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ACCESS AND BENEFIT-SHARING IN PRACTICE:

Trends In Partnerships Across Sectors

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ACCESS AND BENEFIT-SHARING IN PRACTICE:

Trends in Partnerships Across Sectors

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Cover Photos (top to bottom): *Plectrantus "Mona-lavender", a variety of a South African plant, developed and commercialised under the Ball-SANBI bioprospecting agreement* Adam Harrower, South African National Biodiversity Institute; *Teff plant* Suhel al-Janabi, GeoMedia GbR; *Divers,* Courtesy of the Queensland Museum; *Harvesting of prunus africana,* Suhel al-Janabi, GeoMedia GbR

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FOREWORD

At the World Summit on Sustainable Development, in Johannesburg, in 2002, Heads of State called for action to negotiate, within the framework of the Convention on Biological Diversity, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

In response to this call for action, the Conference of the Parties to the Convention on Biological Diversity, in 2004, mandated a subsidiary body—the Ad Hoc Open ended Working Group on Access and Benefit-sharing—to negotiate an international regime on access to genetic resources and benefit-sharing and to complete its work as early as possible and no later than 2010.

In order to further a better understanding of access and benefit-sharing in practice, the Conference of the Parties requested the Executive Secretary to gather information and to carry out further analysis on a number of issues, including "access and benefit-sharing arrangements in specific sectors" and "existing practices and trends with regard to commercial and other utilization of genetic resources and the generation of benefits" (decision VII/19D).

Genetic resources are used by different types of users (e.g. academics, scientists, private companies), in different sectors (e.g. pharmaceutics, biotechnologies, seed and crop), for different purposes (e.g. basic research, commercialization). In addition, with the development of new technologies, the transformation and use of genetic resources in recent years has rapidly evolved.

Although the issue of access to genetic resources and benefit-sharing has attracted increasing attention in recent years, only piecemeal information is available with respect to its application and the challenges faced in implementing access and benefit-sharing arrangements.

In order to respond to the above requests by the Conference of the Parties, the Secretariat commissioned two recognized access and benefit-sharing experts, Sarah A. Laird and Rachel Wynberg. Director of People and Plants International, Ms. Laird has researched and written extensively on access and benefit-sharing issues, including the coauthoring of a well-known publication entitled "The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-sharing" published in late 1999. Dr Rachel Wynberg is an environmental policy analyst and academic based at the University of Cape Town, South Africa. She has also published extensively on the issue of ABS and has a large experience at the national and regional level, in South and southern Africa, related to the development of ABS legislation and dealing with access and benefit-sharing cases in practice.

A first study examining the commercial use of biodiversity, in particular the demand for genetic resources and market trends, was commissioned by the Secretariat and made available as an information document at the fourth meeting of the Working Group on Access and Benefit-sharing in December 2005. This study is available in Volume III of this publication.

A second study was commissioned, and made available at the sixth meeting of the Working Group on ABS, to examine access and benefit-sharing arrangements in different sectors based on recent literature, the analysis of ABS contracts and agreements, interviews with representatives from industry, government, NGOs, international agencies, and research institutions. This study is contained in Volume I of this publication. In addition seven case studies were selected for detailed analysis and are included in Volume II.

Taking into account the information provided in Volumes II and III, Volume I provides an overview of key sectors, including market and research trends, and the demand for access. It also provides key findings across

sectors relating to prior informed consent and negotiations, agreements, compliance and tracking, benefit-sharing, intellectual property rights, and partnerships and arrangements.

I wish to thank the authors for undertaking this work and presenting their findings clearly and succinctly. I am also grateful to the United Nations Environment Programme, which provided part of the financial support needed for this initiative.

As the negotiations of the International Regime on access and benefit sharing are entering a crucial phase under the able leadership of Mr. Fernando Casas from Colombia and Mr. Tim Hodges from Canada, the co-chairs of the Working Group, I sincerely hope that this publication can contribute to shedding some light on current ABS practices and usefully inform the negotiation process.

Ahmed Djoghlaf

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VOLUME I: OVERVIEW

Study on Access and Benefit-Sharing Arrangements—An Overview

Sarah Laird and Rachel Wynberg

1. INTRODUCTION AND BACKGROUND

This study explores access and benefit-sharing (ABS) agreements and practices in different sectors of industry. Despite a flurry of interest in these arrangements in the 1990s, there have been surprisingly few studies to track their evolution, and current understanding with regard to their implementation and status is somewhat unknown. Addressing this gap is essential to ensure that ongoing negotiations to develop an international regime are informed by best practice and lessons learnt from implementation.

A wide range of sectors undertake research and develop commercial products from genetic resources. They include the pharmaceutical, biotechnology, seed, crop protection, horticulture, cosmetic and personal care, fragrance and flavor, botanicals, and food and beverage industries. Each sector is part of a unique market, undertakes research and development in distinct ways, and uses genetic resources and demands access to these resources very differently (Laird and Wynberg, 2005). They also enter into partnerships with providers of genetic resources in distinct ways, have specific sets of stakeholders, negotiate prior informed consent in diverse ways, and have different approaches through which they reach mutually agreed terms with regard to benefit-sharing and intellectual property. Agreements within and across sectors also vary considerably with regard to the legal remedies they use for compliance and enforcement.

This study fills gaps in current understanding of ABS partnerships, collaborations and contractual agreements in the range of sectors using genetic resources. It looks at the nature of these relationships, and whether and how they achieve the objectives of sustainable use and equitable benefit sharing. Also examined are the characteristics and procedures common to different sectors seeking access, and sharing benefits. These include: prior informed consent; the negotiation of mutually-agreed terms, including benefit-sharing (non-monetary and monetary, and technology transfer and capacity-building associated with partnerships), and intellectual property; legal agreements/contracts employed; and compliance and legal remedies if contracts are breached. The nature of these procedures and arrangements for different stages of the research, development and commercialization process is explored, together with an examination of the implementation and monitoring of ABS. A comparative analysis across sectors elucidates practices that are working well, those requiring attention, and some of the lessons learnt for best practice.

The scope of this study is primarily focused on genetic resources—genetic material of actual or potential value—as part of the ABS component of the Convention on Biological Diversity (CBD). However, a number of the sectors that make use of genetic resources may also use biological resources—a broader category that includes genetic resources, but also organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity. Some of the experiences of these sectors are thus examined as part of the study.

This document results from a year-long study commissioned by the Secretariat of the Convention on Biological Diversity. The research involved a review of recent literature, the collection and analysis of ABS contracts and agreements, and interviews with more than 40 individuals from industry, government, NGOs, international agencies, and research institutions (see Appendix 1). Seven case studies were selected for detailed analysis and are included as Volume II.

Section 2 of the paper describes key elements of the case studies and is followed in Section 3 by an overview of the pharmaceutical; biotechnology; seed, crop protection and biotechnology; ornamental horticulture; and the natural personal care and cosmetic, botanicals, flavor and fragrance, and food and beverage industries. Some of the key findings of the study are described in Section 4, and conclusions are presented in Section 5.

This "Overview" is Volume 1 of three volumes contained in this report. Volume 2 includes the full case studies described below, and Volume 3 is a paper prepared for the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, in 2005, (UNEP/CBD/WGABS/4/INF/5) on the commercial use of genetic resources. Volume 3 provides a more detailed overview of market and research trends, trends in benefit-sharing and demand for access to genetic resources, and industry and researcher perspectives on the strengths and weaknesses of the CBD, and ABS measures in particular. It is included here as Volume 3 because much of the information and analysis provides useful background for the preceding volumes, and key elements—including that on industry and researcher perspectives—have changed little in the last few years, and are important context for an analysis of ABS arrangements today.

2. CASE STUDIES

Case studies are profiled for each sector to enhance understanding of current ABS practice, and to illustrate key points. While these case studies are not a comprehensive reflection of existing arrangements, they can contribute to understanding standard practices. They were selected based on a number of criteria, including:

a) Issues central to the ABS arrangement between providers and users of genetic resources—eg prior informed consent, structure of partnership (including use of intermediaries), benefit-sharing packages, compliance, intellectual property rights;

b) The inclusion of cases that use different types of genetic resources and products, including enzymes and microorganisms (of increasing interest to industry but with implications for ABS only partly explored to date) and those that fall outside the definition of 'genetic resources' but that are included in national ABS measures;

c) Cases representing the use of contracts at different stages of the research and development (R&D) process and covering different types of activities (eg some focused on discovery, others on development, raw material sourcing, or commercialization);

d) A mix of cases both with and without a traditional knowledge focus;

e) Geographic distribution.

THE CASE STUDIES INCLUDE:

Case Study 1. AstraZeneca-Griffith University, Queensland Australia

From 1993–2007, AstraZeneca and Griffith University in Queensland ran a natural product drug discovery partnership. It was built upon collections of terrestrial and marine biodiversity primarily from Queensland, and collected by the Queensland Herbarium and Queensland Museum, as well as collections in Tasmania, China, India, and Papua New Guinea. Significant benefits accrued to Griffith University, which has become one of the leading natural products discovery units in the world, and scientific understanding of marine and terrestrial organisms and ecosystems in the region was considerably enhanced. This case is one of the longest running of its kind, and sheds light on how benefits accrue over time, how they serve capacity-building and technology transfer needs in provider countries, and how they generate information and understanding necessary for conservation planning and management.

Case Study 2. Kenya Wildlife Service (KWS), International Centre for Insect Physiology and Ecology (ICIPE), and Novozymes and Diversa (now Verenium)

The industrial process biotechnology companies Novozymes (Denmark) and Diversa (USA) have signed separate agreements with the Kenya Wildlife Service, and ICIPE (in the case of Diversa), for collection of microorganisms in protected areas. Both provide support for laboratories and other infrastructure, training, and capacity-building. This case highlights arrangements based on microorganism sourcing and ABS in the industrial biotechnology sector, and explores ABS partnerships led by in-country conservation institutions and the benefits that result for conservation. KWS also facilitates all permitting for research in protected areas, so companies do not, at present, pursue additional negotiations with government.

Case Study 3. The Ethiopian Institute of Biodiversity Conservation, the Ethiopian Agricultural Research Organisation, and the Dutch-based company Health and Performance Food International: the tef case

The cereal crop tef (*Eragrostis tef)* is a staple diet of Ethiopia and is one of the country's most significant crop species. The grain is gluten free and has various attributes of interest to the food industry. A ten year ABS agreement has been negotiated for the further breeding and development of tef between the Ethiopian-based Institute of Biodiversity Conservation, the Ethiopian Agricultural Research Organisation, and the Dutch-based company Health and Performance Food International. The case study explores the challenges of negotiating ABS agreements between parties with divergent interests, the importance of ensuring the inclusion of all roleplayers in ABS arrangements, and the complexities of including staple agricultural commodities in ABS agreements.

Case Study 4. Ball Horticulture and the South African National Biodiversity Institute (SANBI)

One of the only ABS agreements in the horti- and flori-culture sector was negotiated in 1999 between the South African National Biodiversity Institute (SANBI) and US-based Ball Horticulture. The agreement, which is still ongoing, has involved SANBI using its expertise to select South African plants of horticultural interest for Ball. A number of commercial products have been developed from this collaboration and it has also yielded important experiences for the implementation of ABS. The case study underscores the importance of effective consultation, of good negotiating and legal skills, and the difficulties faced by public institutions who engage in bioprospecting.

Case Study 5. Aveda Corporation and a range of community groups in Western Australia

This partnership is based on the sourcing of sandalwood for Aveda, a US personal care and cosmetic company, in conjunction with an Australian company, Mount Romance, in partnership with a range of indigenous and local community groups. It highlights the ways benefit-sharing is manifested in this sector, and through the supply of raw materials. The case study also discusses agreements for the use in marketing of indigenous peoples' images and cultural property.

Case Study 6. Natura and a range of community groups in Brazil

Natura is a Brazilian personal care and cosmetic company that has formed innovative partnerships with community groups to certify and source raw materials for its EKOS line of products. The company also entered into an agreement with the Ver-as-Ervas Association around the supply of widely-known traditional knowledge for the development of new products. This case explores benefit-sharing associated with the sourcing of certified raw materials for the personal care and cosmetic sector, an agreement for the commercial use of traditional knowledge, and the relationship between these activities and Brazil's developing ABS policy framework.

Case Study 7. The commercial development of *Hoodia*

This well known case involves the commercial development of the succulent plant *Hoodia* as an appetite suppressant, and the variety of ABS agreements developed between the multinational consumer company Unilever, the British phytomedicine company Phytopharm, the South African Council for Scientific and Industrial Research, commercial *Hoodia* growers, and the indigenous San peoples of southern Africa. *Hoodia* has long been used by the San to stave off hunger and thirst but this knowledge was not acknowledged in the initial patent application for the appetite suppressant. However, two benefit-sharing agreements have subsequently been developed to share profits with the San. The case demonstrates the importance of prior informed consent, the complexities of regulating ABS when the resource is used both as a genetic resource and as a raw material, and the difficulties of implementing benefit sharing in marginalized communities that lack institutional capacity.

3. OVERVIEW OF KEY INDUSTRY SECTORS

Axinellidae COURTESY OF THE QUEENSLAND MUSEUM

Pipestela candelabra COURTESY OF THE QUEENSLAND MUSEUM

3.1. THE PHARMACEUTICAL INDUSTRY

Market trends

In 2006, the global market for pharmaceuticals grew 7% to $643 billion (up from $601 billion in 2005 and $559 billion in 2004). About 50% of this growth was in the US market, although the relative contribution to future growth continues to move away from the US and the five major European markets, with low-income countries' contribution increasing (IMS, 2007). North America accounted for 47.7% of global sales; Europe for 29.9%; Japan for 9.3%; Asia/Africa/Australia for 8.6%; and Latin America for 4.5% (IMS, 2007). In addition to dominating global sales, the US and Europe are home to the bulk of large pharmaceutical companies (IMS, 2007; See Table 1).

TABLE 1: TOP CORPORATIONS BY GLOBAL PHARMA SALES, 2006

RANK AND COMPANY	SALES, US $BILLION	% GLOBAL SALES
1 PFIZER (USA)	46.1	7.6
2 GLAXOSMITHKLINE (UK)	37.0	6.1
3 NOVARTIS (SWITZERLAND)	31.6	5.2
4 SANOFI-AVENTIS (FRANCE)	31.1	5.1
5 JOHNSON & JOHNSON (USA)	27.3	4.5
6 ASTRAZENECA (UK)	26.7	4.4
7 MERCK & CO (USA)	25.0	4.1
8 ROCHE (SWITZERLAND)	23.5	3.9
9 ABBOTT (USA)	17.6	2.9
10 AMGEN (USA)	16.1	2.7

Source: IMS, 2007

Research trends and demand for access

Pharmaceutical industry spending on R&D was more than $55 billion in 2006 (PhRMA, 2007). Natural products are only a small part of this, and currently only four large pharmaceutical companies maintain natural products programs of any size, with the capacity to do all facets of natural product drug discovery—Novartis, Wyeth, Merck and Sanofi-Aventis. Many of the companies that had active natural products programs in the 1990s, with associated bioprospecting efforts overseas—such as Bristol Myers Squibb, Pfizer, GlaxoSmithKline, and Monsanto—have closed their programs. A number of Japanese companies continue natural products programs, but the majority of these undertake collections primarily of microorganisms from Japan (Petersen, 2007).

The development in the 1980s of high-throughput screens based on molecular targets led to demand for large libraries of compounds that might inhibit or activate a specific biological target, such as a cell-surface receptor or enzyme. For much of the 1990s, scientists thought the best way to generate compounds for the screens was through mass-produced combinatorial libraries. The importance of natural products as a source of molecular diversity for drug discovery and development was overshadowed by chemical approaches that used combinatorial chemistry and biological approaches such as the manipulation of biosynthetic pathways of microbial metabolites through combinatorial biosynthetic techniques (Cragg et al, 2005; Koehn and Carter, 2005; Newman and Cragg, 2007). Natural products were considered too slow, too costly, and too problematic from both a scientific perspective, and because of the legal and public relations uncertainties associated with gaining access to genetic resources as a result of the CBD (Koehn and Carter, 2005; Laird and Wynberg, 2005).

However, since a multi-billion dollar investment in combinatorial chemistry beginning in the late 1980s, large pharmaceutical companies have found very little in the way of new structurally diverse entities through this avenue. Natural products continue to play "a dominant role in the discovery of leads for the development of drugs" and contribute significantly to the bottom lines of these large companies: between January 1981- June 2006, for example, 47% of cancer drugs, and 34% of all small molecule new chemical entities (NCE) for all disease categories, were either natural products or directly derived therefrom (Newman and Cragg, 2007).

At the same time the limitations of combinatorial chemistry became evident, breakthroughs in technologies (eg in separation and structure-determination) have made screening mixtures of structurally complex natural product molecules easier. An expanded understanding of genes involved in secondary metabolite biosynthesis have made "genome mining" of natural products a potentially powerful new approach to drug discovery, and advances in synthetic chemistry have minimized the "supply issue" associated with natural products

(Koehn and Carter, 2005; McAlpine et al, 2005). The result is renewed interest in natural products as sources of chemical diversity and lead generation, and a view of natural products and combinatorial chemistry as complementary rather than stand-alone approaches (Koehn and Carter, 2005; Newman and Cragg, 2007).

In the meantime, however, most large pharmaceutical companies have moved out of natural products and, as an industry natural products program manager in the US (pers. comm., 2007) explains, natural products research is not an easy field to jump back into: "Natural products research groups are very resource intensive, requiring a large number of staff, and a wide range of expertise, which means that big companies will likely be reluctant to get back into natural products in a major and comprehensive way. But on the flip side, many small companies do new, focused aspects of natural product research that were in their infancy even ten years ago and are now becoming productive—such as biosynthetic engineering and other genomics areas of natural products research. These groups develop hits and leads, and form alliances with big pharma to do development. This is an efficient model, and the one likely to go forward." As in the case of Astra Zeneca and Griffith University, relationships between large companies and smaller natural products discovery units are also often highly collaborative, with discovery undertaken through close communication between the partners, and the smaller company or research institute serving in effect as an extension of the larger companies' R&D program (Case Study 1).

The result is that the majority of natural products research today, particularly that involving bioprospecting, is undertaken in academic and government research institutes (eg The US National Cancer Institute (NCI); Griffith University and IMR in Australia; The Federal University of Ceara, Brazil; Harbor Branch in the US) or smaller discovery companies (eg Merlion in Singapore; Albany in the US; PharmaMar in Spain). In 2007, the NCI issued a half million dollars of purchase orders for plant collections in selected areas. Gordon Cragg and Dave Newman of the NCI have remarked "…while the classical approach to natural products research is in decline, natural products are not dead by any means, and in fact are increasing in importance as many novel ways to explore nature emerge—nature continues to be the source of exciting new leads." An industry natural products manager (pers. comm., 2007) supports this point: "The landscape is a lot different from the heyday of natural products research in the 1970s and 1980s, but on the whole natural products research is expanding and evolving. The reasons and rate vary depending upon who you talk to—like global warming, all agree it is getting warmer, but all do not agree on the reasons why."

3.2 THE BIOTECHNOLOGY INDUSTRY

Market trends

The biotechnology industry spans a wide range of activities, including pharmaceutical, agricultural, and industrial process biotechnology. The industry as a whole grew more than 14% during 2006, with revenues of public companies greater than $70 billion (Ernst and Young, 2007; Table 2). After the collapse of the boom market for biotechnology companies in 2001, the investment cycle entered a 'bust' phase and investors stayed away from the sector, with the result that companies restructured, spun off assets, reduced cash burn rates, refocused their business models to place more emphasis on product development and commercialization and less on technology platforms, and formed alliances with other companies (Europa Bio, 2005; Ernst and Young, 2005; Laird and Wynberg, 2005).

The last few years have borne the fruits of these efforts, with much improved financial performance, a return of investors to the sector, and strong pipelines and product approvals. For example, in the US, there were 36 product approvals in 2006, including 25 new drug applications and biological license approvals. In Europe, publicly traded companies saw a 30 per cent increase in the number of products in clinical development, bringing the overall pipeline to almost 700 compounds, plus 27 in registration and awaiting regulatory approval. Similarly, private companies in Europe have nearly 800 compounds in their pipelines and 12 compounds in registration (Ernst and Young, 2007).

Industrial biotechnology is gaining increasing visibility and investor attention, but it is still small compared with pharmaceutical and agricultural biotechnology (see Sections 3.1 and 3.3), and requires diffusing new technologies into different manufacturing sectors that may not be willing to accommodate innovative but unproven new technologies. Some, like Diversa (now Verenium), have had to restructure in recent years in order to reduce cash burn rates and increase profitability (Sheridan, 2006).

TABLE 2: GLOBAL BIOTECHNOLOGY, INCORPORATING ALL SECTORS, IN 2006 (US$M)

PUBLIC COMPANY DATA	GLOBAL	US	EUROPE	CANADA	ASIA-PACIFIC
REVENUES	73,478	55,458	11,489	3,242	3,289
R&D EXPENSE	27,782	22,865	3,631	885	401
NET LOSS	5,446	3,466	1,125	524	331
NUMBER OF EMPLOYEES	190,500	130,600	39,740	7,190	12,970
NUMBER OF COMPANIES					
PUBLIC COMPANIES	710	336	156	82	136
PUBLIC AND PRIVATE COMPANIES	4,275	1,452	1,621	465	737

Source: Ernst and Young, 2007

Research trends and demand for access

Biotechnology is one of the most research-intensive industries in the world, and in 2006 R&D investment grew by 33% over 2005 (Ernst and Young, 2007). The ways biotechnology companies use genetic resources vary significantly by sector. Some companies develop specialty enzymes, enhanced genes, or small molecules for use in crop protection and drug development; others develop enzymes that act as biological catalysts in the production of polymers and specialty chemicals, or for use in industrial processing; and others might insert genes that impart desirable traits into crops (Laird and Wynberg, 2005; see also section 3.3).

Enzymes have been used for more than 60 years by textile, detergent, food, feed and other industries to make high-quality products and to make production processes more cost-effective and efficient, and therefore more environmentally sound by minimizing the use of water, raw materials and energy. Enzymes are proteins found in every living organism and are the 'tools of nature', cutting and pasting products and speeding up vital biological processes in cells. Those used in the industrial biotechnology industry are usually found in microorganisms, in particular bacteria and fungi (Mathur et al, 2004; www.Novozymes.com, 2007).

The importance of microorganisms to both pharmaceutical and biotechnology R&D programs cannot be underestimated. Microbes are the most abundant, diverse, and least understood organisms on the planet (Friedman, 2007; Mathur et al, 2004). Advances in metagenomic technology allow researchers to extract DNA directly from microorganisms found in environmental samples, making available the 99% of microbial diversity previously inaccessible through traditional cultures (Handelsman, 2005). At the same time a far greater number of secondary metabolites in a given organism can be found through "genome mining' (McAlpine et al, 2005). Both commercial and academic researchers are increasingly studying and collecting microorganisms. For example, the Japanese National Institute of Technology and Evaluation (NITE) and Mongolia's Academy of Sciences (MAS) launched a joint venture last year to prospect for microbial diversity in the search for new commercial products; NITE is also collecting in Indonesia, Myanmar and Vietnam to find heat-resistant microorganisms in these tropical areas (Bulgamaa, 2007).

