the marginal private returns from conservation activities are sufficient to at least correspond with their marginal social returns. If the private returns are less, then the destruction and decline of Australia's biological resource stock rather than its conservation can be expected. *Patents Act 1990* (Cth) patents and other forms of intellectual property take the place and role of delivering a part of the incentive and

compensation contributing to the marginal private return through the negotiated terms of the benefit sharing agreement (see Organisation for Economic Co-operation and Development 2003b; 18-19 and 109; see also Department of the Environment and Heritage 2002b, 4; Commission on Intellectual Property Rights 2003, 57-72; Australian State of the Environment Committee 2001, 110; Department of the Environment, Sport and Territories 1996a, 24; Department of the Prime Minister and Cabinet 1994, 36; see also Department of the Environment, Sport and Territories 1993). This is achieved, at least in theory, by capturing some of the value from innovative, creative and useful applications of the accessed biological resources and returning this as part of the price paid for access and use of the biological resources through the royalty or other benefits (such as access to and transfer of a new technology, and so on; see, for example, Prime Minister's Science Engineering and Innovation Council 2005, 6-9). In assessing the role of patents in addressing the broader question of whether the EPBC Amendment Regulations is an optimal form of regulation for conserving biological diversity, the question is whether patents can deliver value in addition to other benefit negotiated as part of the benefit sharing agreement, so that the marginal private returns from conservation activities (from all sources) are sufficient to at least correspond with their marginal social returns.

At least in theory, the property value established in the biological resources by controlling access under the EPBC Amendment Regulations can be distinguished from the value of the potential intellectual property from using that biological resource, so that some of the value of the intellectual property can contribute to the compensation and incentive for biological diversity conservation (for an overview of the issues see, for example, Swanson and Goeschl 2000, 79-85). At its most simple, property rights over the accessed biological resources under the EPBC Amendment Regulations deals with the tangible 'biological resources' (EPBC Act s 528 ('biological resources'); EPBC Amendment Regulations r 1.03). The *Patents Act 1990* (Cth) patents, meanwhile, relate to the intangible innovation and creativity in products and processes that result from using the biological resource. A patent under the *Patents Act 1990* (Cth) deals with an 'invention' that is novel, non-obvious, industrially useful and described in a way that can be followed by others (see *Patents Act 1990* (Cth) ss 18 and 40), and establishes 'exclusive rights' to certain dealings with the 'invention' (see *Patents Act 1990* (Cth) s 13). These are different economy

commodities, one the tangible biological resource and the other the intangible application of that biological resource for an innovative or creative and useful purpose. This may not, however, be so elegant in practice as a patent under the *Patents Act 1990* (Cth) confounds both the right to deal with the biological resource as it is embodied in a tangible form (such as a purified and isolated gene sequence, or a composition *per se*), and the right to prevent others from using the biological resource in other embodiments (such as the gene sequence in a diagnostic device) (see, for examples, Lawson and Pickering 2000; Lawson 1999; see also UNEP/CBD/WG-ABS/3/INF/4, 32-52). In short, the uncertainty arises because past claims (and disclosures in the public domain) to compositions *per se* may limit the value of future uses of the same or similar compositions, even where those uses are entirely different, because the patent's 'exclusive rights' are attached to the composition *per se* (according to its definition and description) rather than its many and varied useful application(s). As a consequence, the problems posed by the *Patents Act 1990* (Cth) is the potential to undermine the value of the accessed biological resource and other *in situ* biological resources by creating uncertain property and use rights in the tangible accessed materials, and the uses of that material in innovative or creative and useful embodiments, including other innovative or creative and useful embodiments (for overly broad patent claims to biological materials see Lawson and Pickering 1998 and for uncertain definitions and descriptions see Lawson 2004).

The *National Strategy for the Conservation of Australia's Biological Diversity* (Department of the Environment, Sport and Territories 1996a) may originally have acknowledged that existing property rights were not necessarily appropriate (Department of the Environment, Sport and Territories 1996a, 24) reflecting the concerns expressed in the CBD 'that patents and other intellectual property rights may have an influence on the implementation of this [CBD]' and 'that such rights are supportive of and do not run counter to its objectives' (CBD Art 16(5)). In particular, the *National Strategy for the Conservation of Australia's Biological Diversity* was concerned that:

> The development of integrated policies for major uses of biological resources is necessary to coordinate activities within and between all levels of government, to ensure that the full social and environmental consequences, and the opportunity costs, of development activities are considered,

> and to ensure that the public interest is properly taken into account (Department of the Environment, Sport and Territories 1996a, 17).

