



Bioprospecting

Suspicion and mistrust:

Providers and users of genetic diversity are increasingly estranged. As biodiversity-rich developing nations learn to assert their sovereignty rights under the CBD, they may become oversensitive to bioprospectors based on memories of colonial times when Africa was used as a free source of plants. This occurs even when research is not for commercial gain, and the reputation of all is tainted by those that have committed biopiracy.

Lack of legal clarity:

There is a need for clearer, more specific rules on how origins of samples and IK are recorded and their benefits shared, both nationally and internationally. Should the commercial benefit accrue to those who discovered the active ingredient or the biotech company able to identify/improve on this key ingredient? These issues have to be resolved in South Africa for companies to be willing and able to use our resources.

Greater sector involvement:

Many sectors actively involved in bioprospecting remain ignorant of the regulations, and are committing biopiracy. Education and participation in relevant international and national discussions is needed to ensure regulation across all sectors.

Case Study: Honeybush - a unique South African herbal tea

South Africa produces about 200 tonnes of unique honeybush tea each year. Most of this commercial crop is exported, with 35% going to the Netherlands, 20% to the UK, 17% to Germany and 14% to the USA exports. There are many different species of honeybush, and the most successful commercial species are bergtee (*Cyclopia intermedia*), vleitee (*Cyclopia subternata*) and kustee (*Cyclopia genistoides*). Another species, *Cyclopia maculate*, grows naturally around Genadendal in the Western Cape. In a three-year project funded by the Department of Science and Technology (DST) from 2009 to 2012, researchers from the South African Agricultural Research Council, the Medical Research Council and Stellenbosch University worked closely with members of the Genadendal community and neighbouring Bereaville community to work toward establishing ways to successfully grow this species on a commercial scale in the area. In this time, two trial plots were established, with the goal of establishing sustainable production of the crop by the town's small scale farmers. One of the community farmers involved in the project has continued his involvement through another DST-funded project that commenced in 2013.

The project successfully produced a guide for the cultivation of honeybush, which is now being used by existing as well as new, small and emerging honeybush producers.

The guide contains practical tips on topics ranging from how to prepare the soil to how to harvest the bushes. It is hoped that the guide will boost the honeybush crop by supporting the farming of honeybush. The project also produced a flavour and sensory wheel for honeybush, as a communication and quality control tool for the honeybush tea industry.

The intention of the project was that the shared approach would ensure a successful enterprise in which indigenous knowledge (IK) would provide a commercially valuable product that would benefit both the consumer and the community from which it was sourced, and from which it would continue to be cultivated and processed.



This fact sheet has been reviewed by independent experts and has followed SAASTA's Scientific Editorial Process.
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What is bioprospecting?

Bioprospecting, also known as biodiversity prospecting, is the exploration of biological material for commercially valuable genetic and biochemical properties. In simple terms, this means the investigation of living things to see how they can be commercially useful to humans. Small samples of natural resources are collected for their potential value to industry, particularly in the pharmaceutical, biotechnology and agri-business fields. Local communities close to where the material originates may have specialised knowledge on how the resources are used, which can also be collected, and this is known as traditional or indigenous knowledge (IK).

Biological diversity (biodiversity) refers to all living things, including plants, animals, insects and marine life. New technologies are also now enabling microbes to be investigated. However, not all investigations on biodiversity are considered bioprospecting: academic or conservation research is excluded from the term. Nor does it include commercial use of natural resources e.g. medicinal plants as trade commodities. However, gone are the days when scientists could "bring home suitcases of leaves, mushrooms or whatever which would often be sold for cash". When biodiversity or related knowledge is collected without permission from the owners of these resources and used for commercial gain, it is known as biopiracy.

Why is it needed?

The underlying aim of bioprospecting is to find new resources and products from nature that can be used by humans. Improving human health, through both medicine and better nutrition are key focal areas. Bioprospecting plays a dominant role in discovering leads for drug development, since existing/known compounds for developing drugs for human use are limited. Nature can provide original novelty and complexity that can be modified in the laboratory.

A study showed that between 1983 and 2003, almost two thirds of anti-

cancer agents being investigated as drug candidates were derived from natural products. Between 1981 and 2006, 47% of cancer drugs and 34% of all small molecule new chemical entities for all disease categories were either natural products or directly derived from them.