When collecting from nature, industrial biotechnology companies are interested in biochemical diversity, which can be found not only in areas with high species diversity, but also extreme environments and unique

ecological niches like salt lakes, deserts, caves, hydrothermal vents, and cold seeps in the deep sea bed (Lange, 2004; Arico and Salpin, 2005). Collections from nature still generate enormous diversity not available elsewhere to researchers. Novozymes of Denmark, and Verenium Corporation of the US are industrial process biotechnology companies that work with enzymes and microorganisms, and form partnerships with groups around the world to access these resources. Both have agreements with the Kenya Wildlife Service that include collections of microorganisms found in protected areas (see Case Study 2).

However, Ole Kirk of Novozymes predicts that, while the demand for new collections from nature will continue, it will likely decline—even today the need is much less than 10 years ago. Rapid advances in genomic science make it possible to study what is in existing collections, and in the company's back yard, more comprehensively (already most of their products derive from Danish biodiversity); large numbers of microbial genomes are being published and placed in the public domain, on average one a week; and advances in science and technology mean that "artificial" diversity can be generated in the laboratory (Ole Kirk, Novozymes, pers. comm., 2007). The coming years will likely be a time of flux in demand for access to genetic resources in this sector, as advances in science and technology make collections overseas both more and less attractive.

3.3 SEED, CROP PROTECTION AND PLANT BIOTECHNOLOGY INDUSTRIES

Market trends

The seed, crop protection and plant biotechnology industries share a heavy reliance on genetic resources. While there is substantial variation within and across each of these agriculture-related industries, three factors in particular set them aside in the context of ABS: first, their shared focus on the 130 species responsible for feeding humankind; second, their predominant reliance on genetic material from genebanks and private collections; and third, their in-part regulation under the multilateral system of the FAO International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA) for key food crops.

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There has been increasing convergence and consolidation of the seed, agrichemical and plant biotechnology companies over the past decade: in 2004, just ten companies controlled 49% of the global seed market, with an increased trend towards acquisitions and mergers. Currently, these ten companies account for 55% of the commercial seed market and 64% of the patented seed market. Table 3 lists these companies and their sales and describes their core business areas. The value of the overall commercial seed market in 2006 is estimated at $30 billion, almost half of this value comprised of domestic markets in the US, China and Japan. Markets for crop protection products fell by 2.5% in 2006 to reach US$30.425 million (CropLife International, 2007), consistent with an overall decline over the past 5-10 years (Agrow, 2003). Herbicides continue to dominate sales (49%), followed by insecticides (24%) and fungicides (23.5%). Table 4 below indicates the relative value of crop protection products, demonstrating the continued dominance of herbicides in the market.

There has been sustained growth of genetically modified (GM) crops, with the overall planted area rising by 12% to reach 100,8 million hectares in 2006 (Croplife International, 2007). The value of the market for plant biotechnology-based products, comprising sales of seed of herbicide tolerant and insect resistant crops, advanced in 2006 by 14.2% to $6.050 million (Phillips McDougall, 2005). Soybeans (43.9%) and maize (41%) remain the most commonly planted GM crops with the largest share (57%) of the GM crop sector attributable to herbicide tolerant crop varieties. The US continues to represent the bulk of GM crop plantings (54.6%), followed by Argentina (18%) and Canada (11.5%) (James, 2006).

TABLE 3: TOP SEED COMPANIES AND THEIR BUSINESS AREAS (2006)

COMPANY	2006 SEED SALES (US$ MILLIONS)	NATURE OF BUSINESS
MONSANTO (US)	4.028	Corn, soybean, cotton. Traits, Vegetables through acquisition of Seminis
DUPONT / PIONEER (US)	2.781	Corn, soybean, traits
SYNGENTA (SWITZERLAND)	1.743	Corn, soybean, sugarbeet, vegetables, flowers, traits
GROUPE LIMAGRAIN (FRANCE)	1.035	Corn, cereal, vegetables
LAND O'LAKES (US)	756	Alfalfa, maize, soybean, forage and turf grasses
KWS AG (GERMANY)	615	Corn, sugarbeet, cereals, oilseeds
BAYER CROP SCIENCE (GERMANY)	430	Vegetables, traits
DELTA & PINE LAND (US)	418	Cotton, soybean
SAKATA (JAPAN)	401	Vegetables, flowers
DLF-TRIFOLIUM (DENMARK)	352	Cool season clover and grass; grains and flax

Source: Smolders (2005); ETC Group (2007)

TABLE 4: CROP PROTECTION MARKETS, 2006.

PRODUCT	US$ MILLION
Herbicides	14.805
Insecticides	7.380
Fungicides	7.180
Others	1.060
TOTAL	**30.425**

Source: Croplife International (2007)

Research trends and demand for access

Trends in these industries are similar to those reported by Laird and Wynberg (2005) who note substantial scientific and technological changes stimulated by advances in genomics, combinatorial chemistry, information technology and DNA technology. Two trends in particular warrant mention. First, the increasing dominance of modern biotechnology, or genetic engineering; and second, the rate at which commercial varieties can be bred and commercialized. Increased investments for research have paralleled both of these trends, making market entry using these technologies more difficult for smaller companies (Marcel Bruins, International Seed Federation, pers. comm., 2007). In the seed industry, for example, an estimated 10-14% of turnover is spent on research and development (Anke van den Hurk, Plantum NL, the Dutch Seed Association, pers. comm., 2007).

Traits that improve performance and farming efficiency for major crops continue to comprise a key focus area for large seed companies, with the development of high value commercial lines through advanced marker-assisted selection and breeding techniques (Smolders, 2005). In the crop protection industry, chemical discovery has been aided significantly through the use of genomics to identify suitable product candidates, and combinatorial chemistry which has increased the number of products subject to biological screening. A significant trend is the shift in expenditure from conventional agrochemical research to an expansion of in-house R&D efforts on transgenic crops (Phillips McDougall, 2005). Indeed, transgenic technologies are fundamentally changing the nature of the seed, crop protection and plant biotechnology industries, and the

extent to which companies adopt this technology plays a significant role in determining their strategy and approach to ABS.

For example, in the biotechnology industry, *Arabidopsis*, one of the most worked upon plants for plant biotechnology traits, is also one of the most widely occurring weeds in the world and is thus unlikely to require ABS arrangements. Many other similar examples of model species exist, and this, combined with the multitude of species already available for manipulation in private or public collections, and advances in technology, enables companies to use old material in new ways and so avoid complications with countries of origin or those that are perceived to be "difficult" (Kees Noome, Limagrain, pers. comm., 2007). In parallel with these trends it is also believed that genetic resources will increasingly be accessed within the sovereign rights of a country.

Genetic diversity is central to the seed, crop protection and plant biotechnology industries and is, as one representative from the seed industry remarked "the name of the game". However, the types of diversity sought vary across the industries, as do the ABS arrangements to secure the material. The main source of new genetic material for conventional breeders is in modern varieties from private collections and from competitors' varieties registered as plant breeder's rights (PBRs). Genebanks are also important sources of new germplasm although mainly for universities, small companies and national agricultural research systems in developing countries (Fowler *et al,* 2001).

There is a perception that demand for landraces is declining because of bureaucracies in obtaining access to such material but at the same time there is continued interest in genetic variation. Anke van den Hurk of Plantum NL, the Dutch Seed Association characterized this sentiment in a remark that "…the currently freely available germplasm, own collections and varieties from other companies, are like a pot full of candies—enough to work with, but we also like to have access to other candies outside the pot" (pers. comm., 2007). Exotic germplasm is, however, considered to be more risky as it requires costly and time-intensive research investment, and the resulting varieties may be associated with less effective intellectual property protection. Smith and Grace (2007) note that because of these high risks any other uncertainties associated with lack of clarity on title of use would jeopardize arrangements to access genetic resources. The value of exotic material has also been questioned. Commented one representative from the seed sector: "Modern varieties are far more important to us. They contain more relevant genetic material than landraces or gene bank material. Maybe once in ten years we need to look at disease resistance or any other specific characteristic and need access to landraces and/or wild relatives. Modern varieties bring quality—wild products cannot be used directly and need a lot of work before they result in a product that can be sold" (Anke van den Hurk, Plantum NL, Dutch Seed association, pers. comm., 2007).

It is also believed that the lack of knowledge as to what genetic resources are available, and which might be potentially useful, is a major limitation to industry being able to access genetic resources. Changing this situation to facilitate an increased demand for wild germplasm will require considerable effort from provider countries. Costa Rica, for example, has spent a lot of resources in developing an inventory and taxonomy of its biodiversity and "filling its shop window" for potential customers [users] and this, believe some, is what other countries must do. Companies have noted the importance of "greater realism" in terms of the potential opportunities of what is available and interesting. "If you don't know what is available, and who has the rights to provide it, it simply won't work" (Stephen Smith, Pioneer, pers. comm., 2007).

3.4 ORNAMENTAL HORTICULTURE

Market trends

Although ornamental horticulture is growing both in size and worth, the past few years have been characterized by stagnation in the developed world, due in part to changing demographics (Brian Corr, Ball Horticulture, pers. comm., 2007). The world import trade value in horticulture (live trees, plants, bulbs, roots, cut flowers and foliage) in 2006 was US$ 14.386 million, up from the 2005 figure of $12.245 million (UN Comtrade, 2007) (Table 5). However, trade is increasing in developing countries such as China and India

where increasing numbers of people have disposable incomes. Markets are currently considered stable and conservative, and there is a tendency for producers to focus on "tried and true" products that have demonstrated performance and present lower risk than newer products (Brian Corr, Ball Horticulture, pers. comm., 2007). Weak intellectual property in developing countries is perceived as a hurdle to the introduction of new products in these countries.

Research trends and demand for access

Like the seed sector, the horticultural industry has relatively low reliance on wild genetic resources, and many of the genetic resources it uses have been developed over decades and exist within industry collections. Presently, about 100–200 species are used intensively in commercial floriculture (eg carnations, chrysanthemums, gerbera, narcissus, orchids, tulips, lilies, roses, pansies etc) and up to 500 species as house plants, and these represent the mainstay of the industry. Several thousand species of herbs, shrubs and trees are also traded commercially by nurseries and garden centres as ornamentals, many introduced from the wild with little selection or breeding (Heywood, 2003).

While the search for new materials is immaterial to some companies, for others it comprises an important component of their work. Syngenta, for example, have recently launched and patented a new strain of Busy Lizzie, or *Impatiens walleriana*, one of the most popular gardening plants (Barnett, 2006). The Spellbound Busy Lizzie has been specifically developed for hanging baskets and is based on a cross from *Impatiens usambarensis*, a plant endemic to the Usambara mountain range in Tanzania. The variety has been a great commercial success and more varieties have been launched. Amidst much controversy it was revealed that Syngenta obtained the seeds from botanical garden collections, sourced originally from Tanzania. No benefit-sharing agreements have been developed with the country of origin. Like the seed sector, however, it is important to recognise that wild material is seldom 'plucked' out of the wild and introduced, but rather is accompanied by a long process of research and development—more especially where new products are involved.

Low reliance of the industry on wild material, combined with the difficulties of 'proving' the origin of germplasm, has led to the sector, with some exceptions, still having low levels of awareness about the CBD and its ABS requirements. Indeed, it appears that in many cases germplasm acquisition via the 'cowboy approach' is still prevalent with many plant collectors working outside of government approval systems to supply nurseries and horticultural firms. Commentators have mentioned the ease with which the horticultural industry can 'hide its tracks' with regard to the origin of these resources, especially in cases where freshly collected germplasm is incorporated into existing genetic resources. This is a key difference between the horticultural and, for example, the pharmaceutical industry.

TABLE 5: WORLD IMPORT TRADE VALUE IN HORTICULTURE (2006)

	US$MILLIONS	PROPORTION OF OVERALL TRADE
Fresh cut flowers	6.275	43.6%
Live plants	5.644	39.2%
Bulbs, Tubers and Corms	1.263	8.8%
Fresh cut foliage	1.053	7.3%
TOTAL	**14.386**	**100%**

Source: UN Comtrade, December, 2007

TABLE 6: TOP IMPORTERS OF LIVE PLANTS 2002–2006

IMPORTING COUNTRY	TRADE VALUE 2006 (US$ MILL)
Germany	2.167
USA	1.721
United Kingdom	1.661
France	1.321
Netherlands	1.308
Others	5.793
TOTAL IMPORT	**13.973**

Source: UN Comtrade, December, 2007

TABLE 7: TOP EXPORTERS OF LIVE PLANTS 2002–2006

EXPORTING COUNTRY	TRADE VALUE 2006 (US$ MILL)
Netherlands	7.289
Colombia	972
Italy	729
Belgium	625
Denmark	491
Others	3.799
TOTAL EXPORT	**13.908**

Source: UN Comtrade, December, 2007

3.5 NATURAL PERSONAL CARE AND COSMETIC, BOTANICALS, FLAVOR AND FRAGRANCE, AND FOOD AND BEVERAGE INDUSTRIES

The sectors included in this section are quite different from each other and are far from uniform internally. But they share features that make it useful to group them for the purposes of this discussion: a reliance upon bulk sourcing of raw materials for the manufacture of commercial products; roughly similar cost and time investments in new product research and development (much less than those for pharmaceuticals); broadly similar financial profiles (again, much smaller than the pharmaceutical industry); and wide-spread ignorance of the CBD which results in limited use of ABS agreements, despite prospecting for new biological resources and the use of traditional knowledge.

The global market in botanicals (herbal dietary supplements) is comprised of a few different components: in 2005, a $3–4 billion market in raw/crude plant material; extracts derived from this material worth roughly $4–5 billion; and a market of $21 billion for botanicals and functional foods (Gruenwald and Wohlfahrt, 2007; Table 8). The global herbal personal care and cosmetic sector in 2005 was roughly $12 billion. Total sales of herbs/botanicals in the US in 2006 were $4.6 billion; sports and nutrition products were $2.4 billion; and natural personal care and household products was $7.5 billion (Nutrition Business Journal, 2007a).

The US market value for "healthy foods", which comprise functional foods, natural and organic foods and "lesser evil" foods, totaled $120 billion out of $566 billion (21.2%) in 2006 and grew 7.4%. During this same period the global sales value of functional foods, meaning "any modified food or food ingredient that may provide a health benefit beyond the traditional nutrients it contain" (Bloch and Thomson, 1995) or, more popularly, "better for you" applications, was $31.4 billion, representing 5.3% of the $590- billion food industry

(Nutrition Business Journal, 2007a). Fifty six percent of functional food sales were in functional beverages, an industry that has seen continued growth and is believed to be more exploratory and innovative than food. Along with this trend is increasing interest in new products from biodiversity by some of the largest beverage companies in the world, including drinks incorporating the African baobab and marula trees, amongst many other species (see, for example, Merrett 2007). Despite this, the majority of functional foods are based upon waste or by-products from industry (eg grape seed extract, lycopene, soy isoflavones, green coffee extract, omega 3 and 6 oils), sourced through cheap and well-established supply chains that present few ABS issues, have numerous IP opportunities, and have well-researched safety histories (Phytotrade, 2007a). These factors, combined with increasing regulatory hurdles such as GRAS, EU Novel Foods, REACH or the Traditional Herbal Medicinal Product Directive (THMP, 2004/24/EC), play a major role in curbing innovation in novel biodiversity products in this sector.

The environmental footprint of products and the social responsibility of companies have become mainstream features in botanical, personal care and cosmetic, and food sector marketing with labels like "organic", "fair-trade", "natural", "food miles", and "locally grown" increasingly gaining currency with consumers. Kevin Povey of Unilever, for instance, explains that the company's involvement in developing *Hoodia* as a functional food product fits directly into the company's social responsibility values: "There is a massive obesity problem we can help with. There is a large poverty problem in South Africa we can help with. There are big employment opportunities and we can provide technology input, infrastructure and money. There is however a hierarchy of needs—first that it [the product] is safe; second that it is effective. If the answer to these questions is yes we can put more effort into the other [benefit-sharing] areas. For us this project [*Hoodia*] offers opportunities to do well by doing good—good for both producers and consumers whilst offering us the potential to get a return on our investment and risk".

Research and development of new products varies in these sectors, including the cost and time, and the level of science and technology involved. Some companies sell bulk unprocessed herbs, others undertake processing into extracts, and a few might run screens, identify active compounds, and undertake clinical trials, much as pharmaceutical companies. For example, the commercial development of *Hoodia* as an appetite suppressant (Case Study 7), demonstrates the potential longevity of the research process, in this case commencing with research by the CSIR over forty years ago, and currently representing a very expensive project in Unilever's portfolio—and one that continues to face pressure from less costly projects that will come to market earlier (Kevin Povey, Unilever, pers. comm., 2007). Although complicated by political constraints, the development of tef as a product, by contrast, has been relatively quick and straightforward, owing in part to its well-established history of use as a staple food in Ethiopia and thus its lack of novelty in terms of regulatory standards.

All companies in these sectors, however, depend upon nature as the starting point for new product development, even if many fragrances and flavors may eventually be synthesized. A large number of companies also use traditional knowledge as a guide, as the case of Natura developing new ingredients for its EKOS line from widely used traditional knowledge collected in the Ver-o-Peso market in Belem, Brazil demonstrates (Case Study 6). Long histories of traditional use are also often considered a way to ensure safety and efficacy. In Europe, for example, the Traditional Herbal Medicinal Product Directive provides a simplified registration procedure for over-the-counter (OTC) herbal products if they can be proven to have 30 years of documented use (or 15 years within the EC), including use in traditional medicine (Gruenwald and Wohlfahrt, 2007). In many countries novel food, medicine, and cosmetic ingredients must undergo additional testing to substantiate claims, and prove safety and efficacy. While novelty differentiates products in the marketplace and satisfies evolving consumer demand, and so is desirable to companies, it also results in additional costs and time that reduce commercial demand for access to 'new' ingredients and products.

TABLE 8: GLOBAL SALES OF HERBAL SUPPLEMENTS 2005 ($BN)

2005	TOTAL (US$ BILLION)
Europe	7.1
Asia (excluding Japan)	6.0
North America	4.4
Japan	2.5
Latin America	0.9
Australia/New Zealand	0.4
Rest of world	0.5
TOTAL	**21.8 BILLION**

Source: Gruenwald and Wohlfahrt, 2007

TABLE 9: US NUTRITION REVENUES 2006 (CONSUMER SALES)

2006	TOTAL (US$ BILLION)
Supplements	22.5
Natural and Organic Food	23.6
Functional Foods	31.4
Personal Care, Household	7.5
TOTAL	**85**

Source: Nutrition Business Journal, 2007a

TABLE 10: TOP US FUNCTIONAL FOOD COMPANIES SALES IN 2006

	US$MILLIONS	PROPORTION OF OVERALL TRADE
Pepsico US	5.9	9%
Coca-Cola	1.5	13%
General Mills	1.4	2%
Kellogg	1.4	2%
Mead Johnson	1.3	2%
Abbott Labs	1.3	2%
Red Bull	1.2	22%
Kraft	1.1	2%
Nestle	1.0	3%
Hansen's Natural	0.9	56%
Others	14.4	
TOTAL	**31.4**	

Source: Nutrition Business Journal, 2007b

4. KEY FINDINGS ACROSS SECTORS

4.1 ENGAGEMENT WITH THE CBD

Despite a history of sporadic and largely limited involvement in ABS policy discussions, there is increasing engagement by users of genetic resources in CBD forums. This is especially pronounced within the pharmaceutical, biotechnology, and seed sectors. In the early and mid-1990s, a number of academic and commercial researchers from these sectors engaged in ABS policy discussions, but their involvement tapered off in the late 1990s (ten Kate and Laird, 1999). In recent years, industry has re-engaged, in part in response to negotiations for an International ABS Regime, and proposed requirements for "disclosure of origin" on patent applications, and concerns of the impact this may have on industry R&D well-beyond bioprospecting activities (eg EFPIA, 2004; Smith and Grace, 2007). It was also recently fueled by the actions of Indonesia, which has had more human cases of avian flu than any other country, and in early 2007 stopped sending samples of the H5N1 virus to the World Health Organisation (WHO) on the grounds that it required a more equitable system of access to vaccines for developing countries (McNeil, 2007). Although this decision was reversed after WHO agreed to develop a new global mechanism for virus sharing that would be fairer to poorer nations (WHO, 2007), the case brought the attention of industry to the ABS policy process.

One example of the pharmaceutical industry's increased interest in ABS is reflected in the recent development by the International Federation of Pharmaceutical Manufacturers and Associations of Guidelines for their members on "Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization" (IFPMA, 2006). These guidelines support the objectives of the CBD, and lay out the elements of "industry best practice" including obtaining PIC, reaching mutually agreed terms incorporated into a "formal contractual benefit-sharing agreement", and avoiding negative impacts on traditional use when commercializing genetic resources. In return, they request governments to assign national focal points, enact ABS legislation, enter into good faith negotiations, and agree on dispute resolution—in sum, to provide legal certainty over material accessed.

In parallel with this increased attention there is also considerable concern within the pharmaceutical industry about the perceived negative impact of the CBD on natural products research (eg Koehn and Carter, 2005). As Frank Petersen, Executive Director of the Natural Products Unit at Novartis said (pers. comm., 2007): "Natural products came under intense pressure within large pharmaceutical companies and the agribusiness sector during the last 20 years. Innovative technologies such as combinatorial chemistry and high throughput screening became the main strategy in pharmaceutical drug discovery. The identification of pharmacologically active molecules from nature could not easily fit these new streamlined processes, and natural products had to compete with small molecules adapted to high throughput derivation concepts. Today, natural products are still challenged internally, within companies, and externally, with the current CBD discussions. In many countries, jobs in the natural product drug discovery sector are disappearing. In addition, academia educates fewer and fewer people in this complex research discipline, especially in the Western hemisphere; in the last eight years almost the whole of US and UK-based industrial natural products discovery has disappeared."

An important finding of the current study is that concerns about the negative impact of the CBD on natural products research have in part bolstered the use of partnerships as a way of gaining access and legal title to material. Remarked an industry natural products program manager in the US (pers. comm., 2007): "The CBD can serve as a deterrent for companies looking to get involved in natural products. The uncertainty associated with obtaining access to biodiversity, and how a company can comply with the CBD and associated regulations, as well as the time required to obtain government approvals, means that working with experienced governments and organizations is critical. Our company has agreements with several groups around the world, primarily for microorganisms and including an agreement involving the NCI in the form of an NCDGG, as well as ICBGs. These partnerships allow us to access biodiversity, in exchange for sharing technology, doing training, and other benefit-sharing, but with help from others to work with governments and provide us with a clear intellectual property position with regards to the material. It is not impossible for companies to do

this, but you have to actively engage, find partners who are willing to consider the business culture of large pharmaceutical companies, and someone in the company has to get in the trenches and put these agreements together, sometimes for lengthy periods of time."