However, in articulating the *Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* there was express recognition that in introducing regulation for access and benefit sharing 'reassurance should be provided that arrangements do not alter existing property or intellectual property law' (Department of the Environment and Heritage 2002a, 7). Further, a 'comparative advantage' asserted in favour of the form of regulation is that Australia has 'a well-respected and long established system of commercial and intellectual property law that offers security to investors' (Department of the Environment and Heritage 2005a, 6). Perhaps this merely reflects the intellectual property 'cargo cult' in Australia (see Lawson and Pickering 2004), and the divorce between the perceived immediate needs of investment in biological resource-based product research and development ahead of other policy imperatives such as the longer term goals and benefits of biological diversity conservation. However, the consequence is to place a consideration of the most appropriate patents settings outside the consideration of whether they are contributing to or undermining biodiversity conservation, rather than integrating these policies to achieve the best biodiversity conservation outcomes.

If the Australian Government did, however, attempt to tailor patents to promote biodiversity conservation, the challenge in implementing any new patent arrangements would be in adjusting the schemes for patents and other forms of intellectual property to suit biodiversity conservation and sustainable use objectives. Unfortunately, any potential for change has most probably been significantly curtailed by its recent commitment to the *Australia-United States Free Trade Agreement* (AUSFTA). The likely effect of the AUSFTA will be to limit the options available for biological diversity conservation and sustainable use objectives to co-exist with, or take precedence over, the believed benefits of patents in promoting innovation according to the policy settings presently in place (see Lawson and Pickering 2004, 357-361 and 363-366). The following examples of 'most favoured nation' treatment and the failure to re-state the TRIPS principles and objectives illustrate this contention. Unfortunately these issues were not explored further in the public inquires

by the Parliament (see Joint Standing Committee on Treaties 2004; Senate Select Committee on the Free Trade Agreement between Australia and the United States of America 2004).

National treatment and most favoured nation are part of an international norm in the trade law of non-discrimination (see WTO's *General Agreement on Tariffs and Trade 1994* Art 1(a) and *General Agreement on Trade in Services* Arts 2 and 17). The AUSFTA's dealings with intellectual property is significant in that it makes provision for 'national treatment', requiring Australia and the United States to extend the same treatment to each other's national as it does to its own (Art 17.1.6), but makes no provision for 'most favoured nation' treatment. The exact application of the national treatment requirement under the AUSFTA remains uncertain as some derogation from the national treatment is allowed for 'judicial and administrative procedures, including requiring a national of the other Party to designate an address for service of process in its territory, or to appoint an agent in its territory', provided that it is 'necessary to secure compliance with laws and regulations that are not inconsistent with this Chapter' and 'not applied in a manner that would constitute a disguised restriction on trade' (Art 17.1.7), or World Intellectual Property Organization (WIPO) agreements dealing with 'the acquisition or maintenance of intellectual property rights' (Art 17.1.8). However, it is not clear (1) whether the national treatment exceptions in the WIPO's *Paris Convention for the Protection of Industrial Property* and saved by TRIPS remain (see Art 2(1)); and (2) whether Australia and the United States might apply different standards to other nationals avoiding the 'most favoured nation' standards. A likely effect is that the AUSFTA, by providing for national treatment and not for most favoured nation, will require Australia (and the United States) to accord the same treatment required by the AUSFTA to *all* other WTO members according to the TRIPS' most favoured nation requirement (Art 4). In implementing the AUSFTA the Commonwealth appears to adopt this approach applying the same patent standards to all nationals (see *US Free Trade Agreement Implementation Act 2004* (Cth) sch 8), suggesting that the AUSFTA probably does establish the minimum patent standards to be met by all applicants.