Other related sectors, such as crop plant biotechnology, screen natural resources for useful traits, such as disease resistance, but tend to focus more on modern varieties of crops with an emphasis on improving performance and farming efficiency.

Where is it happening?

Although bioprospecting can happen wherever there is biodiversity, it tends to be focused where biodiversity is at its richest, as this raises the chances of finding something useful. Statistically, the chance of a successful "hit" is one in 10,000 for synthetic compounds and one in 30,000 or 40,000 for natural products.

Extreme environments and unique ecological niches, such as Antarctica, are also good sources for diversity. Yet, only a tiny fraction of the world's biodiversity has actually been explored and the richest areas of biodiversity tend to be in developing countries. Legal uncertainties are also causing companies to opt out from bioprospecting in some countries.

How is it done?

Bioprospecting can be divided into three phases: collection, scientific research and analysis, and commercialisation.

Samples and/or indigenous knowledge related to a sample are collected, and then undergo systematic scientific investigation – using a variety of different technologies. In the early days, such research was very time consuming and costly, but in the late 1980's techniques were significantly improved, making the screening of natural product

molecules simpler, faster and easier – a factor which affects both the impact and level of bioprospecting. For example, novel and naturally occurring antibiotics are still being discovered from natural products' libraries that are decades old. These advances ultimately mean that the demand for new natural collections will decline – as existing collections and local biodiversity are studied more comprehensively.

Once a "hit" has been identified, it can take 20 years (depending on how the material is used) before the final product completes clinical trials and can be commercialised. For example it can take 12-15 years and upward of US\$800 million in direct and non-direct costs to bring a drug to the US market. Only 20% of drugs that begin clinical testing proceed to trial and eventually for marketing approval - and only three out of 10 drugs that are finally marketed recoup their development costs. It is a long and costly process which may result in little or no benefits.

Who does bioprospecting?

Bioprospecting cuts across a range of different sectors, including the pharmaceutical, agribusiness (biotechnology, seed, crop protection and horticulture), cosmetic and personal care, fragrance, botanicals, and the food and beverage industries. However, the degree and way in which these sectors access and use these resources vary significantly. The pharmaceutical and agri-business sectors are more involved, whereas, the cosmetic, fragrance, botanicals and food and beverage industries still "do" bioprospecting, but are not always aware of, or compliant to, the regulation and legislation and may commit biopiracy by commercialising natural resources. In the past 15-20 years, large pharmaceutical companies have scaled back their bioprospecting activities and closed their natural products programmes. This is due to the "slim pickings" and extensive financial outlay required, combined with complex negotiations over intellectual property (IP). Natural products research is very resource intensive – requiring lots of money, people and expertise, making large companies reluctant to get involved again significantly. Instead, smaller, focused companies are becoming productive – obtaining leads and "hits" and then working with the larger companies to develop the products.

Today, most natural products research is undertaken in academic and government research institutes or in smaller discovery companies.

Regulation of bioprospecting

The politics of bioprospecting are highly complex and continue to hinder natural product development. The most significant change and the starting point of international regulation and legislation took place at the Rio Earth Summit in 1992, when participating countries discussed bioprospecting and signed the Convention of Biological Diversity (CBD). The CBD recognised the need for conservation, sustainable use and equitable

benefit sharing as cornerstones, and, for the first time, acknowledged the sovereign rights of countries over their natural resources. It meant that biodiversity could no longer be regarded as common property and that the origin of the material used was recognised.

In 2003, international negotiations began for a legally-binding international regime on access and benefit sharing (ABS) in relation to biological resources and traditional knowledge. On 29 October 2010, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity was adopted. It will enter into force 90 days after the fiftieth instrument of ratification. Currently it has 92 signatories and 26 ratifications. South Africa ratified the Protocol in January 2013. Its objective is the fair and equitable sharing of benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity.