The biotechnology industry has increasingly engaged with the CBD policy process through, *inter alia*, its involvement in biosafety negotiations, but only recently have there been more concerted efforts on ABS. Even still, the biotechnology sector and its associated research community are inconsistently engaged with, and aware of, their ABS obligations under the CBD. For example, in recent years the industrial process biotechnology companies Novozymes and Diversa have developed partnerships with the Kenya Wildlife Service (KWS) and the International Centre for Insect Physiology and Ecology (ICIPE) for the collection and study of microorganisms, and have undertaken a process of sharing information on these arrangements with the wider public. But at the same time the US company Genencor has rebuffed efforts by the Kenyan government and KWS to enter into discussions about a product developed from saline lakes in Kenya that causes a faded look in demin, and replaces pumice stones usually employed by the industry (Lettington, 2003; Mbaria, 2004; Lacey, 2006). The Japanese Ministry of Economy, Trade and Industry (METI) is working closely with the Japan Bioindustry Association (JBA) to implement the CBD and the Bonn Guidelines by organizing public seminars, developing ABS guidelines for users in Japan, and building policy and scientific collaboration with countries in the region, with a particular interest in microorganisms (JBA, 2008).

Those in the seed, plant biotechnology, and to a lesser extent crop protection industries have engaged at different intensities in the CBD process, although there is at present an upward trend in their participation in discussions with regard to the International Regime. The primary reason for this increased engagement is because of the exclusion of ornamental and vegetable species from the FAO ITPGRFA, and a concern that continued access to this material could be restricted by the CBD/International Regime: "We are doing damage control", commented one representative from the seed sector. Many within these sectors believe that important lessons can be learnt from the process to develop the ITPGRFA, and that the standard Material Transfer Agreement (sMTA) of the IT provides a useful model from which to work, or at least to understand implementation challenges. Some companies, such as DuPont, have also adopted policy statements with regard to ABS stating an intention to "… identify the owner/s of natural biological resources and knowledge selected for research and product development" and to "develop fair and equitable business arrangements that recognize the contribution of the involved parties" (DuPont, 2005).

Companies in the horticultural sector tend to rely on their interests being represented within ABS policy debates by larger seed companies and groupings that have a horticultural component amongst their programs. The vast majority of horticultural companies, however, remain unaware of their ABS obligations and are detached from the ABS policy process. Some exceptions exist, such as the development of a long-term ABS agreement between Ball Horticulture and the South African National Biodiversity Institute (Case Study 4), but this agreement remains unique to the sector and experiences arising from its implementation do not directly inform the CBD policy process.

The personal care and cosmetic, fragrance and flavor, botanicals, horticulture, and food and beverage industries—with the exception of a few companies—appear to have incorporated few if any of the lessons and requirements of the CBD into their practices, have low levels of awareness of ABS issues, and remain poorly organized and represented at CBD meetings. Some companies have been charged with biopiracy due to their ignorance of the CBD, including the US company Pure World Botanicals, which patented pharmaceutical applications of the traditional edible and medicinal root of *Lepidium meyenii* (Maca), found only on the Andean central sierra of Peru (Brinckmann, 2007). Kodzo Gbewonyo of Bioresources International (pers. comm., 2007), based in the US and Ghana, remarked that "…fragrance and flavor companies actively search out innovative new ingredients in nature, in particular the ingredient supply companies, and—as with many companies in the botanicals sector—they don't feel any need to sign agreements, pay royalties, or otherwise provide benefits. Most have never even heard of the CBD."

The Aveda Corporation (Case Study 5) and Natura (Case Study 6) are examples of personal care and cosmetic companies trying to incorporate new and developing state, national and international ABS measures into their business practices, including through partnerships with local groups. Likewise, in the food sector, companies such as Unilever and the Dutch-based Health and Performance International access genetic material through ABS arrangements but much of this work is exploratory and pioneering or, as in the case of the latter, fraught with complex problems. Most companies in these sectors, however, remain unaware of the new legal and ethical obligations of the CBD.

A few groups are actively working to engage these sectors in the CBD, and implement broader socially responsible business practices, including Phytotrade Africa (see their Bio-Prospecting Guidelines, 2003) and The Union for Ethical Biotrade, which was established to assist companies seeking to make a positive contribution to sustainable development and the objectives of the CBD (www.uebt.ch). In this regard the Union for Ethical Biotrade has introduced a Biotrade Verification Framework for Native Natural Ingredients which includes important principles relating to ABS, such as the need to ensure the prior informed consent of those providing access; the recognition and promotion of traditional knowledge and fair compensation for its use; the fair and equitable sharing of benefits derived from biodiversity use; and the introduction of systems of traceability (Union for Ethical BioTrade, 2007). Such initiatives reflect an increased convergence around ABS amongst sectors using genetic resources and those using raw materials as commodities. This convergence is, however, also associated with greater regulatory confusion at the national level with regard to the scope of ABS.

4.2 PRIOR INFORMED CONSENT AND NEGOTIATIONS

Prior informed consent poses a number of difficulties for companies. While the CBD gives legal authority to national governments to grant PIC, in practice companies or research institutions require consent from a range of parties, including collaborating institutions, communities, land owners/stewards, governments, and others. In many cases, such as Astra Zeneca in Queensland (Case Study 1), and Novozymes and Diversa in Kenya (Case Study 2), companies work through local partner institutions that take responsibility for all permits, approvals and liaisons with local governments and communities. This is often seen as an invaluable service by industry, and relationships between companies and research institutions that can broker these complex negotiations, and manage local bureaucracies, are the most common model through which companies gain access to genetic resources.

There is widespread frustration within industry at the lack of clear competent national authorities to grant PIC. As one representative of a major seed company has remarked: "…we are aware that the CBD website has a list of focal points but it is simply window dressing as we don't have any joy with these focal points". Similarly, one of the most common problems associated with accessing genetic resources cited by German companies in one study was the absence of appropriate focal points (Holm-Muller et al, 2005). A Novozymes staff member, Lene Lange, noted that "… industries will have to choose their countries of CBD collaboration not only based on where the interesting biodiversity is, but also where PIC procedures and the CBD legislation are in place" (Lange, 2004). Even in countries with established PIC procedures—such as those for collections in protected areas managed by the Kenya Wildlife Service—confusion can result when new laws are enacted (Case Study 2).

Prior Informed Consent Office in Mt. Kitanglad, Bukidnon, Philippines ANDREAS DREWS, GTZ

Many in the seed, crop protection and plant biotechnology sectors have commented on the difficulties of operating where there are no clear-cut rules or knowledge of the value of the material. "We typically approach

the gene bank in the country we are wanting to work and ask them to do what is legally required. They must then tell us what material is legally available. But usually the gene bank can't get things in black and white on paper and the process gets stuck because of a lack of rules" (Kees Noome, Limagrain, pers. comm., 2007). Another commentator notes that "we have tried to get agreements in two or three countries but we have given up because it is not clear who one has to go to nor who has rights. If we go to the field we are accused of biopiracy… but there is an established seed bank at the CGIAR centres with defined pathways and MTAs, so we feel confident we have rights to the material" (Peter Freymark, Pioneer, pers. comm., 2007).

In a Latin American country, Dutch seed companies attempted to negotiate with the national focal point for access to wild material in return for student exchanges, facilities and cooperation. However, a representative from the companies noted that "when we asked [the national focal point] who to get PIC from they said "everybody". Reflecting on the case, Anke van den Hurst, senior biotechnology advisor of Biodiversity and Organic Seeds of Plantum NL, the Dutch Seed Association notes that "…countries are not able to estimate the value of their resources—they don't know what to expect. And therefore they won't dare to take decisions on an ABS contract. If it is too difficult for companies they will stay at home and use the material there. Conservation and sustainable use are threatened as a result of the bureaucracy".

Receiving PIC from all parties, and formalizing this in agreements, takes 1-2 years on average and sometimes longer, as found in nearly all of the case studies. Some countries, such as Brazil and India, are regularly avoided by companies, since it takes 1-3 years to get a permit, and researchers fear the hostility that meets their research, and the "national regulatory labyrinths" (Thornstrom, 2005). Many companies report attempting the same, but being stymied by time-consuming deliberations and bureaucratic procedures. Describing a project to collect ornamental species in Brazil, an involved official remarks: "…it was very time consuming to get the project going. It started in 2002, with 19 institutes in Brazil and foreign companies. In 2006 they decided to stop—the partners had disappeared and it took too long. The bureaucracy was too large". As a strategy to avoid such complexities, the trade association Phytotrade Africa focuses on countries with whom it has an established relationship, and avoids conducting research on samples from countries such as South Africa, where the regulatory framework is perceived to be unclear and where relationships with the relevant authorities and stakeholders have not yet been established (Cyril Lombard, Phytotrade Africa, pers. comm., 2007).

As found in the International Cooperative Biodiversity Groups (ICBG) program, a number of constraints and complexities contribute to the time it takes to conclude an ABS agreement: national governments without focal points and clear procedures; the requirements of legal staff involved in complex negotiations; the time required to get sign off from senior and busy management in companies; community outreach and consultation, and the need to follow traditional decision-making practices and timelines; and university or research institution policy deliberations.

In an interesting development, the Venter Institute built a requirement to contact national focal points, and receive PIC from provider countries for the commercial use of data in their metagenomics database, CAMERA. The provision of data for free to scientists around the world is seen as an important benefit associated with the collections they undertook as part of the Global Ocean Sampling project[4]. But in order to access the data within CAMERA, users must register and agree that "As a condition of my use of the CAMERA website, I acknowledge that the genetic information available through the CAMERA website may be considered to be part of the genetic patrimony of the country from which the sample was obtained. As a user, I agree to: (1) acknowledge the country of origin in any publications where the genetic information is presented; (2) contact the CBD focal point identified on the CBD website if I intend to use the genetic information for commercial purposes." They also note that "countries may claim intellectual property rights arising from commercial use of such data" (Friedman, 2007). Such clauses, however, have not precluded the Institute from considerable controversy in its deliberations with source countries (eg ETC, 2004).

4 http://collections.plos.org/plosbiology/gos-2007.php

4.3 TRADITIONAL KNOWLEDGE

Appropriate ways to seek PIC from holders of traditional knowledge, negotiate mutually agreed terms, and share benefits associated with the use of traditional knowledge remain unclear. Because of these difficulties, many companies have adopted a "hands off" approach to the use of traditional knowledge, whilst others have little awareness of the need to enter into ABS arrangements when using traditional knowledge. The diverse ways in which companies use and interpret traditional knowledge adds a further layer of complexity.

For example, traditional knowledge is not widely used in the pharmaceutical industry today (Petersen, 2007), but traditional knowledge is used to guide research in some smaller discovery programs, and efforts have been made to develop ABS agreements around its use. In Nigeria a MOU was developed for a research collaboration between the National Institute for Pharmaceutical Research and Development (NIPRD) and a traditional health practitioner, Rev. Ogunyale, focused on indigenous medical knowledge about sickle cell disorder, and indigenous biodiversity. The collaboration began in 1992, and there existed little guidance on how to structure such an agreement, but an innovative process for reaching mutually agreed terms, signing an MOU, and sharing benefits was developed. XECHEM International was granted a license to the resulting product, in return for providing 7.5% of gross sales as royalties. A shortfall of the arrangement continues to be the lack of sharing financial and other benefits paid by XECHEM to NIPRD with individual NIPRD researchers, and Rev. Ogunyale's Foundation and his community. There are also concerns about the benefit-sharing package as a whole, resulting in part from a lack of involvement of researchers and Rev. Ogunyale in negotiations for the License Agreement (Wambebe, 2007).

Companies within the seed, crop protection and plant biotechnology sectors prefer to avoid using traditional/farmers' knowledge as far as possible because of the legal and ethical complications involved. However, an in-principle commitment exists to share benefits equitably and to resolve the issues raised by the use of traditional knowledge in commercial varieties or new products. Here too ABS partnerships or arrangements have emerged as an important way in which these commitments are realized. For example, most companies prefer to pass the responsibility of resolving these difficult benefit-sharing issues onto the gene banks, governments or intermediary institutions with whom they work, acknowledging that companies have neither the competence nor legitimacy to negotiate with holders of traditional knowledge. "We may make an agreement with the Mexican government and agree with them for instance that 10% can go to indigenous peoples for conservation. We don't want to be involved in a three way negotiation but we do want the issue to be resolved. I am not competent to deal with indigenous peoples. The government must resolve this as it is their people" (Kees Noome, Limagrain, pers. comm., 2007).

Questions of certainty and legal clarity also underpin approaches to traditional knowledge. One seed industry representative noted that "…we would happily use maize from a farmer's field in Mexico but we avoid this because it is unresolved as to whether they [the farmers] have rights to the material and whether they can assure us this is the case" (Pioneer spokesperson, pers. comm., 2007). As a result, it is more common for seed companies to obtain landraces directly from CGIAR gene banks or national gene banks. Similarly, to avoid difficulties associated with the commercial use of traditional knowledge, the trade association Phytotrade Africa only investigates species that are widely distributed and known (Cyril Lombard, Phytotrade Africa, pers. comm., 2007).

SUHEL AL-JANABI, GEOMEDIA GbR

Traditional knowledge is widely used in the botanicals, personal care and cosmetic, and food and beverage industries. Natura uses traditional knowledge in its development of new fragrances and personal care and cosmetic products. Staff collected widely-known traditional knowledge in collaboration with the market association Ver-as-Ervas in Brazil as part of a verbal agreement, which they

considered fair and standard practice at the time. As the ABS policy environment in Brazil evolved, however, and awareness grew of the need to compensate for the commercial use of traditional knowledge—even that which is widely-known—Ver-as-Ervas sued the company, which then entered into an ABS agreement with the association that included sharing financial benefits (Case Study 6). However, as the case of Maca (*Lepidium meyenii*) described above demonstrates, there exists little awareness within these sectors of the need to enter into ABS agreements for traditional knowledge.

In a similar fashion, traditional knowledge of the San was used by the South African-based Council for Scientific and Industrial Research to file a patent and develop anti-obesity products without acknowledgement of the contribution of the San, nor their prior informed consent (Wynberg, 2004; Wynberg and Chennells, 2008). Yet this changed with increased media and international attention, leading to the development of a benefit-sharing agreement between the San and the CSIR.

The commercial use of traditional knowledge raises a range of complex issues. For example, is all knowledge, including that which is widely known, subject to ABS regulations? Who should provide PIC, enter into an agreement, and receive benefits? How are the owners of traditional knowledge identified? And what if knowledge is shared by a number of communities? These and related questions have been raised since the CBD entered into force, but developing effective ways to address them within ABS agreements and partnerships is still in the early stages.

4.4 AGREEMENTS

Scope and Definitions

A wide variety of terms and definitions are used by different sectors to describe genetic resources and related products, and often the same language may be used by two parties to describe two different situations. This, combined with the different understandings and experiences of sectors, has led to a lack of clarity in the concepts and terms used in ABS measures. Some examples include the distinction between "genetic resources" and "genetic material", "biological resources" and biological material"; differences between "origin", "source" and "provenance"; and the use of the terms "traditional knowledge" and "derivatives" (EFPIA, 2004; Rosenberg, 2006; IFPMA, 2006; Hilton, 2007; ABIA, 2008).

Resolving these definitional issues would enhance understanding and agreement about the scope of proposals to regulate access to genetic resources, including the use of ABS agreements. This relates not only to issues associated with bioprospecting for new leads for drug discovery and development, but also to the gray area (under the CBD) of genetic resources used within industry in the production process, as inactive parts of the final product, as elements in vaccines, and as research tools and reagents (eg processing enzymes, control assays, and discovery screen targets, oligonucleotides as probes or primers, and as aids for drug delivery) (Rosenberg, 2006; Hilton, 2007). It also includes genetic resources that have been in use for decades, and have long since been removed from their natural environment (eg vectors, plasmids, cell lines) (EFPIA, 2004). Industry has also questioned the assumptions of ABS measures based on a model of genetic resource use in the pharmaceutical and agricultural industries that grows from collection of samples from nature—ie bioprospecting—while most resources today are not accessed in this way (EFPIA, 2004). Further, although human genetic resources are explicitly excluded from the CBD, there is an absence of policy tools for ABS in cases where human genetic resources are used. There is also a gray area in respect of non-human genetic resources found in humans (eg HIV, H5N1 virus, malaria parasite) and a lack of clarity as to ABS measures that should be used in these complex circumstances (Rosenberg, 2006; EFPIA, 2004; Hilton, 2007).

Types of agreements

Contrary to what is often imagined, bioprospecting partnerships rarely involve a single, framework agreement, and more often utilize an inter-locking web of agreements between the various involved parties. For example,

the 18 International Cooperative Biodiversity Group's 5 year grants have generated over 110 contracts, not counting dozens of amendments or the numerous permits that are often linked to these agreements. "These are diverse in format and structure. In a very few cases, like the University of Illinois-Chicago Vietnam Laos program, they have tried to make a single umbrella agreement cover the entire consortium. Most end up developing 3-7 different agreements that function in interlocking ways. Often they result in a sort of web, but sometimes more a hub and spoke format… While people generally start with some model that they are familiar with or has been recommended to them, they are almost always greatly modified to fit the particular needs of the parties. So in the end, the model agreements are only a starting point," (Joshua Rosenthal, Deputy Director of the Division of International Training and Research at the US National Institute of Health, pers. comm., 2007).

Phased agreements are also prevalent in some sectors, and have been proposed for use in the pharmaceutical industry and others in which there are dramatic differences in the financial profile and activities undertaken during discovery, development, and commercialization. In the seed sector, phased agreements for public-private partnerships are common—for instance, a first phase could be a research agreement whereby the material is examined for its suitability and information is assessed. A second phase would involve the Material Transfer Agreement, which tends to be closer to commercialization and would allow for more detailed evaluation as well as capacity building and knowledge, and technology, transfer. A final phase might include licensing and commercialization agreements. Typically, confidentiality agreements will be introduced at an early stage of negotiations, notes Lloyd le Page of Pioneer (pers. comm., 2007): "…we have to have confidentiality agreements early on so we can look in the shop windows. However there is still a degree of discomfort. This is new territory."

There are also examples—such as the Ball-SANBI horticulture agreement (see Case Study 4)—where research and commercialization are rolled into a single agreement, including royalty rates and technology transfer. The rationale of this strategy is to ensure that both parties enter the agreement with the same level of risk (the assumption being that the negotiating power of the buyer would be reduced if the compound is already found), that there is no requirement to re-negotiate terms, and that products can therefore be moved faster. "There is no standard practice for benefit sharing—I wish there was. It is standardised in that we can only offer so much benefit-sharing and still pay the bills. We have a rough idea of what it will be worth, and what can be returned in benefits. It is an organic process that requires much effort" (Brian Corr, Ball Horticulture, pers. comm., 2007).

4.5 COMPLIANCE AND TRACKING

Compliance and tracking as part of ABS agreements address industry's need for legal certainty associated with material supplied, providers' need to monitor the use of material provided, as well as the overall requirement for a dispute resolution mechanism. Legal certainty and clarity over rights to material protect industry's investment in R&D and commercialization, and shelter them from biopiracy accusations and negative publicity (IUCN-Canada, 2005; Laird and Wynberg, 2005; IFPMA, 2006; Rosenberg, 2006). At the same time, companies seek consistent and clear legislation to ensure legal redress, although many believe that arrangements between providers and users of genetic resources should be based on trust, with an understanding that restrictions will be mutually acceptable and therefore adhered to. In the seed sector, this is the approach used by the ITPGRA. As Smith and Grace (2007) remark: "..it is under the same parameters of PIC and benefit sharing under mutually agreed terms that companies, who may be the fiercest competitors, secure contracts to license technologies or germplasm". In the pharmaceutical industry, the International Federation of Pharmaceutical Manufacturers and Associations Guidelines (IFPMA, 2006) request governments "…to agree that any disputes as to compliance with the clauses contained in formal contractual benefit-sharing agreements are dealt with through arbitration under international procedures or as otherwise agreeable between parties (III.5)".

Tracking material through industry research programs raises different and equally important issues for providers, who want to ensure that they consent to and benefit from any use of material supplied. Most companies

have internal databases to track the movement of material, and restrictions on the ways in which material can be used, and to whom it can be sent. Companies often stand to lose a great deal more than they gain by not living up to agreements: "There are always bad apples in the basket but the vast majority of companies cannot risk their name or reputation; plant breeding companies are focused on long-term developments and relationships" (Kees Noome, Limagrain, pers. comm., 2007).

However, problems with tracking can still emerge. For example, in the seed sector material protected by PBRs can be illegally used for commercial propagation without compensation: "It is a big headache to track. We do have an interest in tracking material protected by PBRs to show someone is taking our varieties, and we can go to court, but the big challenge is how to prove it" (Kees Noome, Limagrain, pers. comm., 2007). Once the genetic identity of material changes, it is also increasingly difficult to track. For example, explains Brian Corr of Ball Horticulture (pers. comm., 2007), it would be difficult to prove the origin of genetic material from an established ornamental species, such as *Pelargonium*, in the development of new varieties: "Even if new material is obtained it will be difficult to prove it doesn't come out of existing breeding programmes, from material gained before the entry into force of the CBD—unless someone knows to look for *Pelargoniums* that have this trait".

Material that gets utilized in a "closed loop" faces fewer of these problems. For example, the licensing agreements to commercialise *Hoodia* have well-defined tracking mechanisms and all contracting parties have a responsibility to ensure material is used only for the purpose stipulated. Similar experiences are noted from other projects where a specific species is the focus of an agreement between three or four parties.

The International Cooperative Biodiversity Groups (ICBGs), which generally involve partnerships for drug discovery, all track sample flow among partners. This is in part an important element of managing the research process, and is common to all such partnerships within the pharmaceutical industry and other sectors. As Joshua Rosenthal, Deputy Director of the Division of International Training and Research at the US National Institute of Health, notes (pers. comm., 2007): "The efforts expended to collect, extract, test, fractionate, isolate, retest, and so on are significant, and no one wants to waste their time or money, or miss something potentially valuable. A misnumbered or misidentified sample can send people on a wild goose chase that can waste a lot of effort and money". But tracking samples is also a way to ensure compliance with an agreement, and partners are contractually obligated to report their findings to each other. If there was a significant violation of the contract there would be legal recourse, generally through lawsuits, but this has reportedly never happened with an ICBG. Some agreements under the ICBGs also require reporting research results to national governments, but "it is important to note that, even when the number of collections is not large, the data flow among partners in these projects is large and complex and few government officials want to receive reams of complicated data that is mostly negative. Be careful what you ask for" (Joshua Rosenthal, NIH, pers. comm., 2007).

Changes in science and technology mean that tracking and monitoring samples as part of bioprospecting partnerships requires an evolving approach. Increasingly, it will be the case that physical material is not what is shared. The DNA sequence of many organisms is available to the broad scientific community in the form of electronic data—short pieces of DNA (the length of a few genes) can be used in the laboratory by reconstructing that piece of DNA from this data. Much research on these sequences is done today by computers, as part of the research area bioinformatics (Endy, 2005; Bio Fab Group, 2006). It is also the case that the subject of agreements—eg plant collections—may not actually be the source of active compounds. Many active compounds, including those used to develop a number of pharmaceuticals (eg taxol, camptothecin, vincristine, and podophyllotoxin), have recently been found to be products of symbiotic microbial species (Newman and Cragg, 2007; Cragg et al, 2005). Promising compounds can also be produced by a range of organisms, since "Mother Nature uses the same genes across the globe with subtle variation", so a genetic probe could look for genes that produce a promising compound, and find them in another organism (Newman and Cragg, pers. comm., 2007).

