A Submission to the Parliamentary Inquiry into "Development of high technology industries in regional Australia based on bioprospecting"

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Summary

There is high potential for the discovery and commercialisation of new and valuable pharmaceutical, agricultural and industrial chemicals from Australia's unique and diverse plants and animals.

Bioprospecting best describes only to the initial material collection stages in the process of developing new chemical products from our biota. The full process comprises the following stages: discovery (of which bioprospecting is only one part), protection of intellectual property, product development, product manufacturing, and marketing.

There are currently significant bioprospecting activities underway in Australia, but because many of these basically sell unprocessed samples overseas, their value to the Australian economy and community is highly questionable.

We currently grossly undervalue our biological resources in terms of their potential for new and valuable chemical products.

Community ownership of our biological resources and associated issues of access rights and royalties need to be more clearly and unambiguously defined.

Export of our biological resources in raw, unprocessed forms (e.g. as freeze dried material or crude extracts) where there is little intellectual property entailed, or little other value adding, should be strongly discouraged or halted.

We should be value-adding by further developing and commercialising chemical products from our biota 'on-shore'. The infrastructure, skilled population base and appropriate expertise in relevant areas of science, technology and industrial processes to do this already exist within Australia in a range of Australian and multi-national companies, and in Universities and government research agencies.

Accessing capital for research and development to underpin the early stages of product development following discovery of new chemicals from our biota is a critical impediment to Australian start-up biotechnology companies.

To date, regional Australia has benefited little from bioprospecting, however, opportunities do exist to create jobs in regional communities especially in the discovery and early product development stages. Appropriate business development programs and support services for start-up companies in the biotechnology area should be better targeted for regional Australia – regional based companies are currently the disadvantaged 'poor cousins' in this respect.

Properly managed bioprospecting and bio-development of new chemicals from our flora and fauna should have negligible impacts on the natural environment. Indeed, as new useful chemicals are discovered and developed from our biota, the community will begin to better appreciate the true value of our unique biological 'assets'.

Policy and other initiatives from Government (both Federal and State) that would foster and facilitate the development of biotechnology industries in Australia based on chemicals discovered and derived from our biota include:

- more rigorous protection of our biological resource (i.e. minimising the loss of our 'raw materials' offshore) to maintain a competitive edge for Australian companies and multi-nationals that have made a commitment and investment in research and development (R & D) within Australia;
- providing a clear legislative framework for accessing our biological resources;
- incentives for capital investment in R & D in Australian start-up companies involved in discovery and development of new products from our biota;
- initiatives or programs to advise and assist start-up companies in effectively protecting their intellectual property;
- incentives for progressing further 'downstream' development of these products (and intellectual property) within Australia, both for local and multi-national companies that have investment and production facilities in this country; and,
- better targeting assistance for the development of regionally-based start-up companies involved in discovery and early product development.

Detail of Submission

The potential for new pharmaceutical, agricultural and industrial chemicals from Australia's biota?

Despite advances in laboratory methods and sophisticated computer applications for 'creating' new chemical structures (so called 'combinatorial chemistry'), nature still provides the major source of lead molecules for the development of pharmaceutical, agricultural and industrial chemicals.

With our unique and diverse flora and fauna, and wide range of physical environments across the continent (from tropical rainforests, to deserts, woodlands, alpine areas and coral reefs), Australia's biota is potentially an extremely rich source of such useful chemicals. Although some of our biota have been examined for particular groups of chemicals and / or particular biological properties, there are very significant opportunities to discover and develop new products. Examples of some of the types of products that could be derived from our biota include:

- Antibiotics
- Fungicides
- Insecticides
- Antivirals
- Antiprotozoals
- Anti-tumour agents
- Muscle relaxants & sedatives
- Sunscreens & energy dispersing compounds
- Herbicides
- Adhesives
- Industrially useful enzymes
- Perfumes & fragrance chemicals

How we best explore and harness our biological resources to discover, develop and effectively commercialise these chemicals for maximum long-term benefit to the Australian economy and community is the key question.

In terms of providing input to the Committee's deliberations on how to maximise capture of benefits for Australia (especially regional areas), it is useful to first briefly outline the key stages in commercialisation of new chemicals. These are:

- ***Discovery***: collecting of material, screening for particular useful properties or 'bio-activities', describing new chemical structures;
- ***Protection of intellectual property***: largely patenting of new structures and / or specific types of bioactivity (e.g. antibiotic, insecticidal or anti-tumour properties);

- ***Product development***: isolation and purification of the new and active chemicals, modification to chemical structures to improve their efficacy, clinical and / or field trials to demonstrate and compare the effectiveness and safety of the product with others currently on the market;
- ***Manufacturing***: developing techniques for larger scale industrial production of the chemicals (e.g. by total laboratory synthesis or by purification from cultivated biological material); and,
- ***Marketing of the final product***.

At any of these stages, the source material or product can be sold or licensed to another company. The further down this development sequence a product is taken, the greater the investment and infrastructure that is required. However, the value of the products and potential economic returns are also much higher.