In South Africa, a number of national policy documents relevant to bioprospecting emerged over the years since the CBD, but bioprospecting-specific legislation came into play in the form of the National Environmental Management: Biodiversity Act, 10 of 2004 (the Biodiversity Act). Prior to this, developing biological diversity commercially involved bilateral agreements between those desiring access to genetic resources (typically a foreign company/research institute) and those providing access (typically a local research institute). Regulations relating to bioprospecting (Chapters 6 and 7 of the Biodiversity Act) came into force on 1 April 2008 - providing a more relevant legal framework for bioprospecting activities. The Bioprospecting, Access and Benefit Sharing (BABS) Regulations of 2008 require users of biodiversity to first obtain permission to commercialise local biodiversity or related knowledge. They must also ensure that they share benefits fairly with holders of knowledge and those providing the biological resources. If applications are in order, bioprospecting and export permits are issued by the Minister of Environmental Affairs, since the Act is enforced and implemented by the Department of Environmental Affairs (DEA). The Act provides for a Biodiversity Trust Fund where all financial benefits will be deposited for redistribution to communities.

The Biodiversity Act is further complemented by the Threatened or Protected Species (TOPS) Regulations, CITES Regulations, the National Biodiversity Framework,

the Provincial Ordinances, the Patents Amendment Act, 2005, and the Indigenous Knowledge System Policy, as well as various norms and standards for biodiversity management. The Department of Environmental Affairs has published South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework: Guidelines for Providers, User and Regulators, which outlines regulations and policies around bioprospecting.

Although the regulations are a significant step forward in the ABS of bioprospecting, there are a number of problems with this relatively new legislation, including:

- Limitations on ensuring the benefits of bioprospecting go to the wider community i.e. and not a landowner or research institute only;
- Capacity development (training and education) for those involved in implementing the CBD and ABS regulations (i.e. government) and in the wider communities and interest groups affected by the regulations. The lack of know-how and specifics of the system are currently causing companies to opt out from using traditional knowledge;
- The establishment of a Task Team has been proposed to advise the Department of Environmental Affairs on ABS regulations and the development of SA positions on the negotiations of an international regime on ABS;
- Greater attention to how beneficiaries are identified, especially indigenous communities – including the development of clear, concrete principles and tools for all the parties involved in bioprospecting;
- Regular review of the regulations and remaining up to date on related issues. Related legislation, South Africa's Patent Act, 57 of 1978, has also been amended to reflect the commitment of South Africa to disclose the origin of genetic material and traditional knowledge by current patent holders.

What is happening in South Africa?

South Africa is recognised as the third richest centre of biodiversity in the world, having well over 20,000 indigenous plant species, apart from animal, marine and microbial diversity.

South African scientists first began looking at the properties of local plants due to farm livestock losses caused by grazing on toxic plants, and at indigenous plants

eaten by rural communities. This well-developed research capacity, combined with the rich biodiversity and traditional knowledge, makes South Africa a prime location for bioprospecting. A 1996 review of bioprospecting activities in South Africa showed almost all research institutes in South Africa to be involved in bioprospecting in one form or another.

In May 2013, during the 2013/1024 Budget speech, the Deputy Minister of the DEA stated that, since the BABS Regulations came into effect in April 2008, the DEA had successfully issued ten permits, whose applications were found to be in compliance with the legislative requirements of the Act and the BABS Regulations.

"Home grown" examples of bioprospecting include the development of South African plants for ornamental horticulture products by the US-based company, Ball Horticulture and, more recently, the identification of a potential new antibiotic from SA soil samples by the pharmaceutical company Merck, as well as a SA Department of Science and Technology-funded project to commercially cultivate a unique African herbal tea in the Genadendal area of the Western Cape (see box).

Indigenous Knowledge

Traditional or indigenous knowledge (IK) is local knowledge that is unique to a culture or society. It is passed down through generations, usually by word of mouth and cultural rituals, and has been the basis for agriculture, food preparation, health care, education, conservation and the wide range of other activities that sustain societies in many parts of the world. The use of IK is even more complex than that of genetic resources and ABS related to IK remains very unclear as no one case is the same. As a result of these complexities, many companies simply avoid using IK altogether and instead obtain material from international or national genebanks where the process is often clearer. When IK is pursued in a country relating to a specific resource, companies tend to use local intermediaries to liaise with local communities as they are considered "better equipped to do so".

Key issues & challenges

Conservation versus exploitation:

Conservation is not always the top priority of nations, and some seek to make a quick profit from their natural resources rather than preserving them. As a result, the biodiversity they wish to exploit is disappearing. Bioprospecting profits could be used to finance biodiversity conservation in species rich developing countries and non-financial benefits could be shared through technology and knowledge transfer to enable these nations to research and conserve their own biodiversity.