These developments mean that tracking and monitoring physical material through the use of bar codes is no longer as protective as it once was. They also mean that the genomic content of samples should be covered in agreements, and intellectual property and other rights are much more difficult to manage for data compared with physical entities such as pieces of DNA or biological molecules. A large element of trust and mutual respect—by-products of partnerships to a far greater extent than agreements solely for the supply of samples—is necessary to make these agreements work in practice.

4.6 BENEFIT-SHARING

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The nature and form of benefit sharing varies significantly by sector, and is understood quite differently by industry players. In part this is because of variations in the financial profile and R&D process of the industries involved in the commercial use of genetic resources, which has an obvious impact on the scale and nature of benefits that are shared. For example, it is estimated that it takes 10-15 years and costs $802 million to develop a new drug, including the cost of failures (PhRMA, 2007). New crop or ornamental varieties are also research intensive. The identification and evaluation of agronomically important traits from exotic germplasm, for example, can take 5-10 years or longer and a further 10 years may be required to develop an improved variety that is acceptable to the farmer (Smith and Grace, 2007). On the other hand, in the biotechnology industry it is not uncommon for the development cycle for an industrial or technical product—such as enzymes for biofuels and detergents—to take no more than 1-2 years from when a lead enzyme is identified. Food and feed products take longer, given more involved approval procedures and requirements for toxicology, and their development could take 2-3 years (Ole Kirk, Novozymes, pers. comm., 2007).

Revenues from commercial products are also dramatically different between sectors. For instance, more than 105 pharmaceuticals achieved "blockbuster" status in 2006 (IMS, 2007), with sales greater than $1 billion. In contrast, for example, Novozymes' annual turnover is roughly $1.5 billion—much the same as a single blockbuster pharmaceutical. Dividing this by their 600 products would yield an average of $2.5 million per product, although some are big sellers, and others like Pulpzyme—developed from a Kenyan microorganism, and the subject of an agreement between Novozymes and the Kenya Wildlife Service (Case Study 2)—have very low sales. On the other hand, Novozymes spends a great deal less than a pharmaceutical company to research and develop its products, and launches 5-8 new products a year (Ole Kirk, Novozymes, pers. comm., 2007). The *Hoodia* case illustrates how two different benefit-sharing streams can emerge from the same genetic resource. Unilever is producing a mass-market consumer product, based on a patented extract, substantial investments and large volumes of raw material, while a range of smaller companies are "riding" on this investment and are selling *Hoodia* as a raw material for the food additive and dietary supplement market, using vastly different cost and profit structures. Both sets of players have negotiated separate benefit-sharing agreements with the San.

One reason for benefit-sharing being understood differently by industry players is because of the complexity of commercialization chains and their variation between sectors. Those in the seed sector take a wide and positive view of "benefit sharing" and interpret it to be an integral and necessary part of business practice, taking place at different levels of the seed value chain and manifesting as a mix of technology transfer, knowledge transfer, royalties in the case of commercialization, license fees, and laboratory improvements. Remarks Stephen Smith, of Pioneer (pers. comm., 2007): "We don't have a problem with benefit-sharing—it makes sense. It also raises the bar on intellectual property—by putting benefits back we raise the bar on what research can be done." Others note that under the multilateral system of the FAO ITPGRFA access itself is the main benefit to be shared (GRAIN, 2005).

Benefit sharing in the seed industry is especially complex because of the cumulative nature of plant breeding, because the entire chain of development leading to the final product may not take place within one company, and because intermediate products themselves are sometimes marketed[5]. Many in the seed industry, however, interpret benefit sharing to be the moment at which seeds are sold to the farmer, rather than the retail of final products to consumers (Kees Noome, Limagrain, pers. comm., 2007). The pharmaceutical industry by contrast sells its product directly to consumers whereas the fermentation industry may use an organism that has no relationship to the final product and will thus require a different strategy for benefit sharing.

For many companies, in particular those in the pharmaceutical industry, a package of monetary and non-monetary benefits associated with bioprospecting is now standard practice. There is concern within industry, however, that the most significant benefits—training, technology transfer, and capacity-building—are de-emphasized in relation to future royalties, which are unlikely to materialize (Finston, 2007). As Frank Petersen of Novartis said (pers. comm., 2007): "Capacity-building opportunities and mechanisms meant to anchor knowledge within the bioprospecting partner group—beyond the expiration date of a cooperation—are clearly at a disadvantage compared to the emphasis on royalties. We have to be aware that in the vast majority of natural products-based drug discovery efforts, no royalties can be generated given the low probability of a market introduction. In our discussions with potential bioprospecting partners, we flexibly balance royalty aspects with training opportunities, know-how or technology transfer, supply of special equipment, and invitations for scientists to work with us in Basel according to the specific needs of the partner institute."

In the AstraZeneca-Griffith University partnership, the wide range of benefits accruing to Queensland, and the University, over the course of 14 years generated a range of information invaluable to biodiversity science and conservation in the region, and built one of the top natural products discovery units in the world—all before any product had been commercialized (Case Study 1). The US National Cancer Institute has also taken the approach of promoting drug discovery in source countries: "We feel strongly that this is the way to go when countries possess the necessary resources and infrastructure—for example, we established screens in countries like South Africa (CSIR), Pakistan (The HEJ Institute of Chemistry at the University of Karachi) and China (Kunming Institute of Botany) (Gordon Cragg and Dave Newman, NCI, pers. comm., 2008).

Botanical medicine, personal care and cosmetic, fragrance and flavor, and food and beverage sectors, when they consider the subject, tend to link benefits to the supply of raw materials, including equipment, premium prices paid for material, training, job creation, and building of local capacity and industries. As seen in the cases of Natura in Brazil (Case Study 6), and Aveda in Australia (Case Study 5), these benefits can be significant, and can build capacity that allows communities to participate in the trade of local biological resources at higher levels, and with greater access to markets. Natura additionally runs the Bio-Qlicar training program for communities, to assist them in building professional skills for working with business, including quality-control, schedules, and so on (Philippe Pommez, Natura, pers. comm., 2007). Similarly, in the case of tef (Case Study 3) stipulated benefits in the ABS agreement extend beyond financial returns to include research collaboration, knowledge and technology transfer, and the development of tef businesses in Ethiopia. It is significant, however, that the inclusion of these more comprehensive elements is also considered to be responsible for impeding the effective implementation of the tef ABS agreement.

Partnerships around the sourcing of raw materials for the pharmaceutical industry are also a potential benefit in that sector, although the odds of commercial product development are small for any one collecting partnership. For example, Novartis has worked with the Shanghai Institute of Materia Medica, other scientists and the government in China on sourcing *Artemisia annua* for production of Coartem, an anti-malarial therapy developed from Traditional Chinese Medicine. Coartem is registered in 81 countries and is an important

5 By way of example, a biotechnology company may utilize material from a genebank with which it has an ABS agreement and this material may in turn be licensed to seed company A, who may license it again to seed company B. Both licensing agreements would represent an agreement on the division of financial and other benefits, and both would represent a transfer of the benefit-sharing obligation through the license (and thus a reduced value license). Company B may then multiply the material and sell it to a farmer, and at this point would be required to make payments. Payments would cascade back down the chain, based on the agreed license agreements, and to those providing the rights to knowledge whether they be competing multinational corporations, developing country institutions, or resource-poor farmers.

part of the World Health Organizations' Rollback Malaria public health initiative. Novartis and its Chinese partners work with thousands of farmers in China and Africa to source *Artemisia*, including investments in knowledge transfer (eg in extraction techniques, good manufacturing practices, chemical production and health, safety and environmental standards), equipment, training, state-of-the-art analytical technologies and good clinical practices. Some partners have been able to build on this capacity to collaborate with other companies (Petersen and Kuhn, 2007).

4.7 TECHNOLOGY TRANSFER

Access to and transfer of technology, articulated in Article 16 of the CBD as one of the benefits countries providing genetic resources should receive, is a central element of benefit-sharing but has occurred inconsistently in the cases explored. Its extent and interpretation has also often been contested—with those providing technology considering it to have major impact, and those receiving technology believing it to be inadequate (see, for example, Case Study 4). In some cases, technology transfer has made a vital difference to the provider institution whilst in others it has been implemented through a "softer" approach of knowledge transfer and/or training, if at all. To a large extent technology transfer is case specific, but it also varies significantly across sectors and companies.

For example, pharmaceutical and some biotechnology companies 'outsource' parts of the earlier stages of research in ways that promote high levels of technology transfer. In some cases, such as the partnership between Astra Zeneca and Griffith University in Australia, a significant part of the discovery process is done in the provider country. AstraZeneca invested more than $100 million over the 14 year lifetime of the partnership, transferring technology and building capacity in high throughput screens, robotics, separation of molecules, and medicinal chemistry, and helping to create a state-of-the-art natural products discovery unit at Griffith University. The partnership also contributed to development of the Queensland Compound Library, which contains 45,000 specimens representing unique biological diversity collected during the course of the partnership, and which is intended to help researchers in the region translate innovative discoveries into commercial products. Now that their exclusive arrangement with Astra Zeneca has ended, the University is well-positioned to take advantage of the growing demand within industry for natural product discovery partnerships (Case Study 1). Similarly, in the *Hoodia* case study the CSIR benefited from the construction of a US FDA approved medicinal plant extraction facility for the manufacture of material for clinical trials, and there are plans for the extraction facility for *Hoodia* to be located in South Africa.

Economic and competitive interests, however, typically underpin the extent to which technology transfer occurs. For example, in the Ball-SANBI case study technology transfer entailed knowledge transfer through technical training rather than representing direct technology investments and product development within South Africa. On this basis the agreement was lambasted for not optimizing local economic opportunities. In response to these criticisms Ball notes that "…people have unreasonable expectations of what we can do. It doesn't make economic sense to set up a Ball equivalent in South Africa: why would we set up a competitor?" (Brian Corr, Ball Horticulture, pers. comm., 2007).

In certain sectors some form of technology transfer is an integral part of business practice. Most seed companies, for example, have a worldwide network of local testing facilities and must build local institutions and know how to ensure the effective functioning of such facilities and the appropriate development of local varieties. However, in many cases ownership continues to be located with the mother company, leading to questions about whether this "softer approach" constitutes technology transfer as envisaged by the CBD. In practice these enterprises are started as subsidiaries of the parent company but typically—through technology transfer, and infrastructure and capacity building—a catalyst is provided for independent business development. Another "soft" approach to benefit-sharing are the contributions made by seed companies to the Global Crop Diversity Trust, a partnership between the FAO and the 16 Future Harvest Centres to conserve in perpetuity the Earth's most crucial agricultural biodiversity through providing a secure and sustainable source of funding for the world's most important crop diversity collections. This currently has a $136 million endowment to create a high quality global system of *ex situ* gene banks.

The International Seed Federation (ISF) reports that technology transfer associated with the maintenance of plant genetic resources for food and agriculture is common practice, with more than 40% of ISF members granting licenses free of charge to developing countries and some members also participating in programs for technology transfer (ISF, 2005). Specific examples of technology transfer by the private sector are an insect-resistant maize project between CIMMYT and Syngenta , a project on drought tolerance between Pioneer and CIMMYT, the *GoldenRice*™ project (www.goldenrice.org), and the "African Biofortified Sorghum" project. This so-called "super sorghum" project aims to develop genetically modified sorghum and has been funded for $17 million over ten years by the Bill & Melinda Gates Foundations and others. Collaborators include the University of Pretoria, South Africa's Agriculture Research Council (ARC) and Council for Scientific and Industrial Research (CSIR), International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), the Forum for Agriculture Research in Africa (FARA) and various universities in the USA. Through this project DuPont Crop Genetics Research (Pioneer) has transferred technology valued at US$4.8 million in its unclaimed IPR earnings. The IPR-free GM sorghum is engineered to contain 50 per cent more lysine.

It should be noted that "softer" approaches to technology transfer, combined with a growing trend towards public-private partnerships, including those in which IPR-free material is provided to developing countries, have come under criticism in some cases for their limited ability to allow for wider adaptation of technologies, their underpinning commercial interests, and their perceived intent to "legitimise controversial technologies" (Lettington, 2003; GRAIN, 2007). Strong arguments have been made by provider countries for more substantial technology transfer, but some in industry fear that an imposed form of technology transfer could create competitors in the same marketplace, with negative economic ramifications for those companies transferring the technology.

4.8 INTELLECTUAL PROPERTY RIGHTS

A key determinant in benefit-sharing is the extent and nature of intellectual property protection. In most sectors patents or plant breeder's rights protect genetic material or associated processes from unauthorized use, and this is the basis from which royalties are determined. The relationship between IPRs and benefit sharing varies considerably from sector to sector, depending on industry-specific approaches to IP protection. IPRs tend to assume greater significance in pharmaceutical, biotechnology and seed sectors, and thus play a greater role in benefit sharing in these sectors, while companies working in botanical medicine, cosmetic and personal care, fragrance and flavor, and food and beverages focus less on IPRs and more strongly on benefits linked to the supply of raw materials. In general, however, intellectual property rights are given prominence as a mechanism for benefit-sharing, over and above the frequently more concrete gains of building domestic scientific and technological capacity.

A number of IPR models have been adopted in ABS agreements but most commonly companies have sole ownership of intellectual property rights. For example, in the partnership between Diversa Corporation, the Kenya Wildlife Service (KWS) and the International Centre of Insect Physiology and Ecology (ICIPE) in Kenya, the company retains intellectual property rights over any products that it develops, provided that ICIPE and KWS have the option of a royalty free license that allows them to research, develop and otherwise make use of any products or inventions developed from the material supplied within the jurisdiction of the Republic of Kenya (but not beyond this jurisdiction) (Case Study 2; Lettington, 2003). Similarly, IPRs in the *Hoodia* case study (Case Study 7) are assigned to the CSIR, despite the involvement of traditional knowledge. As Weiss and Eisner (1998) note, those wishing to share in the intellectual property from a successful development must be prepared to make a significant financial investment to share the risk of failure, but such investments are often beyond the reach of many providing institutions.

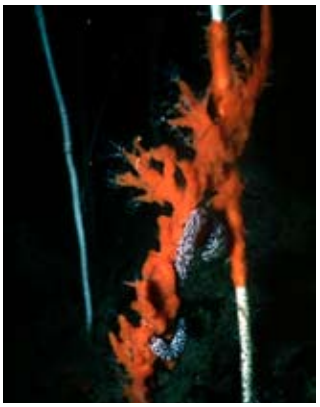
Joint ownership of patents by providers and users is thus complex, rare, and expensive, although examples exist. These include the joint Maruline patent of the trade association Phytotrade Africa (on behalf of marula providers in southern Africa) and Aldivia France. The partnership between PhytoTrade Africa and Aldivia is considered groundbreaking and was cemented with the launch in 2005 of Maruline, the world's first patented

active botanical ingredient developed through scientific collaboration between traditional resource users and a specialised research and development company (Aldivia & Phytotrade Africa, 2005). Uniquely, the patented process to develop the oil recognises the contribution made by traditional users of marula through assigning co-ownership of the patent to Phytotrade Africa on behalf of rural producers. Although it is still too early to determine the significance of this development, its potential commercial value is estimated to be between US$120.000 to US$1.7 million, excluding the direct costs of developing and protecting Maruline (Cyril Lombard, Phytotrade Africa, pers. comm., 2004). Its real value, however, may lie in the establishment of a method to deal equitably with the commercialisation of traditional knowledge, and the stimulus this provides towards broader heritage protection (Cyril Lombard, Phytotrade Africa, pers. comm., 2005).

The relationship between IPRs and benefit sharing varies considerably from sector to sector but is especially complex in the seed sector, where conflicting views exist as to the most effective intellectual property environment for plant varieties and associated benefit-sharing mechanisms. In this sector material is typically either protected by plant breeder's rights (PBRs) (in the EU and elsewhere) or plant patents (in the US). Unlike other sectors, where patents protect genetic material from unauthorized use, PBRs include a breeders' exemption which involves new material being made freely available for others to use. If PBRs exist some feel that no further financial benefit-sharing is required, since free availability of the improved material is a significant benefit. Under a plant patent system, however, additional payments would be required since these patents place constraints on the free availability of breeding material (Kees Noome, Limagrain, pers. comm., 2007.). In the tef case study, however, new tef plant varieties are to be co-owned by Health and Performance Food International and the Ethiopian Agricultural Research Organisation, allowing for Ethiopia to share in benefits that arise out of the use of tef genetic resources. Smith and Grace (2007), remark that the free availability of future breeding material is not sufficient for plant breeders to meet the threshold of benefit sharing under the ITPGRFA. Here it is argued that the requirement to share benefits should not be dependent upon the type of IP, and should be mandatory for all commercialization of germplasm that contains ITPGRFA material in its pedigree.

4.9 PARTNERSHIPS AND ARRANGEMENTS

The nature of ABS arrangements, and the extent of collaboration and partnership, varies significantly, and the case studies and other ABS examples exist along a gradient from the supply of samples/raw material to full partnerships involving joint research and significant technology transfer and capacity building. A wide range of groups are parties to ABS arrangements; for example, they may be developed between a company and a local research institution or gene bank, a research institution and a community, a company and a local testing organization, or between a trader and a producer. Typically they will be initiated by companies trying to locate materials for research or commercial product development, but they can also be based upon a more involved, mutually-beneficial, research collaboration linked to these materials, such as that between Griffith University and Astra Zeneca, or those formed by the US National Cancer Institute.



Haliclona COURTESY OF THE QUEENSLAND MUSEUM

Partnerships are also emerging from groups such as the trade association Phytotrade Africa, which represents small producers and looks for the "right company" to promote their products and philosophy. Phytotrade Africa works across 8 countries in southern Africa, and has 58 members, representing some 100,000 rural producers. Its stated vision is to develop a natural products industry from which low-income rural producers will be able to generate meaningful long-term incomes (Phytotrade, 2007b). A pragmatic strategy of early proactive engagement with potential bioprospecting partners is adopted and trade is pursued with the objective of achieving an outcome that is in rural producers' long-term interest. This ensures legitimacy and seeks to preclude biopiracy. The lessons here, as articulated by market development manager Cyril Lombard, are to "get organized, get informed, and to get proactive with companies with R&D capability and market access. It is all about engaging the right people, institutions and companies. It is about a process".

The seed, crop protection and plant biotechnology industries have a number of private-public arrangements to access material, and undertake the characterization of material, largely with the CGIAR centres and national gene banks and programs using the standard Material Transfer Agreement (sMTA) agreed upon in the ITGRFA. Working with the sMTA, however, can be viewed as a multilateral arrangement rather than a partnership. The breeder's exemption is recognized as a benefit as newly developed varieties can be freely used for research and breeding (Marcel Bruins, ISF, pers. comm., 2007). To a large extent these arrangements are encapsulated between users and participating institutions, which lay down the terms and conditions of use in the sMTA of the multilateral system.

Over time all of these arrangements may develop into a longer-term and more substantial relationship between the parties, and a more comprehensive package of benefits for both. Under these circumstances partnerships between users and providers yield far more significant benefits than the supply of samples, or raw material, alone. The natural product discovery unit built at Griffith University in Australia, the innovative arrangement between Aveda, a local sandalwood company, and indigenous peoples and local communities in Australia, Natura's partnerships with communities providing raw material and traditional knowledge in Brazil, Novozymes and Diversa's partnerships with Kenya Wildlife Service and ICIPE, the relationship between SANBI and Ball, and the agreements developed around *Hoodia* all provide significant benefits that would not accrue to providers otherwise: advanced laboratories and processing facilities, transfer of technologies, training, job creation, capacity-building, and in some instances, monetary benefits in the form of milestone payments and royalties. Initiating, nurturing and maintaining these partnerships takes time, money and commitment, and these factors should not be overlooked at the outset of collaborations.

5. CONCLUSIONS

1. Continued dialogue and information exchange between users and providers of genetic and biological resources is vital. An important reason for lack of progress in developing international and national ABS regimes appears to be limited participation in the policy process by industries that use genetic resources. This has been in part due to what some perceive as the frustrating nature of the policy-making discussions, particularly in the CBD process. In part it has also been due to industry itself remaining unaware of the new policy environment, not realizing the importance of these debates for them, or having largely negative perceptions about the new policies. This may be changing, as the last meeting of the governing body of the CBD, COP 8, saw unprecedented numbers of industry representatives participate and satellite events being organized by industry. The engagement of different sectors with the CBD varies substantially but remains highest amongst the pharmaceutical, biotechnology and seed industries. Efforts to bring industry into the ABS policy process, and promote dialogue amongst the range of stakeholders and between the diversity of sectors, remains essential to ensure that ABS measures are drafted based on the scientific and technical realities of this complex and rapidly changing area of research and commercialization.

2. Different sectors use genetic and biological resources in vastly different ways and adopt a diversity of approaches and tools for access and benefit-sharing associated with these resources. It is important that the dramatic differences in the ways genetic and biological resources are used by the various sectors are incorporated into policy deliberations. It is likely that only a broad framework that ensures uniformity of principles and consistency in approach is possible. This generic framework could then be elaborated in different, and flexible, ways for different sectors, types of research (eg academic vs commercial, discovery vs development and commercialization), and scales.

3. An important finding is that the alleged bureaucracies and difficulties created by ABS, and perceived negative impacts of the CBD on research, have in part **bolstered the development of relationships** between companies and intermediaries that can broker these complex negotiations, and manage local bureaucracies. These ABS relationships have emerged as the most common model through which companies gain access to genetic resources, and may manifest as a gradient of arrangements—from, more superficial situations set up

specifically to secure access, through to long-term partnerships based on trust and goodwill. Over time all of these arrangements may develop into a longer-term and more substantial relationship between the parties, and a more comprehensive package of benefits for both. Under these circumstances partnerships between users and providers yield far more significant benefits than the supply of samples, or raw material, alone.

4. There is a need to build capacity in many provider countries and amongst intermediary institutions to ensure that **potential negotiating and other inequalities between parties are reduced;** knowledge of business, law, and advances in science and technology is significant; and opportunities for long-term, mutually beneficial relationships are enhanced.

5. There is increasing **convergence around ABS between sectors using genetic resources and those using raw materials as commodities**. However, this is also associated with greater regulatory confusion at the national level with regard to the scope of ABS and whether or not regulation extends beyond genetic resources.

6. Widespread frustrations are experienced by all sectors in securing **prior informed consent** from national competent authorities. Protracted and often fruitless negotiations are commonplace between providers and users of genetic and biological resources. Companies often avoid countries which cannot grant legal certainty over material and work increasingly in countries where the rules are clear and where there is knowledge about the value of the genetic material. In those countries where they do work, companies usually seek out local partners to assist with prior informed consent and stakeholder consultations.

7. Appropriate ways to seek PIC, negotiate mutually agreed terms, and share benefits associated with the use of **traditional knowledge** remain unclear. Basic questions remain unanswered, such as: is all knowledge, including that which is widely known, subject to ABS regulations? Who should provide PIC, enter into an agreement, and receive benefits? How are the owners of traditional knowledge identified? And what if knowledge is shared by a number of communities? These and related questions have been raised since the CBD entered into force, but developing effective ways to address them within ABS agreements and partnerships is still in the early stages. Because of these difficulties, many companies have adopted a "hands off" approach to the use of traditional knowledge, whilst others have little awareness of the need to enter into ABS arrangements when using traditional knowledge. In cases where traditional knowledge is used, there is typically strong reliance by companies on the use of intermediary institutions such as research institutions, NGOs or governments, to resolve difficult issues.