Bioprospecting usually only refers to the initial collection part of the first stage of the above commercialisation process for new chemicals. I have adopted this narrow definition of bioprospecting in this submission to the Inquiry, but will also suggest that opportunities for Australia extend well beyond bioprospecting to later stages in the product development and commercialisation process.

My comments are provided as the Managing Director of a start-up biotechnology company, EcoBiotics Pty Ltd, based in regional Australia and involved in commercialising new chemicals from Australia's tropical rainforests. Our experience and perspectives on key issues, opportunities and impediments in developing such an industry in regional Australia may be of particular interest to the Committee.

Bioprospecting – current status and benefits to Australia.

There are significant bioprospecting activities currently occurring in Australia, usually focussed on the process of collecting and selling biological materials (e.g. freeze dried specimens or crude extracts) overseas to large pharmaceutical and agro-chemical companies. The key commodity being traded is the genetic resource. Unfortunately, this currently entails little genuine intellectual property and consequently is a relatively low value process. Although the 'commodity' (the biological resources) occurs largely in regional Australia, even the collectors are often only in transit on 'expeditions' from the capital cities in which they are based. There also appear to be few mechanisms where the genetic resource rights for this material are adequately captured by Australia. Under the definitions in the appropriate articles of the Convention for Biological Diversity, some of the current bioprospecting in Australia could be interpreted as 'biopiracy'.

Overall, the value or return from many of the current bioprospecting activities to the Australian economy and the broader community is highly questionable. In our view, there are two issues related to bioprospecting and export of 'unprocessed' biological materials from Australia that need to be addressed urgently. These are that:

- we are grossly undervaluing our biological resources (chemical and genetic) by selling them off overseas much too cheaply with few of the benefits of commercialisation likely to flow back to Australia
- we are inadequately addressing the issue of community ownership of our biological resources.

In relation to the first of these, there are opportunities even at this basic level of 'provision of raw material' to value add to the process by using a stronger knowledge base to target collections. By being able to provide materials that are likely to yield higher levels of potentially new chemicals, it is possible to command a premium in the marketplace. An example is the approach we use at EcoBiotics. We have developed a powerful method to target materials that are promising sources of new chemicals with specific types of activities based on our knowledge of tropical forest ecology. Our approach results in a bioactivity hit rate of greater than 67% of our samples, while the industry average from 'traditional', non-targeted bioprospecting is usually less than 8%. Although we are not interested in selling our 'raw' materials (because we aim to value-add by moving to at least the patenting and product development stages within Australia) we have been approached and offered significantly higher prices for our crude extracts than is the industry standard, in some instances up to 10 times as much. This clearly shows that some value adding is possible even at this early stage in the product development sequence. As an aside, by using a knowledge-based pathway to discovery we can not only value-add but also better demonstrate and subsequently protect our intellectual property.

In relation to ownership and export of materials, we are unaware of the intricacies of legislative frameworks that relate to these issues, but on principle, our position is that we should at least have stronger legislation and regulation to severely limit or halt the flow of our biological resources offshore for commercial and chemical research purposes. Australia must capture more of the benefits of its unique biological resources, both for industry and the community. If we are to continue to export any of these 'raw' materials overseas, we should be ensuring that appropriate resource access rights and agreements for bioprospecting have been negotiated with the relevant State governments and that details of exported materials are well documented. Either some form of export duty on the raw material or a longer-term royalties agreement with the relevant State governments for any future products developed should be prerequisites before export of material is allowed. Ideally however, we should be providing strong incentives for local

and multi-national companies with investment and infrastructure in this country to further develop these products onshore.

Even for bioprospecting where there is some further onshore processing and value-adding on materials, genetic resource access and ownership issues need to be clarified. For example, at EcoBiotics we are currently in the process of negotiating a resource access and benefits-sharing agreement with the Queensland Government. Although we are not exporting materials overseas and intend to significantly develop the products within Australia, we still believe that it is essential to recognise that the biological resource that is being commercialised is, under the terms of the Convention of Biological Diversity, the property of the Australian community. Perhaps any such future royalties from products developed could be directed by government to conservation initiatives or to community projects in regional Australia from which the biological resources originated.

Beyond bioprospecting – onshore value adding to maximise the benefits for Australia

From our perspective, Australia should be looking well beyond this basic provision of raw materials. We should be putting in place mechanisms and incentives to developing products from our biota that have been significantly value-added within Australia and have clear pathways of intellectual property. Such intellectual property can be protected in the international marketplace. Being the only country in the developed world with a 'mega-diverse' flora and fauna we have some distinct competitive advantages in developing new pharmaceutical and agricultural chemicals that we should be using much more effectively. These are:

- Foremost, our unique and diverse biological resources are a valuable asset
- Our good education standard provides a 'technology literate' workforce
- Our strong scientific knowledge-base, infrastructure and general research capacity in relevant areas such as chemical ecology, chemical characterisation of natural products, synthetic chemistry, clinical medicine, and agricultural research (in most of which we are recognised internationally for our leading edge, innovative research capability); and,
- Our industrial infrastructure, stable government and legal institutions.