The consequence of failing to re-state the 'most favoured nation' standards in the AUSFTA may then be to entrench the patent standards articulated in the AUSFTA

(see Arts 17.1.1, 17.9.1, 17.9.2, 17.9.4, 17.9.5 and 17.9.7), and in particular losing the significant 'flexibility' in TRIPS to deal with other social and economic policy objectives that exist in TRIPS (Art 7) but are not restated in the AUSFTA (see Lawson and Pickering 2004, 357). If the TRIPS provisions dealing with other social and economic policy objectives are interpreted to mean that each provision of TRIPS should be read in light of these provisions, and that TRIPS co-exists with other public policy objectives (see IP/C/M/31, 4; IP/C/W/296, 5-6; WT/MIN(01)/DEC/2, 1), then TRIPS' patent standards might be tailored to meet other policy objectives including the transfer and dissemination of technology, public health and nutrition and socio-economic and technological development. This interpretation is certainly open to Australia and appears to be favoured by other WTO member states that consider TRIPS is sufficiently 'flexible' to enable member states to implement their TRIPS obligations as well as their other public policy objectives (see, for example, IP/C/W/296, 3 and 6). This interpretation is also consistent with the decision in *Canada – Patent Protection of Pharmaceutical Products* where the Panel rejected the European Union argument that the phrase 'provided that such measures are consistent with the provisions of this [TRIPS] Agreement' (Art 8(1)) meant that any other considerations beyond the patent holders rights were subordinate to the protection of the minimum intellectual property rights guaranteed by TRIPS (WT/DS114/R, 50). The Panel instead accepted that adjustments to a patent holder's rights were contemplated according to the objectives and principles (and other relevant provisions) of TRIPS (WT/DS114/R, 154), and expressed the view that these provisions were to be 'borne in mind', although a re-negotiation of the balance of TRIPS was not appropriate (WT/DS114/R, 154).

Thus, leaving TRIPS' principles and objectives provisions out of the AUSFTA probably confirms that Australia prefers to consider patents as a fixed and necessary incentive to promote investment in new inventions and, as a consequence, this promotes the objectives and principles of TRIPS. This is a view shared by other developed states (see, for example, IP/C/M/31, 36; IP/C/W/280, 2). In effect, the AUSFTA is likely to affirm that TRIPS, and the TRIPS-plus measures set out in the AUSFTA, override other regulatory schemes providing paramountcy of AUSFTA's standards over those articulated by TRIPS. The consequence for implementing the CBD in Australia is that patent (and other intellectual property) considerations are

likely to override biodiversity conservation and other CBD considerations, entrenching the patent as an end in itself, rather than a policy tool to be tailored to most efficiently and effectively address the market failure for biodiversity conservation.

Conclusion

The concern of this submission was not to review the extensive and contested literature on economics and conservation, but rather to point to the Australian Government's acceptance of a market failure for biodiversity conservation that required specific access and benefit sharing regulations (see Department of the Environment, Sport and Territories 1996a, 23; see also Department of the Environment and Heritage 2002a, 2-3). Once there was an assertion in the Australian Government's regulatory jurisdiction that regulation might be necessary to address a market failure (Department of the Environment, Sport and Territories 1996a, 23; see also Department of the Environment and Heritage 2002a, 2-3), and further that the regulation was consistent with the NCP (Department of the Environment and Heritage 2005a, 5; Au/NR/03, 171; Commonwealth of Australia 2000a, 29; see also UNEP/CBD/WG-ABS/3/INF/1/Add.1, 6), then the outcomes of the CPA assessment might be expected to have provided some insight into the configured values in the ultimate decision about how to address biodiversity conservation through regulating access and benefit sharing. A failure to release or disclose the RIS means that the configured values in justifying the regulation are open to speculation. Further, failing to comply with the CPA leaves open claims that the EPBC Amendment Regulations do not reflect informed governmental decision making or a necessarily desirable outcome (see Productivity Commission 2005, 140).

While a failure of process may appear to be of little consequence, the significant contention of this submission is that the likely configured values are likely to have been disclosed through that process and that in the EPBC Amendment Regulations those values are not about biodiversity conservation, but rather, something else. The speculated configured values are promoting investment in the biological resource-based product research and development industries. The key concern about this speculated approach is the apparent failure to address the CPA assessment for price setting access to Commonwealth controlled biological resources, and then the failure

to set a price that at least addresses the matching of the private and social values (or the subsidies for underpriced access). The role and place of *Patents Act 1990* (Cth) patents is to make this price setting yet more complicated by introducing another regulatory arrangement to address a different market failure and creating uncertain property and use rights that cannot be tailored to meet biodiversity conservation objectives. Patents in their present application may, in practice, be imposing an incentive that promotes biodiversity destruction and decline. This is a significant conclusion as it must also challenge the Australian Government's commitment to making sure that its *Patents Act 1990* (Cth) patents promote the CBD's objectives of biodiversity conservation and sustainable use (Arts 11 and 16(5); see also Organisation for Economic Co-operation and Development 2004b).