8. The **variety of terms and definitions** used by different sectors to describe genetic resources and related products has led to a lack of clarity in the terms and concepts used in ABS measures. Resolving these definitional issues would enhance understanding and agreement about the scope of proposals to regulate ABS.

9. ABS agreements seldom involve a single, framework agreement but instead are characterized by an **interlocking web of agreements** between multiple parties which may or may not be divided into research and commercialization phases.

10. **Legal certainty and clarity of rights to material** is vital to promote and protect industry investment in research and development and commercialization. In this regard, the extent to which ownership and/or legal status of genetic resources is resolved at the national level plays a key role for those seeking access to genetic resources and PIC. Where there is legal clarity with respect to ownership of genetic resources, ABS arrangements are more easily facilitated.

11. Problems of genetic identification, combined with capacity constraints and the sheer complexity of designing a **monitoring and tracking system** that suits different types of genetic material and sectors pose significant challenges for the development of a compliance system that is both cost effective and effectual. Moreover, changes in science and technology mean that the physical material may not be what is eventually shared, suggesting the need for genomic material to be included in agreements, and posing immense chal-

lenges for tracking and monitoring. These difficulties point to the need for provider country institutions and companies to enter into ABS arrangements and partnerships, and to build trust and collaboration over time. Because of complexities of identification and capacity constraints, it is unlikely that countries presently can effectively and comprehensively regulate, or groups can adequately track and monitor, the use of resources they provide to users. This stresses the importance of building monitoring capacity amongst parties, ensuring their commitment to agreements and to transparent and fair transactions, and establishing on-going and long-term partnerships. Such approaches are vital to ensure that the use of material can be monitored and benefits down the road assured.

12. **Governments in both user and provider countries should build capacity within national focal points**, and ensure their mandate, scope, roles and responsibilities are clear. Expertise in the scientific, commercial, and legal areas that make up ABS should be found within these focal points. The process for granting access should be transparent, minimally bureaucratic, and should promote communication and collaboration, rather than suspicion and frustration.

13. Access to and **transfer of technology** has occurred inconsistently in the cases explored, and, in cases where it has taken place, opinion varies as to how effective and comprehensive this has been. In some cases, technology transfer has made a vital difference to the provider institution, in others it has been implemented through a "softer" approach of knowledge transfer and/or training, and in others it has not featured. Strong arguments have been made by provider countries for more substantial technology transfer, but some in industry fear that an imposed form of technology transfer could create competitors in the same marketplace, or financial disincentives for research on biodiversity or natural products.

14. The relationship between **intellectual property rights** and benefit sharing varies considerably from sector to sector, depending on industry-specific approaches to IP protection. IPRs tend to assume greater significance in pharmaceutical, biotechnology and seed sectors, and thus play a greater role in benefit sharing in these sectors, while companies working in botanical medicine, cosmetic and personal care, fragrance and flavor, and food and beverages focus less on IPRs and more strongly on benefits linked to the supply of raw materials. In general, however, intellectual property rights are given prominence as a mechanism for benefit-sharing, over and above the frequently more concrete gains of building domestic scientific and technological capacity.

15. Provider countries and institutions that actively **build and market their biodiversity knowledge base and associated capacity**, and enter into partnerships that help them to do this, receive greater benefits from their biodiversity, and support biodiversity conservation through these activities.

16. Commercialization chains are very complex and are highly variable between sectors. Benefit-sharing is thus understood differently by industry players. **Different benefit-sharing streams** can also emerge from the ***same*** genetic resources when they are used for different purposes, or by different sectors. The main determinant for benefit-sharing is thus the **use** to which the resource is put, rather than the resource itself.

17. **ABS partnerships have the potential to provide a wider range of benefits, over time, than agreements based on the supply of samples alone**, or those which emphasize monetary benefits, particularly royalties, over the range of capacities that can be built and technologies transferred by companies. The real gain from ABS partnerships is found in the building of domestic capacity within provider countries to undertake research on, and develop commercial products from, local biodiversity. This includes scientific and technological capacity, as well as knowledge of markets and industry requirements. Partnerships can also help build capacity in biodiversity management and conservation, including information on species, populations and ecosystems, and funds provided to support taxonomic research and collections that would otherwise not be possible.

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VOLUME II: CASE STUDIES

1.INTRODUCTION

The preceding overview in Volume I drew to a large extent upon the detailed case studies presented in this section. Each of these seven case studies has been selected to illustrate aspects of ABS arrangements for the research, development and commercialization of biodiversity. While some of these case studies may not fall squarely within conventional understandings of ABS, they are included to explore issues of scope with regards to "genetic" and "biological" resources. The range of case studies also presents an opportunity to examine differences between sectors in demand for access and benefit-sharing, to highlight complexities in regulating a wide range of activities under ABS policies, and to raise issues that require further clarification.

While these case studies are not a comprehensive reflection of existing arrangements, they can contribute to understanding current practices. They were selected based on a number of criteria, including:

a) illustration of issues central to ABS arrangements—eg prior informed consent, structure of partnership (including use of intermediaries), benefit-sharing packages, compliance, intellectual property rights;

b) The use of a range of genetic resources and products, including enzymes and microorganisms (of increasing interest to industry but with implications for ABS only partly explored to date) and those that fall outside the definition of 'genetic resources' but that are included in national ABS measures;

c) The use of agreements at different stages of the research and development (R&D) process and covering different types of activities (eg some focused on discovery, others on development, raw material sourcing, or commercialization);

d) A mix of cases both with and without a traditional knowledge focus.

2. CASE STUDIES

CASE STUDY 1:

Griffith University, Queensland-Astrazeneca: A Partnership for Natural Product Discovery[6]

Sarah Laird, Catherine Monagle, Sam Johnston

1.1 KEY PLAYERS

AstraZeneca

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Based in the UK, AstraZeneca is one of the largest pharmaceutical companies in the world, ranked number six in 2006 with global sales of $26.7 billion USD (IMS Health, 2007). AstraZeneca employs over 12,000 people worldwide, around 4500 of which are part of Global Discovery. There are 6 major Discovery and Development facilities in the UK, US and Sweden, and 4 Discovery sites in the US, Canada and France. In Japan, the company runs a facility for clinical development. R&D investment in 2006 was $3.9 billion USD, and 21 candidate drugs were added to the early development portfolio in 2006 (AstraZeneca, 2007). More than 1,700 external R&D collaborations and agreements have been formed to complement in-house capabilities, reflecting an industry-wide trend towards such external partnerships in the industry. In 2006 alone 325 new collaborations were formed (AstraZeneca, 2007). In Australia, AstraZeneca employs more than 1,000 people as part of export, sales and marketing to the region, through research collaborations at major teaching hospitals and universities, and as part of its collaboration with Griffith University (Denerley, 2006). The major research areas for AstraZeneca are respiratory (asthma, COPD), inflammation (osteo-arthritis), CNS (Alzheimer's, depression, anxiety, psychosis), pain (neuropathic, and chronic nociceptive), infection (antibacterials), cancer (anti-invasives, anti-angiogenics), and cardiovascular (thrombosis, metabolism, arrhythmia) (AstraZeneca, 2007).

Eskitis Institute for Cell and Molecular Therapies, Griffith University

The natural product drug discovery partnership was originally established between Griffith University between Astra Pharmaceuticals and Griffith's Queensland Pharmaceutical Research Institute in 1993, following a submission by QPRI to Astra in 1992. The Eskitis Institute is a research centre of Griffith University, founded in 1988 and located in Brisbane, the capital of Queensland (Griffith University, 2007). The Eskitis Institute undertakes research on the molecular and cellular mechanisms of human diseases, specifically cancer, infection and immunity, neglected diseases, neurological diseases, and stem cell biology. Specific research programs include Bioactive Molecule Synthesis, Cancer Biology, discovery biology, Chemical Biology, Clinical Neurosciences, Drug Discovery and Design, Molecular Libraries, Stem Cells, Structural Chemistry and Systems Biology (Eskitis, 2007). Of these, the Drug Discovery & Design, Molecular Libraries and Discovery Biology programs are evolutionary developments from the GU/AZ partnership. Eskitis also includes five key features that add considerable strength to the institute: the Queensland Compound Library, the National Centre for Adult Stem Cell Research, the Queensland node of Cancer Therapeutics CRC Ltd, *Nature Bank* and Eskitis Molecular Screening (Eskitis Institute, 2007).

6 This case study is excerpted from a longer study published by UNU-IAS: *Queensland Biodiscovery Collaboration: A Case Study of the Griffith University Eskitis Institute and AstraZeneca Partnership for Natural Product Discovery*, by SA Laird, C Monagle, and S Johnston (in press).

The Queensland Herbarium

The Queensland Herbarium was established in 1855, and is located on the grounds of the Queensland Botanic Garden in Brisbane. Administratively, the Herbarium falls within the Queensland Environment Protection Authority, an authority of the Queensland Government. The Herbarium undertakes a range of activities including maintaining historical specimens and reference collections, surveys and mapping of Queensland vegetation, and research into plant diversity (Environment Protection Authority Queensland, 2007), The Herbarium in 2003 employed 68 staff, including 33 botanists (Queensland Herbarium, 2003).

The Queensland Museum

The Queensland Museum, established in 1862, is situated in Brisbane with regional services delivered through the Museum Resource Centre Network in six regional sites across the State of Queensland (Queensland Museum, 2007). The Museum provides museological services in science, natural environment and cultural heritage, and employs over 215 people and many volunteers (P.Riley, pers. comm., 2007). The museum's organisational structure reflects its focus on the themes of knowledge generation, knowledge management and knowledge dissemination. Falling within the Knowledge Generation theme are the substantive divisions of Biodiversity and Geosciences, Cultures and Histories, and Science and Technology in Society (Queensland Museum, 2006). Within the knowledge management theme falls the museum collections maintenance and accession activities. In recent years, these accessions to Museum collections have been from a range of activities including but not limited Griffith/AstraZeneca partnership. Other collection programs include invertebrate marine life and fish specimens through the Great Barrier Reef Seabed Marine Biodiversity Project, and the Torres Strait Seabed Mapping Project, funded by the the Commonwealth of Australia Scientific Organisation (CSIRO). The Museum, like most public institutions in Australia, is funded through a combination of government funding, research grants, consultancies, corporate sponsorships for particular activities, and business endeavours, such as retail shops (Queensland Museum, 2006).

1.2 BACKGROUND

In 1993, the State of Queensland's Griffith University formed a partnership with Astra Pharmaecuticals to pursue a natural product (NP) drug discovery programme under the banner of the Queensland Pharmaceutical Research Institute (QPRI). This partnerships persisted through the merger of Astra Pharmaceuticals with Zeneca to form AstraZeneca AB in 1999 This Institute was renamed AstraZeneca R&D Brisbane, then evolved into the Natural Product Discovery Unit (NPD), and finally moved under the aegis of the Eskitis Institute for Cell and Molecular Therapies, thus coming full circle to the original research institute concept of the QPRI.

Now in its 14th year, Eskitis screens extracts of flora and fauna—including plants from Queensland's rainforest and sponges of the Great Barrier Reef—to identify bioactive molecules as potential leads for discovery and development of novel pharmaceuticals. More than 45,000 samples of regional biota have been collected since the start of the partnership. Terrestrial collections are made by the Queensland Herbarium, who have discovered more than 100 plant species new to science; marine collections are made by the Queensland Museum—of the more than 3,000 sponge species collected, around 70% are new to science (Camp and Quinn, 2007; Hooper, 2007). Collections have also been made under sub-contract in Tasmania, China, India, and Papua New Guinea. The drug discovery programme at Eskitis has discovered over 800 new bioactive compounds from its approximately 45,000 specimens.

Griffith University makes extracts of samples, and then runs these samples through high throughput screens (HTS) against targets provided by and of therapeutic interest to AstraZeneca. Active compounds are then identified and isolated at Griffith University via bioassay guided fractionation, and structures are elucidated using nuclear magnetic resonance spectroscopy (Quinn et al, 2002; Camp and Quinn, 2007; Denerley, 2006). The role of Griffith University evolved during the course of the partnership—originally, the HTS and lead discovery were to be done at Griffith and the leads sent to collaborators at AstraZeneca, but over the years

Griffith also performed selected lead-optimization and medicinal chemistry components based on their in-house expertise (Quinn, pers. comm., 2007).

AstraZeneca invested more than AUD$100 million in the collaboration, which has resulted in a state of the art natural product drug discovery capability. In mid-2007 the partnership employed 50 scientific and support staff, including 10 HTS biologists, 12 natural product chemists, 7 medicinal chemists, 5 compound management chemists and 2 NMR anaylsts. The drug discovery programme at Eskitis has served, in effect, as an arm of the AstraZeneca R&D network, and as such had an exclusive partnership with AstraZeneca. The exclusive nature of this relationship concluded in 2007, although collaboration on specific projects will continue. The end of this exclusive arrangement with AstraZeneca will allow Griffith University to leverage its facilities, know-how, and staff to build collaborations with other research and commercial groups. While no commercial products have resulted from the partnership to date, this is not unusual given the long timelines for drug discovery and development, particularly for natural products, and the high attrition rate observed during developing commercial products in this sector.

ABS Legal Frameworks

The Griffith University/AstraZeneca partnership spanned a critical time in the development of policy guiding access to "genetic resources" and sharing of benefits from their use, beginning in the same year—1993—that the Convention on Biological Diversity entered into force (Box 1). International access and benefit-sharing obligations were provided for by the Government of Australia in the Environment Protection and Biodiversity Conservation Act (1999) and later detailed in Part 8A of the Environment Protection and Biodiversity Conservation Regulations. In 2002 and consequent to the adoption of the Bonn Guidelines all Australian states and territories agreed to a nationally consistent approach to access to genetic resources and to apply the Guidelines. In Queensland and the Northern Territory this has resulted in specific legislative measures, the Queensland Biodiscovery Act 2004 and the Northern Territory Biological Resources Act 2006 (DEWHA, 2007). In other states and territories no dedicated legislation yet exists, though in some jurisdictions there are limited access and benefit sharing measures implemented pursuant to more general legislative and policy instruments. All states remain committed to the implementation of the Bonn Guidelines, with most having already initiated legislative development processes. For example, in Tasmania a comprehensive access and benefit sharing approach is currently being developed in a process led by the Tasmanian Department of Primary Industries (K.Kent, pers. comm., 2007). Western Australia has also indicated in its Biotechnology Industry Development Strategy that dedicated legislation will be developed in that jurisdiction by the end of 2008 (http://www.doir.wa.gov.au/documents/businessandindustry/WABiotechnologyDevelopmentStrategy.pdf, page 22).

The activities undertaken under the aegis of the Griffith University/AstraZeneca partnership are subject to the laws of Queensland and the Commonwealth of Australia. When accessing materials outside Queensland (whether in other states and territories of Australia or internationally) the University is also subject to any applicable laws in the jurisdiction in which collections take place, as well as the Convention on Biological Diversity, which Australia has ratified. To meet its access and benefit sharing obligations under the Queensland Biodiscovery Act 2004, the Griffith University/AstraZeneca partnership has an approved Biodiscovery Plan lodged with the Queensland Department of Tourism, Regional Development and Industry. When collecting on Commonwealth Lands or waters collection is subject to obtaining the appropriate permits under Part 8A of the Environment Protection and Biodiversity Conservation Regulations 2000. When research is for commercial purposes, as it is in this case, a benefit sharing agreement with the access provider must also be lodged with the Department of the Environment, Water, Heritage and the Arts. Permits for access to genetic resources from Commonwealth controlled lands and waters only came into effect for samples collected after December 2005, however.

1.3 ACCESS TO RESOURCES

Griffith University subcontracted collections to the Queensland Herbarium for terrestrial samples, and the Queensland Museum for marine samples. Most collections were made in Queensland, but others came from

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Tasmania, China, India and Papua New Guinea. In 2007, the biota collection, containing collections from the lifetime of the NPD partnership, had in excess of 45,000 biota samples, including vascular plants, algae and macro fungi from Queensland (>20,000), PNG (5,743), and China (6,545). Marine invertebrate samples number more than 9,500 biota from tropical and temperate Australian waters. The collection also includes more than 2,000 soil and aquatic microbial extracts from India and Australia (Camp and Quinn, 2007). The plant collection represents more than 9% of the world's species diversity of higher plants, with representation from 73% of the world's plant families. The marine collection contains more than 10% of global diversity of sponges and ascidians, and 5% of soft corals and gorgonians (Griffith University, 2007; See Table 1). The 2004 Queensland Biodiscovery Act requires samples of all specimens collected to be lodged with the Queensland Museum or Herbarium, something which has been done since the beginning of the partnership in 1993.

The Queensland Museum

The sea is considered by Eskitis to be a greater potential source of genetic diversity than the land, having a much larger variety of life forms (phyla). Of the 28 marine phyla less than a third of the total number of species living in Australian waters—which are in turn estimated to comprise about 30% of the world's marine fauna—were known to science at the start of the partnership (Quinn et al, 2002). Over the course of the partnership, the Queensland Museum has collected more than 12,000 specimens of around 5,000 species of marine invertebrates and algae. 8,000 specimens have been extracted and subjected to HTS. Target phyla were predominantly sessile invertebrates—animals fixed to the seabed—including soft corals and gorgonians (cnidarians), lace corals (bryzoans), sea squirts (ascidians) and sponges (Porifera). Of particular interest to NPD are sponges, which show the greatest bioactivity at low "tissue" concentration, highest diversity, and span a greater range of marine habitats (Hooper, 2007). Sponges have extraordinary chemical diversity compared to other phyla, and along with ascidians have yielded the majority of novel compounds and new bioactive natural products. Sponges show such proportionally high chemical bioactivity compared to other marine phyla because: toxins are produced to repel predators, 'free-loaders', and provide a competitive advantage in crowded encrusting communities; many sponges excavate the substratum, breaking down and recycling calcium carbonate back to the reef system; they have a chemical mechanism to facilitate mutualistic associations in the reef; and they form symbiotic relationships with microorganisms (Hooper, 2007).

Examples of sponge species from the Great Barrier Reef demonstrating significant bioactivity include: *Stylissa flabellata*, with a new compound showing significant activity as an anti-inflammatory agent; *Aplysinella rhax*, showing bioactivity against cardiovascular and metabolic assays; *Haliclona ('Adocia') aculeata*, with several new compound analogues showing potential efficacy against osteoporosis; and *Citronia astra*, a new genus and species of sponge, showing significant bioactivity against anti-thrombosis screens (Hooper, 2007)

For both the Queensland Museum and the Queensland Herbarium, agreements were made with Griffith University that guided the collections and provided up front payments to the institutions to complete the work, including hiring professional staff to manage the project, undertake collections and identify specimens, and to purchase equipment and other materials. A percentage of the royalty received by Griffith University from any commercial product developed was also negotiated, to be shared with the State of Queensland, because both institutions are part of the government.

The Queensland Herbarium

The Queensland Herbarium began a scientific partnership with Griffith University in 1990, and in 1992 entered into a contractual agreement with Griffith to supply plant samples for the AstraZeneca biodiscovery program. During the first 10 years of the agreement, The Herbarium supplied plant samples for the growing collection, and in the last five years focused only on re-collection of species of interest. The collection of plant samples and herbarium vouchers were initially to include all species occurring in Queensland, but as the partnership progressed families without intebioactivity were eliminated (eg Poaceae, Cyperaceae and later Eucalypts). Collections for the partnership were undertaken only in Queensland, and by staff of the Herbarium. Collections were comprised of plant material of either flowers, fruits, leaves, stems, and sometimes roots, up to a maximum of 100g dry weight for each taxon (species, subspecies variety), plus a herbarium voucher specimen. During the course of the collections, more than 16,000 plant specimens were added to the Herbarium collection, and at least 100 species new to science were discovered (G. Guymer, pers. comm., 2007).

Unlike the Museum, which provides taxonomic and location details with samples, the Herbarium initially supplied plant samples without these details, and instead provided a bar code to trace specimens within the Herbarium collection. This was done in part to require a return to the Herbarium for re-collection, and also to protect the identity and location of rare and endangered species. In 2001, after many years of collaboration and building of trust between the partners, the Herbarium provided Griffith University with family and genus level taxonomic information on all species in the collection. This assists with literature and database searches on promising leads, and clustering plants for further analysis and de-replication. Griffith University can also obtain species-level detail upon request. Locations for collections remain sensitive, and are not necessary for the partnership on a regular basis in any case, although these too are provided if there is a specific request.

TABLE 1: THE ESKITIS BIOTA COLLECTION, 1993–2007

REGIONS/COUNTRIES OF COLLECTION AND TYPE OF COLLECTION	NUMBER OF SAMPLES	NUMBER OF SPECIES (OR OPERATIONAL TAXONOMIC UNITS, OTUS)	NUMBER OF FAMILIES	COLLECTING INSTITUTION
QUEENSLAND VASCULAR PLANTS, ALGAE AND MACRO FUNGI	>20,000	>8,000	276	Queensland Herbarium
QUEENSLAND MARINE INVERTEBRATES	>8,000	>3,500		Queensland Museum
TASMANIAN MARINE INVERTEBRATES	>1,200	>700		Queensland Museum
CHINA PLANTS (ZIYUAN COUNTY, GUANGXI PROVINCE)	6,545	>2,000	183	ZiYuan Medical Company
PAPUA NEW GUINEA PLANTS	5,743	>1,500	163	Biodiversity Limited

Source: Griffith University, 2007

China

Terrestrial collections in China are made in Zi Yuan county, of Guangxi Province in the southwest of the country. It is a mountainous region with interesting biological niches, and one of the five most biologically-diverse areas of China. Collections are undertaken by the Zi Yuan Medicine Company, which is a major supplier of Traditional Chinese Medicine (TCM). Collections include plants used in TCM, as well as those of taxonomic interest (ie from families showing interesting biological activity). However, traditional knowledge about species use within TCM is not supplied with samples—their use in TCM is used instead as a general screen for activity of any kind (A Carroll, pers. comm., 2007). Voucher specimens for the collection are retained within

the company. A taxonomist from the Department of Biology at Guangxi University coordinates collection programs for the Zi Yuan Medicine Company, of which he is a director. Zi Yuan Medicine Company was a state-owned company in the early years of the partnership, which began in 1997, but has since become a privately run company.

Collections of new samples in China concluded in 2003, although re-collection of larger volumes of species already in the collection continues. These recollected samples are now provided in extract form, with Zi Yuan Medicine Company subcontracting extraction to an industrial facility that specializes in TCM extracts (A. Carroll, pers. comm., 2007). It proved difficult to get large quantities of "unknown" bulk plant material into Australia, due to strict quarantine requirements given government concerns about pests and diseases and invasive species, and China has high levels of capacity in extraction that are utilized by botanical medicine and other companies around the world.