Taken together, all of these components should allow us to very competitively develop and protect new products and biotechnologies (derived from our biota) for the global pharmaceuticals and agrochemicals markets.

The critical issues associated with this onshore value-adding are:

1. protecting our biological resource (i.e. minimising the loss of our 'raw materials' offshore) to maintain a competitive edge for Australian companies and multi-nationals that have made a commitment and investment in research and development within Australia;

2. providing a clear legislative framework for accessing our biological resources (a basis for securing access and identifying royalty pathways);

3. accessing capital to back the research and development that underpins the early stages of product development (e.g. via low interest loans, tax breaks and other incentives to R & D investors etc);

4. assisting start-up companies to effectively develop their business and protect their intellectual property via patents (e.g. increased funding to schemes like COMET to aid in business development; low interest loans to help offset high patenting costs);

5. policy and incentives to encourage further downstream development of these products (and associated intellectual property) within Australia; and,

6. better targeting assistance to regionally-based biotechnology start-up companies which recognise some of the unique problems that they face.

Currently it would be feasible to progress new chemicals discovered from our biota to the end of the product development stage totally within Australia. We have the biological resource and the expertise to develop the products, run clinical trials and protect our intellectual property. Manufacturing on-shore is more problematic but there are certainly examples of local companies (e.g. Herron Pharmaceuticals, Fauldings) and a significant number of multi-nationals with manufacturing facilities in Australia.

What opportunities for regional Australia?

Although most of the nation's biological resources are located in regional Australia, it is apparent that communities in these areas have received little benefit from bioprospecting activities to date. However, there are opportunities for biotechnology industries based on our biota to make a larger contribution to regional economies and communities, especially during the 'discovery' and early product development stages.

Our experience at EcoBiotics provides a good example of this. We are based in Yungaburra on the Atherton Tableland near Cairns in north Queensland.

We are located near to the biological resources that we access for our discovery program. Our understanding of the local environment and ecology of the biota is one of our key competitive advantages; our discovery program would be much less successful if we were not located in close proximity to forests that we access for materials. However, in addition to just collection of material, we also have a well equipped laboratory in Yungaburra that allows us to do all necessary sample preparation, initial activity screening, bioassays, and extract purification on site, demonstrating that these activities can be undertaken successfully in regional Australia. As our company grows we plan to take on further staff to run this facility. Our location in regional Australia is a conscious decision, the strength of our business is in the discovery stage, we feel that this is most effectively done near the resource we are accessing.

As we progress further in product development, more infrastructure is required and smaller regional centres become less suitable. At EcoBiotics we plan to remain a regionally based company and to either outsource or enter strategic alliances with other companies, government laboratories and / or universities which have expertise in chemical characterisation, clinical and field trials, etc to further develop our products. These product development activities by their nature, infrastructure and workforce requirements will be largely based in capital cities.

Overall, we believe that Australia can get smarter at the discovery process by using knowledge of the ecology of our biota and the environments in which they live. This provides a genuine opportunity for development of knowledge-based businesses in regional Australia. However, there are some impediments to this. For example, from our experience the costs early in the life of the business associated with travelling to capital cities to participate in investment seminars appropriate to biotechnology, business skills training courses, 'networking' and negotiating with Government agencies are often prohibitive of frequent contact. Although business development seminars and programs are provided in regional areas their focus is generally inappropriate for start-up companies in biotechnology and other knowledge-based industries. There is also a degree of 'chauvinism' in the biotechnology community (and to a lesser extent government) in dealing with regionally-based biotechnology companies --- why aren't we based where the action is in the 'intellectual and financial hothouses' of our capital cities? For discovery companies like EcoBiotics, the biological resources in regional Australia are where the action is!

Environmental impacts and benefits

Properly managed bioprospecting for new chemicals from our flora and fauna requires only very small amounts of material (grams) to be collected initially, and has negligible impacts on the natural environment. Subsequent

collections from target species may be required for further product development (e.g. detailed characterisation of the active chemicals). However, again only small quantities are required and impacts are minimal.

If chemicals are advanced to the manufacturing and marketing stage, and these chemicals cannot be synthesised in the laboratory, a source of living material will be required. However, this should not be sourced from the wild and would involve cultivation of the species in plantings (as occurs for the Mexican yam which is the source of the base chemicals for the contraceptive pill and most cortico-steroids). The cultivation of these species in plantations may create additional opportunities for benefits to flow to regional Australia – farmers could diversify to produce new-high value primary products as source materials for the chemicals industry.

Interestingly, there are also potentially positive impacts for the conservation of our native flora and fauna through the development of a biotechnology industry based on chemicals derived from these organisms. The new economic values associated with commercialising these resources and the contributions of these products to human health and agriculture will be increasingly appreciated by the community. Hopefully, this will translate into recognition of the need to adequately protect the genetic diversity of these unique biological 'assets'.

Concluding remark

We have within Australia all the essential building blocks to develop a profitable and vibrant biotechnology industry based on our unique biota. Such an industry has the long term potential to make a significant contribution to our future economic well-being. What is required urgently are policy initiatives from Government to help "devise the plans" and "provide the mortar" to build this future.

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