The likely solutions will lie with the future negotiation of the *International Regime on Access and Benefit Sharing* (see UNEP/CBD/COP/8/6, 22-28). The CBD's Ad Hoc Open-ended Working Group on Access and Benefit-Sharing has began developing 'targets and indicators for access to genetic resources and in particular for the fair and equitable sharing of benefits arising from the utilization of genetic resources' (UNEP/CBD/COP/8/5, 44). The kinds of 'outcome-oriented indicators' were notable in not including a link between benefits shared and levels of biological diversity conservation. But by setting a target and indicators there is at least explicit recognition of the value of biological diversity and possibly some accountability for sharing that value (Balmford *et al* 2005). The challenge for Australia in negotiating the proposed *International Regime on Access and Benefit Sharing* will be to develop ways of valuing biodiversity conservation and reflecting this value in the price of access so that the 'low price' for access to biological resources will match the 'high price' of other uses of the land and water promoting biodiversity conservation in favour of those other uses. In the meantime, the EPBC Amendment Regulations should be subjected to a proper CPA assessment and the most efficient and effective form of regulation adopted. This means that the regulation in force should be both 'efficient', in terms of 'minimising compliance and other costs imposed on the community' and 'effective' in 'addressing an identified problem' (Productivity Commission 2003, 1). This is important because if the Australia Government does consider the possible returns from bio-prospecting are unlikely to be large enough to create a significant incentive for biodiversity conservation, then this will colour the Australian

Government's negotiating stance for the proposed *International Regime on Access and Benefit Sharing* and focus attention on other mechanisms for balancing private and social values that promotes biodiversity conservation. Further, such an admission would also extinguish the expectation that bio-prospecting itself will deliver any direct benefits to the land and water conservators that might address the market failure for biodiversity conservation.

Notes

1. Meaning 'includes genetic resources, organisms, parts of organisms, populations and any other biotic component of an ecosystem with actual or potential use or value for humanity' and 'genetic resources' means 'any material of plant, animal, microbial or other origin that contains functional units of heredity and that has actual or potential value for humanity': EPBC Act s 528.
2. Meaning '(a) land owned by the Commonwealth or a Commonwealth agency (including land owned in Norfolk Island) and airspace over the land; (b) an area of land held under lease by the Commonwealth or a Commonwealth agency (including an area held under lease in Norfolk Island) and airspace over the land; (c) land in: (i) an external Territory (except Norfolk Island); or (ii) the Jervis Bay Territory; and airspace over the land; (d) the coastal sea of Australia or an external Territory; (e) the continental shelf, and the waters and airspace over the continental shelf; (f) the waters of the exclusive economic zone, the seabed under those waters and the airspace above those waters; (g) any other area of land, sea or seabed that is included in a Commonwealth reserve': EPBC Act s 528. It is notable that this *does not* include lands and waters held by the States, some Territory lands and waters and privately held lands and waters: see Commonwealth of Australia 2000a, 41-50; see also Commonwealth State Working Group 1996.
3. The key phrases being: 'Australia ratified the [CBD] in 1993. The Convention has three primary objectives, the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the use of genetic resources. This nationally consistent approach, addresses that third objective of the Convention and in particular responsibilities set out at Articles 1, 3, 6, 8(j), 10(c) 15, 16 and 19 …Objective

2.8 (Access to genetic resources) of that National Strategy states: “Ensure that the social and economic benefits of the use of genetic material and products derived from Australia's biological diversity accrue to Australia”. This nationally consistent approach addresses that objective’: Department of the Environment and Heritage 2002a, 2-3.

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United Nations, *Convention on Biodiversity* [1993] ATS 32.

World Intellectual Property Organisation's *Paris Convention for the Protection of Industrial Property* [1972] ATS 12.

World Trade Organisation, *Marrakech Agreement Establishing the World Trade Organisation* [1995] ATS 8, Annex 1A (*General Agreement on Tariffs and Trade 1994* Art 1(a)), Annex 1B (*General Agreement on Trade in Services* Arts 2 and 17) and Annex 1C (*Agreement on Trade Related Aspects of Intellectual Property Rights*).