The original agreement between Griffith University and the central Chinese Government was signed in China in 1997, after several years of discussions between partners, and with a range of government institutions. The Zi Yuan Medicine Company facilitated the dialogue with government, hiring a lawyer from the region to negotiate with the central government in Beijing for the first agreement, and for the second agreement with the Zi Yuan County Peoples Government of the Zi Yuan Autonomous Region, which granted the collecting permits, and signed off on the partnership between Zi Yuan Medicine Company and Griffith University. The Trade, Development, and Food and Drug bureaus within the County government reviewed and approved the permits. For the second agreement, the central government said that only county government approval was necessary, and that they, rather than the provincial or central governments, should review and grant such permits. China did not have a central body dealing with ABS, or a national ABS focal point, through which the agreement passed during the negotiation of these agreements (A. Carroll, pers. comm., 2007) (see Box 5).

The agreement between Griffith University and Zi Yuan Medical Company is similar in content to those signed with the Herbarium and Museum, guiding sample quality (eg specifying moisture content, mesh size for grinding), quantity of samples supplied per year, information supplied with samples (eg identified to species level, GPS location of samples), and detailing benefits to be received by the company. The latter include payments for the agreed-upon work plan and samples, provision of a vehicle and the equipment necessary to do this, and royalties (of the same percentage received by the Herbarium and Museum) should a commercial product be developed (A. Carroll, pers. comm., 2007).

Papua New Guinea

Terrestrial collections in Papua New Guinea were undertaken by Biodiversity Limited, a small company run by a natural products researcher who is also based at the Department of Chemistry of the University of Papua New Guinea in Port Moresby. Collections began in 1997. Voucher specimens were lodged with the Papua New Guinea National Herbarium, Lae. As in the case with China, Griffith staff felt they had large and representative enough collections for the library and the AstraZeneca partnership, and so concluded collections in 2003. Collections were made throughout the country, and of the more than 1500 species collected, many were new or previously unknown to science. The collections did not include traditional knowledge, and were random or taxonomically-driven (A. Carroll, pers. comm., 2007).

Negotiation of an agreement with Papua New Guinea took a few years to conclude. This process included discussions between Biodiversity Ltd and Griffith University, and subsequent approval for collections from the PNG Department of Environment. At the time, the government of PNG did not have an ABS measure in place, nor a national focal point to deal with these issues, so permission was sought through the traditional agency within government for plant collections, the Department of Environment. The elements of the agreement are similar to those described above for China, although in this case royalties go to the government of PNG, as well as the company.

Tasmania

Marine collections in Tasmania were undertaken by Aquenal Pty Ltd., a marine environmental consultancy company. The focus of the collection was temperate marine invertebrates and algae. Around 1600 samples were provided to Griffith through this partnership. Aquenal has expertise in collecting and cataloguing samples, and do some in-house taxonomic identifications, particularly for bryozoan, ascidian and algae, but they also partner with the Tasmania Museum on identifications. The Queensland Museum does all the sponge identifications and is paid separately for this by Griffith. Voucher specimens are held at Aquenal, the Tasmanian Museum, and the Queensland Museum. Aquenal use the collection data for their surveying purposes and to assist with recommendations for coastal management in the region (A. Carroll, pers. comm., 2007).

Two, three year agreements have been signed between Aquenal and Griffith University since 2002. Tasmania does not have biodiscovery legislation, so government approval for collections was obtained by Aquenal through collection permits. The agreement between Griffith and Aquenal is similar in content to those used for the Queensland Museum and the Queensland Herbarium, in terms of samples received, payments, and royalty sharing.

India

Between 1996–2000 a collection of approximately 1800 strains of soil fungi were provided by Biocon Ltd, a private company based in Banglalore India. The agreement between NPD and Biocon is similar in content to those used for the other international collections (A.Carroll, pers. comm., 2007).

1.4 THE ROLE OF TRADITIONAL KNOWLEDGE

Traditional knowledge was not collected as part of the AstraZeneca- Griffith University partnership. This is primarily because for the disease categories of interest to AstraZeneca—in particular those afflicting older and more affluent populations—traditional knowledge is not considered an important lead for drug discovery efforts (Ron Quinn, pers. comm., 2007). In some cases, species that show promise in the discovery process have also been used in traditional medicine, but traditional knowledge, given the broad, systematic screening process undertaken at Eskitis, did not lead researchers to these species. Indirectly, traditional knowledge informed collections in China, in that species, genera, and families used in TCM were requested as part of collections made by the ZiYuan Medical Company, but this was as a way of selecting broadly for activity, and information on how species are used traditionally was not supplied with the samples.

Concerns associated with traditional knowledge and indigenous peoples' rights to control the use of their knowledge and resources have also been raised about collections, especially those made on Aboriginal lands, and the need to develop side agreements with the Aboriginal people whose land and resources are accessed (eg Tooth, 2001). It is clearly critical that the role of indigenous stewardship and ownership over resources found on their lands is recognized and respected, even if traditional knowledge is not used in the research process (eg see Article 8j of the Convention on Biological Diversity). However, the Queensland Herbarium did not collect on Aboriginal lands as part of this partnership, and most collections were made in national parks like the Daintree Forest or otherwise on crown lands (P.Forster, pers. comm., 2007; G.Guymer, pers.comm., 2007)

1.5 BENEFITS FROM THE PARTNERSHIP

AstraZeneca invested more than AUD $100 million over the 14 year lifetime of the partnership, and Australian institutions contributed expertise, infrastructure, and financial incentives. Queensland, and to a lesser extent China, India, PNG, and Tasmania, provided access to their remarkable biological diversity. Of the AstraZeneca investment, AUD $45 million went to build the research unit at Griffith University, annual costs of running the partnership came to roughly AUD $9 million/year USD, and AUD $9 million went towards collection of samples by partner institutions. Benefits accrued to the range of collaborators in the partnership—AstraZeneca,

Griffith University, The Queensland Herbarium, The Queensland Museum, and companies and institutions in China, India, Papua New Guinea, and Tasmania. At the same time, broader benefits were achieved or may still emerge for the State of Queensland, the Australian research community, the Australian public, and the international community. Benefits that accrue to a cross-section of stakeholders include those that helped build scientific and technological capacity within the State and country, and contributed to the management and conservation of biodiversity.

COURTESY OF THE QUEENSLAND MUSEUM

Benefits included monetary benefits like fees for samples (or to cover the costs of an agreed-upon workplan) and royalties. Non-monetary benefits included the provision of vehicles, equipment, technology, training, building of a state-of-the-art natural product discovery unit, and increased knowledge of biodiversity. Royalties may or may not materialize, since they are dependent upon a drug reaching the market. However, immediate monetary benefits in the form of funds to support the work of collaborators—eg collecting samples, undertaking extractions, HTS, and optimizing leads—and non-monetary benefits like facilities, equipment, training, and capacity-building were shared throughout the partnership. Following is a discussion of the benefits that accrued to various partners and groups during the course of the partnership.

The Eskitis Institute, Griffith University

The Eskitis Institute received the bulk of monetary and non-monetary benefits over the course of the partnership. Monetary benefits include royalties, at a rate standard to the industry but not publicly available (as is standard practice in bioprospecting agreements with pharmaceutical companies). Financial support for agreed workplans, including hiring staff, purchase of equipment and support of infrastructure were also significant, with annual payments to Griffith University averaging just over AUD $7 million/year.

The most significant benefit for Griffith University is the combination of enhanced expertise, biota collections and compound libraries, scientific and technological capacity and know-how, and infrastructure, in the form of a new state-of-the art facility, acquired during the course of the partnership which—together—have created a leading natural product discovery unit. Now that the exclusive partnership with AstraZeneca has switched to a non-exclusive, project-by-project basis, Griffith University can leverage these assets into new partnerships with academia, government, public-private partnerships, and with other companies.

The GU/AZ partnership was extremely unusual for bioprospecting partnerships, which generally involve little more than the collection of samples sent to companies for screening. The high level of involvement of Griffith University staff in the R&D process, and their close and regular contact with researchers at AstraZeneca, resulted in enormous benefits for science and technology in the region. It allowed staff to gain experience in working with industry and to their requirements and timescales, as well as in the science and technology of HTS, robotics, separation of complex mixtures, and medicinal chemistry, and to become a leader in those areas within the country. Griffith University is now able to identify, separate, and convert a natural product into a normal medicinal chemistry product, which removes much of the complexity and cost traditionally associated with natural products. At a time when natural product discovery programs are starting to be outsourced by the large pharmaceutical companies (Koehn and Carter, 2005), natural product discovery is increasingly undertaken by smaller companies, and academic and government research institutes, which then license compounds to large pharmaceutical companies for development, Griffith University is well-situated to play an important role in this field in the coming years.

Specific benefits to the Eskitis Institute that combined to create this state-of-the-art natural product discovery unit over the last 14 years, include:

BUILDING EXPERTISE

Roughly 113 staff received training and worked for the partnership at Griffith University over the course of 14 years; many of these have gone on to other institutions and companies (eg MerLion in Singapore, Walter & Eliza Hall Institute, Bionomics, Kyoto Pharmaceutical University, Victorian College of Pharmacy, Institute for Molecular Bioscience). Given the shortage of training opportunities in natural product research, this building of expertise is a significant benefit not only for the University, but for the country and the field of natural product research.

Students were not actively involved in the partnership, given their need to publish and constraints placed on publications resulting from the research partnership, but they will be involved in new partnerships, such as that on neglected diseases (see below). A stream of graduates were, however, hired over the years as research assistants by the NPD, and after their work with advanced technologies and equipment 14 went on to do PhDs.

BIOTA COLLECTIONS AND COMPOUND LIBRARIES

Griffith University retains ownership over the samples collected as part of the partnership. The result today is *Nature Bank*, a collection of over 200,000 optimised natural product extracts derived from a biota collection of plants and marine invertebrates from the region. Nature Bank is stored in the Queensland Compound Library. This screen-ready set of fractions, stored in the Queensland Compound Library, has been developed using proprietary optimisation techniques to create a library of "Lead-Like Peaks".

The entire biota collection is composed of 45,000 samples reside from biologically diverse terrestrial and marine sites in Queensland, Tasmania, China, India, and Papua New Guinea. These represent "unparalleled taxonomic breadth containing almost 60% of global plant diversity at the family level, including all major plant families containing more than one genus… and 9,500 samples of marine invertebrates, including 10% of global diversity of the world's sponges and ascidians and 5% of global diversity of soft corals and gorgonians" (Eskitis Institute, 2007).

The Institute has developed advanced systems for chemical isolation and structure identification led to the discovery of more than 800 bioactive compounds, some of which have been developed further by AstraZeneca, and some of which are stored in the Queensland Compound Library.

SCIENTIFIC AND TECHNOLOGICAL CAPACITY AND KNOW-HOW

The partnership exposed Australian scientists to natural product discovery in an industry setting, and access to the latest scientific and technological advances. HTS was first performed at Griffith University in the early 1990s, some ten years before any other public group in the country. The partnership, by incorporating the most advanced and 'cutting edge' equipment and technologies, also allowed Australian science to stay abreast of new developments in imaging and separation technologies (Camp and Quinn, 2007).

PUBLICATIONS

Publications are a measure by which individual scientists, scientific institutions and universities are judged. Past publication records are often directly linked to recruitment criteria, and to institutional funding allocations. The ability to publish is also a feature that helps to attract the best students and staff to a project, and ensures research results reach a wider audience with the associated benefits that the free flow of information generate. Despite restrictions placed on their ability to publish scientific articles from research arising from

the drug discovery program, staff of Eskitis Institute published more than 140 articles and papers over the course of the partnership. [7]

Griffith University

Beyond the Eskitis Institute, Griffith University benefited from the partnership with AstraZeneca through the contribution of the partnership to its overall funding base and enhanced research reputation, and as a result its being significantly more competitive in university league tables. The University also benefits from the resulting facility and assets of the Eskitis Institute, which are now available to other research scientists within the University, and other Australian and international research institutions, as well as new public/private partnerships.

The Collecting Institutions

The benefit-sharing package in place for collecting institutions is standard across institutions and includes up front fees per sample that cover costs of collection including staff, equipment (eg compound microscopes, computers, field equipment), and vehicles, as well as identification of species, and royalties should a commercial product be developed. Roughly $9 million was spent on collections over the course of the 14 years of the partnership. Royalties accrue to the State of Queensland for collections made by the Queensland Herbarium and Queensland Museum, to the government for collections in Papua New Guinea, and to companies collecting under contract in China, India, and Tasmania. The financial benefit-sharing received by collecting agencies is 15% of those, including royalties, received by Griffith University.

STAFF AND TRAINING

The Queensland Herbarium was able to employ a botanist and technical officer for the duration of the program, which required an experienced botanist who knew what to collect, how to collect, and with good field knowledge and good knowledge of the flora (G. Guymer, pers. comm., 2007). Graduate students associated with the Queensland Herbarium used collections to discover new compounds, and these were published in the scientific literature with Herbarium staff as joint authors (G. Guymer, pers. comm., 2007).

The Queensland Museum supported 4 full-time parataxonomic positions at the Museum each year, some individuals remaining for many years, and receiving more in-depth training in taxonomy, curation, and marine collection skills. A total of 20 individuals received training over the 14 years of the partnership, and 5 of these have gone on to become taxonomists, and a few to also study molecular biology and chemistry, one of whom now heads-up the Sponge Barcoding Project (Hooper, 2007; J Hooper, pers. comm., 2007; www.spongebarcoding.org). Taxonomic research on newly acquired collections was also supported through postdoctoral research fellowships partially funded by the NPD collaboration and partially by other traditional sources of funding (Hooper, 2007).

The value of support for staff, and training in collection, curation and taxonomy cannot be overstated. Although the government promotes academic and commercial partnerships based on the country's unique flora and fauna, and there is increasing demand for taxonomic skills to assist with environmental planning, management and conservation, funds for taxonomy remain limited. The Australian Marine Sciences Association reports a steady decline in the number of taxonomists over the last decades, with the latest count showing 23 marine taxonomists in Australia's museums and research agencies. Nine have retired in the past five years and have not been replaced (Leung, 2007). State governments are the main employers of taxonomists through their herbaria and museums, but are unable to maintain the taxonomic work force in the face of competing claims on State budgets. The Federation of Australian Scientific and Technological Sciences has initiated a research project looking into the taxonomy skills shortage in marine, plant, insect and parasite science (Leung, 2007).

7 A selection of these are listed on the Eskitis web page of the director Ron Quinn at http://www.griffith.edu.au/professional-page/professor-ron-quinn/publications, for example, A. R. Carroll et al., Dysinosin a: A novel inhibitor of factor Vila and thrombin from a new genus and species of Australian sponge of the family dysideidae, Journal Of The American Chemical Society 124, 13340 (Nov 13, 2002); Davis, R. A.; Carroll, A. R.; Watters, D.; Quinn, R. J. The absolute stereochemistry and cytotoxicity of the ascidian-derived metabolite, longithorone J. *Natural Product Research* 2006, 20, 1277–1282

"There are potentially millions of species that remain undocumented and yet fewer and fewer people are employed in this area, or have the necessary taxonomic expertise. Commercial partnerships are currently a major source of employment and support for the development of taxonomic capabilities in research institutions in this country, especially long term collaborations such as that with NPD for which a few key staff were employed for over a decade …" said John Hooper of the Queensland Museum, "Some people, particularly those with political and managerial agendas, feel naming things is futile without a direct economic outcome—this is another reason why biodiscovery has been good in Australia. Not only does the partnership have immediate non-monetary benefits (data for management decisions, conservation planning, and so on), and potential downstream monetary outcomes (royalties), but it also has the knock-on effect of making government more interested in supporting these kinds of jobs." (J Hooper, pers. comm., 2007).

BIODIVERSITY INFORMATION

The most common and significant benefit cited by collecting institution staff is the support for collections that would otherwise not be possible within institutions dependent upon limited government support, and the biodiversity information with important scientific and conservation applications that resulted. Marine invertebrate biodiversity, in particular, is poorly known, expensive to collect, and the expertise to document it is grossly inadequate (Hooper, 2007). Taxonomic identification is expensive and time-consuming, and most research institutions have backlogs which cannot be covered with government support; commercial partnerships are seen as an important way to get this work, central to the Herbarium and Museum's mission, done. "Without knowledge about what species exist, their distribution and their interaction, no informed and sensible environmental management decisions can be taken. Without a comprehensive taxonomy governments cannot safely allocate resources and set priorities for conservation and natural resources utilisation" (Geoff Burton, pers. comm., 2007)

The Queensland Herbarium "always viewed the increase in the knowledge about the State's flora as its [the partnership's] major benefit and the funding from the program delivered this outcome" (G. Guymer, pers. comm., 2007). The GU/AZ drug discovery partnership supported collections and research by the Herbarium that resulted in the discovery of more than 100 species new to science, many of conservation concern, together with hundreds of new records for the distribution of species (eg the extension of range), and collections in parts of Queensland that had never before been systematically surveyed (G. Guymer, pers. comm., 2007).

Expansion of collecting institution collections are a significant benefit of the partnership. More than 16,000 plant specimens were added to the herbarium collection (G. Guymer, pes comm., 2007), and the Queensland Museum incorporated 12,000 specimens of roughly 5,000 species of marine invertebrates and algae into its permanent collection (Hooper, 2007).

These marine specimens yielded more than 200 bioactive compounds, most with novel bioactivity, and 23 new structural classes discovered. Sponges (Porifera), in particular, were most productive, both in terms of new chemical compounds and species diversity (Hooper, 2007). In 1994, there were 1385 species of sponges described for the entire Australian fauna (including its external territories), with less than half of these known to live in tropical waters; this knowledge took 200 years to acquire (Quinn et al, 2002). In contrast, over the past 15 years, 3,000 sponge species were discovered, about 70% new to science, providing a three-fold revision of previous estimates of sponge diversity in Australia and worldwide (5,000 and 15,000 respectively). (Hooper, 2007). The conservation benefits linked to the biodiversity information yielded by the NPD is further discussed below.

BENEFITS FOR BIODIVERSITY CONSERVATION

Although "access and benefit-sharing" (ABS) arrangements are linked to the conservation of biodiversity within the Convention on Biological Diversity and national ABS measures, in practice many ABS partnerships manifest few concrete benefits for conservation . When samples are provided but specimens are not lodged with national research institutions engaged in this process, and these institutions are not supported through

collections, the benefits for conservation are limited or none. In a very few cases, bioprospecting partnerships include payments to protected areas and support local conservation activities, such as the case of InBio and Merck in Costa Rica. But even in that case, and overall, the most significant benefits for biodiversity conservation resulting from this type of research have generally been found in the biodiversity information they provide that is critical for setting conservation priorities, conservation planning, and for management.

The collecting that took place under the partnership is an extraordinary example of this type of benefit for conservation, providing support for collections of marine and terrestrial organisms, particularly in Queensland, that identified new species and populations of endangered species, provided critical information on biodiversity 'hot spots', and was used not only in drafting the Queensland Biodiversity Act 2004, but in environmental planning and management throughout the region.

In addition to collecting and identifying 100 species new to science, and new records on the distribution of species as described above, the Queensland Herbarium also found new populations of threatened species in remote areas, providing genetic resources to propagate the species, and documented weed encroachment in native forests that has helped inform forest management (Camp and Quinn, 2007). Increased knowledge of species distribution has also been used in environmental planning for Queensland.

The Queensland Museum made astounding taxonomic discoveries as a result of their work for the partnership, and has also made some major advances in the knowledge of spatial distribution of marine organisms across northern Australia, which in turn has contributed to marine conservation and planning processes. This has included the delineation of Marine Protected Areas (MPAs) based on faunal characteristics. It also provided data to undertake biodiversity "hot spot" analysis across northern Australia, identifying areas of comparative species richness, high endemism, and phylogenetic relationships amongst these regional faunas (Hooper, 2007). The material collected from the Eskitis biota collection and other projects also allowed the study of population genetics of some species, and an analysis of "beta diversity" trends (spatial patterns where there are major species turnover points across an environmental gradient) at medium and large spatial scales. As a result, it was possible to delineate a number of biogeographic transition zones across northern Australia and compare these data to traditional marine biogeographic models for Australia. These sorts of data were useful to national bioregional planning processes in both State and Commonwealth waters such as the Great Barrier Reef Marine Park Authority and the Representative Areas Program (Hooper, 2007).

AstraZeneca

AstraZeneca benefited from their partnership with Griffith through access to the remarkable marine and terrestrial biological diversity of Queensland, and to a lesser extent Tasmania, China, India and Papua New Guinea. They also benefited from collaboration with an increasingly sophisticated natural products discovery unit that worked closely with AstraZeneca researchers, from the existing high levels of scientific expertise within Griffith University and the country, and from working in a country with a robust legal system, and an increasingly clear ABS regulatory environment that grants them legal certainty over the material they study. The Commonwealth and Queensland State governments also provided financial incentives to AstraZeneca in the form of pricing incentives through the Commonwealth's Factor F scheme, and provision of the research building and other support through the Government of Queensland. While Griffith University retains ownership over the biota samples and compound libraries that resulted from the partnership, intellectual property rights to commercial products developed from the partnership remain with AstraZeneca.

Queensland, Australia and the International Community

The State of Queensland and the country at large benefited from the investment of $100 million by AstraZeneca in Griffith, the employment and building of expertise it provided, as well as increased scientific and technological capacity, including the first natural product HTS facility in Australia, and the Queensland Compound Library and Molecular Screening Collaboration that resulted in part from the partnership. Opportunities for private/pub-

lic partnerships and investment in Australia are also enhanced, as is the potential to employ Australian scientists and so alleviate the scientific brain drain which has afflicted the country. Australia will also benefit from the type of innovative business partnerships described in Box 8, which describes a potential analgesic from the tree *Barringtonia acutangula*, which build upon the unique biological and cultural diversity of the country.

The range of benefits for biodiversity conservation described above serve the public in Queensland, Australia, and worldwide, as do the contributions to scientific knowledge and the potential development of new medicines. For example, the Eskitis Institute is working with a range of international organisations in the search for new therapies to combat neglected diseases. These include the Seattle Biomedical Research Institute (SBR) on the biology of disease-causing parasites, the Medicines for Malaria Venture (MMV) and the Drugs for Neglected Diseases Initiative (DNDi). These groups are supporting HTS campaigns at Eskitis Institute to identify natural products that show promise against malaria and sleeping sickness (Quinn, pers. comm., 2007; Eskitis 2007).

1.6 CONCLUSIONS

The Griffith University/Astra Zeneca partnership provides a valuable opportunity to examine the ways bioprospecting partnerships can yield benefits for provider countries, and for biodiversity conservation, over time. Running for 14 years—much longer than most other such ABS partnerships—it offers a window onto the extent of scientific and technological capacity that can be built, the enormous wealth of biodiversity information that might be collected and analysed, and the ways that the many benefits regularly articulated in ABS policy documents can come together over time to add up to more than the sum of the parts.

Pipestela candelabra COURTESY OF THE QUEENSLAND MUSEUM

Monetary and non-monetary benefits in this case fall within the standard package for "best practice", but it is in the accumulated and multi-faceted nature of the benefits that the real gain for Queensland and Australia are to be found. These include the collections and compound libraries, the advanced natural product discovery unit, and the enormous gains in taxonomic and ecological understanding that resulted from the collections. This case demonstrates that these benefits can be of equal, or greater, importance to potential monetary benefits from royalties should a product be commercialized.

The pre-conditions that attracted AstraZeneca are also the very things that make this a difficult model to reproduce in many other countries—eg existing high levels of scientific and technological capacity, unique biodiversity, a legal system that provides legal certainty, and government incentives for investment. However, study of this partnership is instructive in terms of providing an example of what ABS "best practice' in partnerships generally seeks to achieve. This includes a wide range of benefits in the short, medium and long term, undertaking high levels of research within provider countries, building scientific and technological capacity, and significant benefits for biodiversity conservation. The building of ABS policy capacity within the collaborating institutions, including working with new state and federal ABS regulations, is also a significant benefit of the partnership.

Conclusion of the exclusive AstraZeneca-Griffith University partnership provides an excellent opportunity to view in the coming years how the significant accumulated benefits of such a "best practice" partnership can be leveraged to form new collaborations with a range of partners, serve a wider range of public needs (e.g. research on neglected diseases, innovative partnerships based on the country's biological and cultural diversity, support for Indigenous peoples' priorities), and generate benefits for science, medicine, and biodiversity conservation over time.

CASE STUDY 2:

The Kenya Wildlife Service (KWS), The International Centre for Insect Physiology and Ecology (ICIPE), and Novozymes and Diversa (Verenium) Corporation: Agreements in the Industrial Biotech Sector

Sarah Laird

2.1 KEY PLAYERS

Kenya Wildlife Service

Kenya Wildlife Service (KWS) is an autonomous parastatal body supervised by a Board of Trustees with exclusive authority over national parks and significant influence over other categories of protected areas. The KWS was established under the Wildlife (Conservation and Management) Act of 1977 (and amended in 1989) (Lettington, 2003). KWS is charged with the protection and conservation of the country's biodiversity, and its mission is "to sustainably conserve and manage Kenya's wildlife and its habitat in collaboration with stakeholders for posterity". As a parastatl, KWS reports to a parent Ministry, with the Ministry changing from time to time depending on how ministries are constituted by the president. At present, KWS is part of the Ministry of Tourism and Wildlife, and to date has been the ABS focal point for collections made in Kenya's 61 national parks and reserves (but not outside these areas), which include a number of Rift Valley soda lakes with microorganisms of interest to the biotech industry. KWS is also responsible for conducting and coordinating research activities in the field of wildlife and conservation management, as well as regulating research in protected areas, including vetting research proposals and issuing permits for research and for the export of any samples (KWS, 2006; Lettington, 2003). As such, they have directly entered into a number of agreements with outside partners, including Novozymes and Diversa. Other commercial partnerships include natural products from plants and microorganisms for crop protection, and another focused on insect venoms.

The International Centre for Insect Physiology and Ecology (ICIPE)

ICIPE was established in Kenya in 1970 to "help alleviate poverty, ensure food security, and improve overall health of peoples of the tropics by developing and extending management tools and strategies for harmful and useful anthropods, while preserving the natural resource base through research and capacity building." ICIPE has over 200 regular staff members, drawn mainly from the developing world, and of these over 40 are professional scientists. Most staff are based at the headquarters in Nairobi (www.icipe.org). ICIPE partners with KWS and other institutions for bioprospecting contracts, with the ICIPE-KWS relationship detailed in the "Memorandum of Agreement for Partnership in Discovery and Development of Products Identified from Kenyan Arthropods, Microorganisms, and Plants". For academic agreements involving the transfer of material, ICIPE drafted in 2000 an "Agreement for the Transfer of Biological Material and/or Related Information" (www.wipo.int/tk/en/databases/summaries/icipe.html). ICIPE is also involved in commercial partnerships associated with its work on insects, including that with the venture capital company Bridgeworks, based in Switzerland. Bridgeworks Africa involves a partnership with ICIPE to develop botanicals, biopesticides and fertilizers, microbial pest control, and insect attractants, repellents and traps. The agreement affords Bridgeworks a "right of first refusal" on all new developments coming out of the research partnership, with benefit-sharing including royalties and technology transfer (www.bridgeworks.ch).

icipe Headquarters in Nairobi, 2008 FABIAN HAAS

Novozymes

Novozymes is a biotech company based in Denmark, primarily owned by Novo A/S, a wholly-owned subsidiary of the Novo Nordisk Foundation. The company focuses on products that improve industrial performance and quality while saving water, energy, raw materials, and waste. Novozymes has around 4,500 employees, 15% of whom work in R&D, and over 700 products used in more than 40 different industries, and sold in 130 countries (www.novozymes.com). Novozymes' annual sales in 2006 were DKK 6,802 million, with an operating profit of DKK 1,340 million, and net profit of DKK 911 million. The company makes a commitment to support the International Chamber of Commerce's Charter for Sustainable Development, the Convention on Biological Diversity, the UN Universal Declaration of Human Rights, and the UN Global Compact (www.novozymes.com).

Novozymes spends 11-13% of sales on R&D focused on microbiology, biotechnology and gene technology. Their "core competencies" are genetic and biochemical diversity (culture collection, strain screening, genome sequencing, expression cloning); protein design; protein chemistry; pathway engineering; strain development and improvement; and large-scale production. They find, develop or refine enzymes and microorganisms into commercial products, and through 'state-of'the'art' biological production, produce them in large quantities for sale. Microorganisms are responsible for much of the building up and breaking down of different kinds of organic material in the environment, and Novozymes makes use of these capabilities for commercial products that clean surfaces and wastewater or improve the growth of plants. Microorganisms such as bacteria and fungi are also efficient and safe producers of enzymes that Novozymes sells for industrial applications (www.novozymes.com).

The company launches 5-8 new products a year, with development cycles for industrial or technical products—such as enzymes for biofuels and detergents—taking no more than 1–2 years from when a lead enzyme is identified, and for feed and feed products taking roughly 2–3 years, given the more involved approval procedures and requirements for toxicology (Ole Kirk, Novozymes, pers. comm., 2007).

Novozymes has 2-3 partnerships with overseas research institutions running at any one time, including one previously with BIOTEC, Thailand for the collection of insect pathogenic fungi (Lange, 2004), and currently that with Kenya Wildlife Service and another in Portugal (Ole Kirk, pers. comm., 2007).

Diversa (Verenium Corporation)

Verenium Corporation develops biofuels derived from low-cost abundant biomass and specialty enzyme products. Verenium, a publicly-traded company based in the US, was formed in 2007 through the merger of Diversa Corporation, which worked in enzyme technology, and Celunol Corporation, a developer of cellulosic ethanol process technologies and projects. The combination produced a company with "integrated end-to-end capabilities to make cellulosic biofuels a commercial reality" (www.verenium.com). Diversa signed an agreement with KWS and ICIPE in 2001, as part of collections to feed its research on enzymes that can be used in industrial processing. Examples of products in this area include Luminase PB-100 and Luminase PB-200, enzymes that enhance the process of pulp bleaching in the paper making industry while reducing the use of harsh bleaching chemicals (www.verenium.com). Luminase was developed from a microbe found in a thermal feature in Kamchatka as part of a partnership between Diversa and the Center for Ecological Research and BioResources Development (CERBRD) in Russia. Enzymes are also used in products to convert plant material into cellulosic ethanol for fuel, and in animal care, including to improve the nutritional value of feed (www.verenium.com). Diversa focuses on enzymes found in microorganisms, since they are the world's most genetically diverse organisms, with broader and more varied characteristics than those observed in plants or animals. In 2005, Diversa had 18 partnerships with groups in 10 countries across six continents, and was collecting in all international waters around the world (Mathur et al, 2004; Diversa, 2005). But the 2007 merger of Diversa and Celunol into Verenium followed a restructuring at Diversa in 2006 (Sheridan, 2006). This restructuring was intended to improve product sales and to focus on commercializing the significant

resources obtained from the previous decade of bioprospecting. This refocusing effort has limited the number of new partnerships to those considered most strategic to the commercialization efforts of the company (David Nunn, Verenium Corporation, pers. comm., 2008).

2.2 THE KENYA WILDLIFE SERVICE—NOVOZYMES PARTNERSHIP

Background

In May 2007, The Kenya Wildlife Service and Novozymes entered into a five year partnership for the collection, identification, and characterization of microorganisms from Kenya's national parks. The current agreement grew out of pre-CBD collections that Novozymes received, and their subsequent efforts to address the absence of an agreement associated with these collections after they led to the development of a commercial product, Pulpzyme. Pulpzyme reduces the amount of chlorine needed to bleach wood pulp (Odhiambo, 2007). It remains unclear who collected the samples, or where, and they may have been the result of a staff person collecting while on holiday, a practice common in the years prior to the CBD. Within the company's database, however, the country of origin—Kenya—was clear. It was assumed that collections took place in a protected area, and thus under the management of KWS, so the company approached KWS to reach an agreement.

Commercial sales of Pulpzyme have been modest, but Novozymes sought to develop a benefit-sharing agreement for proceeds from this product in order to "make things straight… in the spirit of the CBD" (Ole Kirk, Novozymes, pers. comm., 2007). A deal was negotiated to pay an accumulated royalty on past sales (the exact amount is not available), and running royalties on any future sales, as well as to build a new partnership around microorganism collection, identification, and characterization. Novozymes will train Kenyan students in taxonomy, isolation and identification of microorganisms, and will transfer advanced technology to Kenya, including knowledge of how to collect and isolate micro-organisms and how to characterize microbial diversity. The new agreement also grants Novozymes "rights on similar terms to commercially make use of specific strains isolated in Kenya which are already in Novozymes' possession." (Novozymes/KWS press release, 2007).

The partnership between Novozymes and KWS will run for five years as of 2007. Novozymes has found that with similar agreements in other countries, five years is a reasonable amount of time to allow for training and technology transfer to provider country institutions, and for Novozymes to fully evaluate the potential of the project, and the available biodiversity (Ole Kirk, pers. comm., 2007).

The 2007 Novozymes-KWS agreement did not result from a particular interest in bioprospecting partnerships in the region on the part of Novozymes, and instead resulted from commercialization of much earlier collections, and a desire to negotiate a benefit-sharing agreement. However, the microbial diversity available in Kenya is of interest to the company, which stands to benefit from its new partnership through access to the novel genetic resources. However, the company is not as dependent upon collections from nature as it was even 10 years ago. Advances in science and technology, in particular genomic science, have made it possible to access the enormous biodiversity in Denmark alone, and most of their products derive from Danish biodiversity. The company also has access to increasing numbers of genomes placed in the public domain (on average, one new microbial genome is published a week), and they are able to generate 'artificial evolution" and "diversity" in the laboratory (Ole Kirk, pers. comm., 2007).

Prior informed consent

Under the Wildlife and Conservation Management Act of 1972 (amended in 1989), KWS has jurisdiction over the management of Kenya's 61 national parks and reserves, which form the core of the conservation system. KWS is responsible for regulating research in these areas, including vetting research proposals and issuing permits for research and for the export of any samples (KWS, 2006). National parks are central government property, and reserves are the property of communities, but KWS manages research in the latter areas, as

well. Additional prior informed consent from local councils or communities for collections undertaken in reserves is not required.

While KWS serves as the national focal point for ABS in national parks and protected areas, these responsibilities, and their relationship to those of the parastatl National Environmental Management Authority (NEMA), currently of the Ministry of Environment and Natural Resources, have been unclear since new ABS regulations were propagated in December 2006. Prior to these new regulations—Legal Notice 160 "The Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit-Sharing) Regulations, 2006", under the Environmental Management and Coordination Act (No 8 of 1999)— there was no specific ABS regulatory regime in Kenya, although elements of a potential ABS regulatory structure were in place, and a range of statutory, regulatory and policy provisions affected access and benefit sharing (Lettington, 2003). In the new regulations section 53 directly addresses access to genetic resources. NEMA is identified as the national ABS focal point, but the relationship between this new role for NEMA, and KWS' existing authority, remains unclear. Discussions are ongoing to address confusion about respective mandates and jurisdictions. At the same time, and typical to the establishment of national focal points around the world, NEMA is a new institution within government with a broad mandate and limited resources, so ABS must compete (often unsuccessfully) with other priorities (Lettington, 2003).

In the meantime, KWS continues to operate according to previous arrangements in which it grants access and receives benefits from ABS partnerships undertaken in protected areas. KWS undertakes to ensure that all necessary permits and authorizations are obtained for partner companies (Lettington, 2003). In the absence of clear ABS measures, procedures, and institutional authorities, many companies are reluctant to engage in ABS partnerships, however the KWS role as broker and facilitator appears to provide the certainty companies need. In the case of the Novozymes partnership, KWS facilitated permits and signed the agreement with Novozymes. Directly partnering with companies in this way is somewhat unique for park managers, although one that has been widely proposed as a way of funding expensive and critical research and management activities in conserved areas.

Access to resources

KWS will undertake all collections, and these will be in Kenyan national parks and reserves. The collections do not involve traditional knowledge. Biotechnology research programs like these do not incorporate traditional knowledge into their collecting programs due to the emphasis on microorganisms, and because their research approaches and technologies do not lend themselves to incorporation of this type of information (Lange, 2004; Mathur, 2004). The numbers of samples to be collected per year are not specified in the agreement, and the intention is that this will evolve alongside the partnership in the coming years. In the microbial discovery laboratory set up by Novozymes, and staffed by KWS researchers trained by Novozymes, KWS will undertake isolation and characterization of microorganisms. They will supply research results to Novozymes, which will then decide whether to pursue a lead or not.

Benefit-sharing

MONETARY BENEFITS

Under the agreement, KWS—as a representative of the government—will receive running royalties on any commercial product developed. The rate is confidential (see discussion below in section on the Diversa partnership). Novozymes also provides KWS with an upfront payment, a 'lump sum' that covers the costs of sample collections and laboratory work. If research results from the microbial discovery laboratory in Kenya show promise, and Novozymes wishes to pursue something further, it will request samples for research within the company's laboratories, and this will trigger a milestone payment to KWS.

NON-MONETARY BENEFITS—TECHNOLOGY TRANSFER AND CAPACITY-BUILDING

As part of the benefit-sharing arrangement associated with Pulpzyme, Novozymes sought to expand benefits beyond the purely financial, and develop a broader collaborative project. As elaborated in the 2007 agreement, this includes establishment of a microbial discovery laboratory at KWS, with advanced technology to isolate and characterize microorganisms within Kenya. Necessary materials for implementing enzyme screening in Kenya will also be supplied (Novozymes/KWS, 2007). Staff of KWS will travel to Novozymes, with costs born by Novozymes, to be trained in these techniques, and Kenyan students will be trained in taxonomy, isolation, and identification of microorganisms. The laboratory can be used for other partnerships, as well—Novozymes does not have exclusive rights to its use.

BENEFITS FOR BIODIVERSITY CONSERVATION

Financial benefits will accrue to KWS, whose mission is "to sustainably conserve and manage Kenya's wildlife and its habitat". They will support the wide range of research and conservation programs undertaken by KWS, and as a result—unlike most bioprospecting agreements—financial benefits will directly support conservation work in the region. Biodiversity resource inventories and mapping are made alongside the routine sample collections, and results are held in Resultant Resource Databases; as a result the collections will generate information and understanding about biodiversity critical to ecological monitoring for conservation management and planning (Paul Mungai, KWS, pers. comm., 2008).

BENEFITS FOR SCIENTIFIC AND TECHNOLOGICAL CAPACITY

By building a laboratory at KWS to undertake identification and characterization, and training researchers, a higher level of scientific research will take place than those associated with bioprospecting agreements that involve only the supply of samples. The laboratory is also available for other research projects—academic and commercial—allowing KWS to build upon the capacity resulting from this partnership. As KWS Director Julius Kipng'etich reported, in reference to this partnership: "Tourism is low level income generation. We need to graduate to a higher level where biotechnology takes us" (Odhiambo, 2007).

Intellectual property rights

Any intellectual property that comes out of the partnership will be co-owned by both parties. Both KWS and Novozymes will be listed on patents. Novozymes has a very active patenting policy, with an extensive portfolio of more than 4,200 active patents, patent applications, and licensed patents (www.novozymes.com).

Tracking and monitoring of samples

Given the structure of this agreement, with Novozymes not receiving samples, but data instead, and the request for samples for further study in Denmark triggering milestone payments, there are fewer concerns associated with tracking samples within the company program, and monitoring and compliance, than in many cases. However, Novozymes does have a very well-established tracking system in place. In general, however, developments in science and technology, and dramatic changes in the ways genetic resources are studied and used, mean that tracking and monitoring the use of genetic resources has become increasingly difficult. As a result, trust and regular communication associated with solid partnerships are important elements of tracking and monitoring, and compliance with agreements.

Agreements employed

The agreement used as the basis for discussion between Novozymes and KWS, and adopted with fairly minor changes, was one proposed by KWS. A single agreement guides this partnership, with KWS acquiring permits directly from the government on behalf of the partnership.

2.3 THE KENYA WILDLIFE SERVICE-THE INTERNATIONAL CENTRE FOR INSECT PHYSIOLOGY AND ECOLOGY (ICIPE) AND DIVERSA (VERENIUM) CORPORATION PARTNERSHIP

Background

In 2001, the Diversa Corporation signed a three-year agreement with the KWS and ICIPE. This was during a time of expansion in Diversa's collecting partnerships around the world, with a total of 18 partnerships by 2005 (Mathur et al, 2004; Laird and Wynberg, 2005). In 2004, the agreement was renewed, and at that time, small changes were made in the agreement, including an increase in the flat amount payable annually for the supply of samples, and a simplification of the royalty structure in order to make it easier to manage.

Biochemistry laboratory at icipe, Nairobi, 2008 FABIAN HAAS

KWS and ICIPE work together in this case, under the 2000 "Memorandum of Agreement for Partnership in Discovery and Development of Products Identified from Kenyan Arthropods, Microorganisms and Plants". The agreement signed with Diversa is with both KWS and ICIPE, with ICIPE managing the partnership, undertaking communication with Diversa, and receiving and then distributing to KWS its share of any financial benefits.

Prior Informed Consent

Prior Informed Consent was facilitated by KWS and ICIPE. Because collections are undertaken only in protected areas, KWS served as the ABS focal point for the research, as described above in the case of Novozymes.

Access to Resources

KWS undertakes all field collections of material on behalf of Diversa, which provides guidance for collections, formalized in their agreement, as follows:

" Collaborators will be responsible for the collection, processing and shipment to Diversa of environmental samples from diverse habitats within the Republic of Kenya and/or DNA samples isolated from such environmental samples using the Technology. Collaborators shall further be responsible for planning and execution of collection trips with and without the participation of Diversa personnel. Collaborators will provide laboratory space for the collaboration activities. Environmental samples shall include, but not be limited to, soils, sediments, mire, earth, microbial mats and filaments, plants, ecto and endo symbiont microbial communities, endophytes, fungi, animal and/or insect endosymbionts, marine and terrestrial invertebrates, air and water. Collaborators will provide Diversa a minimum of 50 and up to 250 environmental samples per year. All such environmental samples shall be considered "Material" under this Agreement" (Appendix A, Materials, Biodiversity Collaboration Agreement).

Benefit-sharing

All KWS-ICIPE agreements with the private sector include annual fees, royalties, and technical cooperation and training, and most also include some form of milestones (Peter Munyi, ICIPE and Robert Lettington, GRPI, pers. comm., 2007).

MONETARY BENEFITS

An annual payment is made to ICIPE/KWS from Diversa in order to cover personnel, equipment, and other costs associated with the collections. There is also a bonus mechanism ("milestone payment") built into the partnership, in which the local institutions receive a small bonus, as a percentage of base funding, if seven criteria are met: completion of data sheets; DNA from samples is supplied when requested; DNA is isolated according to agreed protocols; shipping protocols are followed; specific sample collection or re-collection requests are fulfilled; maximum coverage of biotypes and habitats is achieved; and the partners respond in a timely and professional manner.

Dependent upon a successful commercial product, milestone payments and royalties will be paid. As with the Novozymes case, and standard to commercial partnerships, the royalty rate for the Diversa case is not publicly available. However, on a general basis, "the range of royalties currently active for KWS-ICIPE partnerships is between 0.5%–10%, with the lower end tending to involve highly specialized technologies that require significant value adding outside Kenya. The highest tend to involve less direct values, such as know how and other forms of licensing etc to third parties, although this obviously only involves specific technologies and not material or broader rights. The mid range of royalties tends to involve the use of material in applying more established technologies and where more of the science can be done in Kenya before delivering material. Associated with this, some agreements have incentives where there can be bonuses of up to 5% of the base annual access fees for meeting key recipient requirements for the standards of material delivered." (Peter Munyi, ICIPE and Robert Lettington, GRPI, pers. comm., 2007).

Of the monetary benefits received as part of these agreements, KWS and ICIPE divide them 50/50. In other cases in which protected area managers are parties to agreements, such as that with Yellowstone National Park in the US or government research institutions, such as the Queensland Museum and Herbarium in their partnership with Griffith University and AstraZeneca, financial benefits do not accrue directly to the park managers or research institutions, and will often go to state or federal government coffers.

For an overview of the "Compensation to Collaborators by Diversa for Product(s) sold by Diversa", which is detailed in Appendix B of the agreement, see Box 1.

NON-MONETARY BENEFITS

License to products and inventions

KWS and ICIPE retain the right to a royalty free license to any products or inventions developed from Materials provided under the partnership, in order to allow them to research, develop and otherwise make use of any products or inventions developed from the Material within the jurisdiction of the Republic of Kenya (but not beyond this jurisdiction). This is not understood to "confer any commercial rights, or rights to transfer any products, inventions or commercial rights to third parties" (12., Agreement Terms, Biodiversity Collaboration Agreement).

Training

Under the agreement, KWS and ICIPE will receive training in technology relevant to the partnership, primarily at Diversa, and undertaken at Diversa's cost.

Research results

Under the agreement, KWS and ICIPE have the right to complete information developed by Diversa, and to research results on any novel genes or organisms discovered therefrom.

Publications

Diversa, KWS and ICIPE researchers will jointly publish the results of any research work when there is a substantive contribution by both parties, and after all parties have provided written approval. The submission and

subsequent publication, however, will be delayed until any intellectual property or confidential information contained in the proposed publication is adequately protected as mutually agreed by all Parties (8., Agreement Terms, Biodiversity Collaboration Agreement).

Benefits for Biodiversity Conservation
In addition to the potential financial benefits that will go to KWS, and the increased biodiversity information and understanding resulting from the project, Diversa suggested that "it might consider providing matching funds for biodiversity conservation activities relating to its fields of interest' (Lettington, 2003).

Benefits for Scientific and Technological Capacity
Diversa provides funds for laboratory equipment, training within Kenya and at Diversa's facilities in the US, and capacity-building in technology for molecular analysis of different habitats including extraction techniques, techniques for generating gene libraries, cloning, and information technology for DNA analysis (see Box 1).

Intellectual Property Rights

Under the agreement, the company retains intellectual property rights over any products that it develops, provided that ICIPE and KWS have the option of a royalty free license for local adaptation in Kenya when, and if, this is feasible (Lettington, 2003).

There were discussions within KWS and ICIPE at the time of the first agreement, and it was decided to not pursue intellectual property rights, which in any case it might be difficult for ICIPE and KWS to utilize effectively, and rather to focus on seeking greater monetary and non-monetary benefits as part of the partnership (Robert Lettington, pers. comm., 2007). The text in the Biodiversity Collaboration Agreement relating to IPRs is as follows: in the Preamble, "Whereas, Collaborators agree that Diversa will own any invention made by Diversa using the Material; and…" and in the Agreement Terms, 11. "Diversa agrees and understands that if Diversa's use of the Material results in identification of new genes, or any invention, improvement, useful composition, structural modification or derivative of the Material (any of which shall be considered a "Diversa Invention"), Diversa shall promptly disclose any such Diversa Invention to Collaborators. Collaborators agree that, subject to the provisions of this Agreement, Diversa shall own all right, title and interest in and to any or all Diversa Inventions."

Tracking and monitoring

In the agreement, Diversa agrees to assign unique identification numbers to Material sent by Collaborators, and to assure that its identification system allows Collaborators and Diversa to identify all Material and research results (Agreement Terms, Biodiversity Collaboration Agreement, 10.).

BOX 1. APPENDIX B TO AGREEMENT

COMPENSATION TO COLLABORATORS BY DIVERSA FOR PRODUCT(S) SOLD BY DIVERSA

1. For each calendar year during the term of this Agreement, Diversa shall pay to Collaborators a royalty based on Product(s) sold by Diversa, its Affiliates and/or licensees as follows:
   i. **x %** of the first **y** US dollars (**US $y**) in Net Sales of Product(s) sold by Diversa;
   ii. **a %** of Net Sales of Product(s) sold by Diversa in excess of **y** US dollars (**US $y**);
   iii. **b %** of Net Sales from any licensing, assignment, sales, lease and/or rental (hereinafter "distribution") of any copyrighted work (including books or other publications) created using the results of research under this Agreement.

Provided, however, that Diversa's Gross Margins with respect to all such Net Sales after payment of all applicable royalties to third parties, including without limitation, Collaborators equals a minimum of **c** Percent (**c %**) of Net Sales over **y** US dollars (**US $y**). "Gross Margins" is defined as Net Sales, less costs of manufacturing (including direct and indirect costs) and of materials, but not the cost of capital investment, as these terms are recognized under United States generally accepted accounting principles. In the event that Diversa's Gross Margins with respect to such Net Sales are less that **c** Percent (**c** %), then the payment(s) otherwise due to Collaborators under this subsection(i) shall be reduced by a percentage equal to the difference between such Gross Margins and **c** Percent (**c** %)

iv. **d %** of the first **y** US dollars (**US $ y**) in Product Sales Net Revenue that Diversa receives, recognizes as revenue, or is otherwise entitled to receive (without duplication) in such calendar year;
v. **e %** of Product Sales Net Revenue in excess of **y** US dollars (**US $ y**) that Diversa receives, recognizes as revenue, or is otherwise entitled to receive (without duplication) in such calendar year;
vi. In the event that Diversa's compensation from its licensees does not include royalty payments on sales of Product(s) by such licensee, the Diversa shall further pay to Collaborators a royalty of **a** % of all licence fees actually received by Diversa in consideration of such licence, including, but not limited to, licence issues fees, annual maintenance fees and sublicence revenue.

Notwithstanding the foregoing, no royalty will be due on any Product(s) which is/are sold solely for the purpose of performing research on or analysis of such Product(s), such as in Diversa's enzyme library kits, enzyme subscription program, or small scale pilot Product(s) sales, or on any Product(s) sold to Collaborators or their affiliates.

Royalty payments will be made in US Dollars by wire transfer to the account designated by Collaborators, with **n** (**n**) days after the end of each quarter during which revenues form net Sales and/or Product Sales Net Revenues are received by Diversa. Payments shall be accompanied by written reports to Collaborators stating the number, description and sales prices of the Product(s) sold during the preceding quarter upon which royalties are paid.

Diversa will make available to Collaborators such supporting information and documentation as Collaborators may reasonably require for the purpose of verifying the written reports furnished by Diversa and the amount of royalties payable hereunder. Diversa shall further permit the authorized representatives of Collaborators to have access to the accounts, records and information maintained by Diversa in relation to all matters relevant to such verification upon reasonable notice during normal business hours.

2. Further, Diversa shall provide to Collaborators, on an annual basis, a list of goals that shall be directly related to Collaborators' work under this Agreement. Such goals may include, but not limited to, items such as the following:

i. **f %** Complete environmental/isolate sample data sheets submitted for all environmental samples received by Diversa with g (g) business days of receipt of the sample each calendar year;
ii. Providing DNA for each sample when requested (for soil samples insuring that both DNA and soil are sent for each sample);
iii. **f %** compliance with Diversa protocols for DNA isolation;
iv. **f %** compliance with shipping records;
v. Fulfilling specific sample requests according to sampling capabilities of Collaborators;
vi. Achieved maximum coverage of biotopes or habitats; and
vii. Responds to requests in a timely and professional manner.

In the event that Collaborators achieve all of such goals, then Diversa shall pay to Collaborators a milestone payment in an amount of **x** percent (**x %**) of Collaborators' annual funding hereunder. In the event that only a portion of such goals are achieved, then Diversa will determine what portion of the milestone shall be paid based upon percentage of the milestones completed and the relative value of the completed milestones.

3. Diversa shall provide funding to Collaborators for salaries and overhead for personnel in the amount of **h** dollars (**US $ h**) for the periods of **jjj** to **kkk** to perform work under this Agreement including but not limited to, sample collection and processing. Such payments shall be made quarterly in advance at the beginning of each calendar quarter. Diversa shall further provide funding for sample collection expenses and supplies of up to **m** dollars (**US $ m**). This funding shall be reviewed annually and mutually agreed in writing by the Parties. All payments made in accordance with this paragraph will be made in US Dollars by wire transfer to the bank account of Collaborators as set forth below:

_____

_____

_____

_____

4. Diversa shall also provide Collaborators with training in technology for the molecular **nnn** analysis of different habitats, including the following techniques (hereinafter "Technology"): a)techniques for **ppp** extraction from environmental samples; b) techniques for generating **qqq** gene libraries; c) techniques for **rrr** cloning of **qqq** genes directly from environmental samples; and d) information technology for DNA analysis.

5. Additionally, the above referenced personnel may visit Diversa's facilities for purposes of training in the Technology for an equivalent of one person for one month's time (for example, two people for two weeks, etc). Diversa will plan and providing funding for all travel with connection with such training.

2.4 CONCLUSION

The partnerships formed between KWS and ICIPE, and the industrial biotech companies Novozymes and Diversa, provide a range of short, medium and long term benefits. They are also based on procedures for prior informed consent that conform to government standards for collections in protected areas, although these procedures may be in flux alongside the ABS legal framework. These partnerships build scientific and technological capacity, as well as providing support for biodiversity conservation. The scale of investment in laboratories, training, and collections is significant, if far smaller in size and scope than those that might result from pharmaceutical industry partnerships (eg see the Griffith University and AstraZeneca partnership in Queensland).

However, these partnerships are not necessarily indicative of standard practice in the industrial biotech sector, nor of bioprospecting activities within Kenya. The details of these partnerships are uniquely public, and staff of both Novozymes and Diversa have spent a great deal of time engaging with the CBD policy process and entering into similar partnerships around the world. Both KWS and ICIPE have a number of other commercial partnerships, the terms of which are less well known, and which may or may not live up to current standards of 'best practice'—although given the institutional capacity of KWS and ICIPE in this area, and the model contracts and agreements from which they work, it is likely that they follow these standards.

At the same time, however, a great deal of bioprospecting is underway in the country, both within and outside of protected areas, that appears to be difficult to monitor and control, and that operates without clear PIC, and sharing of benefits. The KWS-Novozymes and KWS/ICIPE-Diversa partnerships grew up at the same time concerns were raised about the use of an enzyme from a saline lake in Kenya by the US company Genencor International (eg Ngare, 2006; Mbaria, 2004; Lacey, 2006; McGowan, 2006). In 2002, the company announced the development of a product that causes a faded look in denim, and might replace the pumice stones usually employed by the industry. Genencor acknowledges that the enzyme was obtained in Kenya, but there is little detail available on the legal basis for their obtaining the enzyme. All of Kenya's saline lakes fall within the boundaries of protected areas, which means collections might have been undertaken with a KWS research permit (Lettington, 2003). Genencor says that it obtained the sample from a Netherlands-based company that took part in an academic research project with Leicester University in the UK, and that all necessary research permits were obtained (Lacey, 2006). This case remains unresolved, but has heightened awareness within the country about the need for effective ABS measures as an important complement to ABS arrangements between parties.

CASE STUDY 3:

The Ethiopian Institute of Biodiversity Conservation, the Ethiopian Agricultural Research Organisation, and the Dutch-based company Health and Performance Food International: the Tef case

Rachel Wynberg

3.1 INTRODUCTION

Teff *plant* SUHEL AL-JANABI, GEOMEDIA GbR

In 2004 a ten year access and benefit-sharing (ABS) agreement was concluded for the breeding and development of tef (*Eragrostis tef)* between the Institute for Biodiversity Conservation in Ethiopia, the Ethiopian Agricultural Research Organization (EARO), and the small Netherlands-based company Health and Performance Food International (HPFI). Tef is one of the most significant cereal crop species in Ethiopia and Eritrea, having been cultivated there for thousands of years. The grain is overwhelmingly important in the national diet, where it is commonly made into *injera,* a flat, spongy and slightly sour bread, eaten as porridge or used in alcoholic drinks (Board on Science and Technology, 1996). Tef is also grown for livestock forage and is used to reinforce mud or plasters in the construction of buildings. Because the grain is gluten free, tef is increasingly desired in Western markets and has various other attributes of interest to the food industry. These are a central focus for HPFI, which develops tef products for Western markets in forms such as bread, sports bars and beer.

Ethiopia's status as the centre of origin and diversity for tef, its paralleled richness of local farmers' knowledge of plant genetic resources, and the strategic importance of tef to the country, have positioned this case as a crucial one from which to draw lessons regarding ABS arrangements. This short analysis provides an overview of the agreement and its implementation to date.

3.2 NEGOTIATIONS AND PRIOR INFORMED CONSENT

Negotiations to develop tef for Western markets were initiated by Hans Turkensteen, the Chief Executive of HPFI who explained that initially his company obtained tef varieties from gene-banks around the world and subsequently selected ten varieties suited for cultivation in Western Europe. However, insufficient tef was produced because of different climatic and environmental conditions. Approaches for access to additional material were made to a local university in Ethiopia, followed by negotiations between HPFI and EARO, who drafted a Memorandum of Understanding and gave consent for access.

Although a parallel process to develop Ethiopian ABS legislation had designated the Institute of Biodiversity Conservation[8] [and Research] (IBC) as the Competent National Authority for ABS, this was not well known at the time and formal procedures were largely overlooked (B. Visser, Director, Centre for Genetic Resources, pers. comm., 2008). However, media reports and greater exposure of the agreement, including a "Captain Hook" award by the NGO Coalition Against Biopiracy led to further dialogue and discussion of the agreement. In 2004, at the 7th Conference of Parties to the CBD in Kuala Lampur, the IBC were drawn into a further round of negotiations, together with the Dutch Ministry of Agriculture (B. Visser, Centre for Genetic Resources, pers. comm., 2008). In this same year the agreement was settled and signed, with the Dutch ambassador as

8 The Institute of Biodiversity Conservation is established by Proclamation No 120/1998 as an autonomous body of the Federal government of Ethiopia. It is accountable to the board of the Ethiopian Agricultural Research Organisation, is funded from the national fiscus, and its general manager is appointed by the government, on the advice of the board. The objective of the Institute is to "cause and ensure the appropriate conservation, research, development and sustainable utilization of the country's biodiversity." Amongst other things, it has to implement international conventions, agreements and obligations on biodiversity, and issue permits to those who need to collect, dispatch, import or export any biological specimen.

witness (Dr Tewolde Berhan Gebre Egziabher, Director General, Environmental Protection Authority of Ethiopia, pers. comm., 2008.).

Low levels of awareness as to the role and responsibilities of the Competent National Authority, and even its identity, were key elements responsible for these protracted negotiations, emphasizing the importance of including the right players and procedures from the outset. Failure to do so was in part due to the fact that the agreement was signed prior to the 2006 promulgation of Proclamation No. 482/2006 "Access to Genetic Resources and Community Knowledge, and Rights"[9], which sets out the procedures and institutions for the administration of ABS in Ethiopia. This requires: (i) a permit and genetic resources access agreement stipulating the prior informed consent of the IBC to access or export genetic resources; and (ii) a permit and access agreement from the IBC and relevant community to access community knowledge. Thus the state, on behalf of the community, is required to negotiate on issues relevant to genetic resources. Moreover, permission to collect germplasm of any kind is under the mandate of the IBC. Farmers are however not forced to allow collecting of germplasm from their fields or stores and they also have the right to demand the restriction or withdrawal of PIC given by the IBC if this is detrimental to their socio-economic life or natural or cultural heritage (Feyissa, 2006).

SUHEL AL-JANABI, GEOMEDIA GbR

In addition to low levels of awareness, negotiations were also protracted by, what Hans Turkensteen of HFPI refers to as "differences in culture and mentality". He remarked: "Working with governments in Africa takes time. Africans think that the rest of the world must apply to their rules rather than understand what rules in the Western world can be beneficial for their use. The Ethiopian government wanted to talk to the Dutch government, not to our company. But we don't want to have to deal with the Dutch government … there is an issue with regard to the involvement of governments in ABS agreements" (Turkensteen, 2007). The perspective of Ethiopia, in contrast, was to follow both the letter and the spirit of the CBD. Article 15.1, for example, recognises states as the entities with legal rights to grant access while Article 15.7 obliges the state in which the user operates to "take legislative, administrative or policy measures" to ensure fair benefit sharing. As Dr Tewolde (pers. comm., 2008) notes, "A providing country that does not ensure that the country of the recipient of the genetic resources is involved in any ABS will merely depend on the whim of the recipient once the genetic resources have left its territory".

3.3 SCOPE

The scope of the agreement is limited to the provision by IBC to HPFI of tef "for the purpose of developing non-traditional tef based food and beverage products". These include tef, incorporated into a range of gluten free flours, breadmixes, beer and distilled drinks. The company is not allowed to use tef for other purposes such as chemical or pharmaceutical applications without getting consent from the IBC and is not permitted to access the traditional knowledge of Ethiopian communities on the conservation, cultivation and use of tef without written agreement[10]. For its part, IBC cannot grant access to tef genetic resources to other parties for the purpose of producing the products listed in the annex without getting the consent of HPFI.

9 The purpose of the legislation is to ensure that "the country and its communities obtain a fair and equitable share from the benefits arising out of the use of genetic resources so as to promote the conservation and sustainable utilization of the country's biodiversity resources

10 At first glance this seems perplexing given that farmers' varieties harbour traditional knowledge. The interpretation, therefore, is that this restriction applies specifically to any additional traditional knowledge, for example, relating to traditional recipes (Dr Tewolde Berhan Gebre Egziabher, pers. comm., 2008)

TEF COMMERCIAL CHAIN

The envisaged chain of commercial development is as follows:

Step 1. HPFI obtains access to tef genetic resources from the genebank at the IBC

Step 2. HPFI conducts research and development on tef genetic resources and applies for plant variety protection

Step 3. HPFI sells tef varieties to farmers for cultivation, with 30% of this profit returning to the IBC

Step 4. HPFI buys tef grain from farmers for incorporation into products

Step 5. HPFI develops tef-specific products and sells tef to companies wishing to develop and/or retail tef products—a proportion of profits are returned to the IBC and to the FiRST foundation.

3.4 BENEFIT-SHARING

The agreement stipulates an array of long-term benefits[11], ranging from direct profits through to royalties, contributions to a fund for local farmers and scientific and technical capacity development. Reflecting on the benefit-sharing provisions of the agreement, Dr Tewolde Berhan Gebre Egziabher, one of the key Ethiopian negotiators of the agreement, noted a deliberate focus on developing a long-term partnership, and rejecting "upfront payments and similar concepts". "It is not the sweets they give you at the beginning but the meal you want to share", observed Dr Tewolde. These are articulated in Section 8 of the agreement which includes:

(i) an agreement by HPFI to pay the IBC a lump sum of profits arising from use of tef genetic resources;

(ii) royalties to the IBC of 30% of net profit from the sale of seeds of tef varieties;

(iii) a license fee, linked to the amount of tef grown by HPFI or anybody supplied seed by HPFI; and

(iv) contributions by HPFI of 5% net profit, no less than €20,000 per year, to a fund named the Financial Resource Support for Tef (FiRST), established to improve the living conditions of local farming communities and for developing tef business in Ethiopia.

The FiRST is to be administered by the University of van Hall/Larenstein to ensure the transfer of Dutch scientific knowledge and experience with product innovation to Ethiopia. HPFI will also share its research results on tef and will involve Ethiopian scientists in its research. To this end a research breeding program has been set up between EARO in Debre Zeit.

Unusually, the agreement sets out a commitment by HPFI to create joint ventures with Ethiopian counterparts to establish tef businesses in Ethiopia such as farming, cleaning and milling enterprises.

While the FiRST is now established and controls a fund of €438,000 for use in Ethiopia, up until now no benefits have been distributed to farmers. This has been due in part to a lack of clarity about its governance. To date there is no steering committee and questions about decision-making processes and structures and reporting mechanisms remain unresolved. A key issue is the extent of involvement of the Ethiopian government in determining use of the funds and this remains under discussion between the parties. Objectives of the FiRST that have been identified by HFPI include:

- support to local Ethiopian farming groups to grow high yielding tef varieties;
- coaching and teaching farmers 'improved agricultural practices';
- introducing tools to improve the seeding and harvesting of tef in Ethiopia;

11 Article 9.2 of the 2006 Proclamation "Access to Genetic Resources and Community Knowledge, and Rights" provides communities with the right to 50% of the share that the state obtains in monetary form from the use of genetic resources.

- the introduction of high yielding tef varieties;
- implementing new standards for storage and cleaning tef.

Implementation of the ABS agreement also remains thwarted by a decision of the Ethiopian government to ban tef exports. The reasons for this are complex but need to be considered in the light of tef shortages within Ethiopia, by the fact that 85% of Ethiopians derive their livelihood from small-scale agriculture, by the heavy reliance on tef as a staple food by Ethiopian consumers, and by Ethiopia's national imperative to protect local markets and ensure adequate local supply of tef. Another view, articulated by Hans Turkensteen of HPFI, is that there is no shortage of tef, but there is resistance within Ethiopia to changing farming methods and increasing volumes produced. Ethiopia, in his view, is "hindering private interests by overly regulating the market" and "the small scale nature of farming in Ethiopia is a barrier to large scale commercial tef production in the country" (Turkensteen, 2007). The complexity of these factors, and their unintended negative impact on the ABS agreement, yields important lessons for other ABS agreements based on staple commodities.

3.5 INTELLECTUAL PROPERTY RIGHTS

The agreement includes clear statements affirming the ownership of tef varieties by Ethiopia and agreeing to acknowledge Ethiopia as the country of origin of tef varieties used. According to Section 5 of the Agreement, the company may not claim or obtain any intellectual property rights of the genetic resources of tef, but can obtain plant variety protection over tef varieties. These varieties are to be co-owned by the company and EARO. Tef varieties that are not developed shall be owned by the IBC on behalf of local farming communities in Ethiopia, or registered by EARO, at the cost of the company. To date three plant varieties have been registered for co-ownership by EARO and HPFI (Turkensteen, 2007).

Health and Performance Food International currently hold a European patent for the processing of tef flour (EP 1646287B1), related specifically to a technique to increase the stability of the tef product and produce gluten-free flour. Despite concerns from some quarters, this is considered to be distinct from the traditional processing of tef. However, a proportion of the profits generated from sales of the flour and its products will benefit Ethiopia in terms of the provisions of the ABS agreement: "The ways they process tef for their European customers is their own affair, it is not our business. But we will share from it through the benefits they will make from making tef cookies and other products" (Dr Tewolde Berhan Gebre Egziabher, pers. comm., 2008).

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3.6 COMPLIANCE

The agreement is to be in effect for ten years. Provisions are included on penalties, monitoring and follow-up, and dispute settlement, the latter incorporating the arbitration procedure set out in part I of Annex II to the CBD and parts of a COP6 decision. Of interest is a section stating the prominence of the CBD over provisions of the Union for the Protection of New Plant Varieties (UPOV) in cases on which the two do not agree. Matters not included in the agreements are to be addressed by provisions of the CBD, the International Treaty on Plant Genetic Resources for Food and Agriculture, and the Bonn Guidelines.

None of these provisions have been tested because of the lack of implementation of the agreement. However, compliance is acknowledged to be a major concern. Remarked Dr Tewolde Berhan Gebre Egziabher, Head of the Ethiopian Environmental Protection Agency: "We said the Ethiopian law would apply for compliance and we agreed on a procedure but we know it is feeble. If there is no international law on compliance it is a matter of a gentleman's agreement. If there is a failure you go to court—but which court and under which law? Once genetic resources leave a territory that is it, especially as those providing the resources are the

weakest members and users are the strongest. It is very expensive to hire lawyers and the owners are usually resource poor".

In the specific case of tef, this may be more easily resolved. Ethiopia is the main producer of tef and, although it is cultivated in parts of Europe, America, South Africa and elsewhere, yields are generally low. Almost all tef produced thus originates from Ethiopia or Eritrea, making tracking and monitoring relatively straightforward. However, as Dr Tewolde notes, tef is likely to be the exception rather than the rule with respect to plant genetic resources.

3.7 CONCLUSION

A number of lessons emerge from this case. First, although parties came together with the best interests in mind, the failure at first to engage the right players and implement the correct rules significantly delayed the process. This underscores the need to ensure that information about the competent national authority and appropriate procedures to follow is widely known and understood. Ironically, the hiccups experienced for the tef agreement provided the basis for clarifying these procedures, thus laying the ground for future agreements. For example, an ABS agreement to develop *Vernonia galamnensis*, the oil of which is used in plastic formation and coating, was successfully concluded between the IBC and the British company Vernique Biotech in 2005, with negotiations reportedly progressing much more easily and effectively than for tef (Feyissa, 2006).

Second, there are interesting lessons to emerge with respect to the scope and benefit-sharing provisions of the agreement. Unusually, the contract deals not only with the provision of access to genetic material, but also with the trade of tef as a commodity. Shortfalls of tef in Ethiopia have thus directly impacted implementation of the ABS agreement. It could be argued that a more contained contract may have led to a less complicated situation, but this is countered by the fact that the current agreement enables far more significant benefits to be received by the providing country than is the norm. Important precedents have thus been set by the agreement

Finally, as noted by Mesfin Bayou, a legal advisor to the negotiations, the process has highlighted the critical need for provider countries to develop ABS negotiating and administrative skills and to have ready access to information about markets and market potential (Bayou, 2005).

CASE STUDY 4
Ball Horticulture and the South African National Biodiversity Institute

Rachel Wynberg

4.1 INTRODUCTION

Glasshouse built at the South African National Botanical Institute's Kirstenbosch Gardens as part of the initial donation to Kirstenbosch from the Ball-SANBI collaboration. ADAM HARROWER, SOUTH AFRICAN NATIONAL BIODIVERSITY INSTITUTE

In 1999 the then National Botanical Institute—NBI (now constituted as the South African National Biodiversity Institute—SANBI) entered into a Research and Licensing Agreement with the Chicago-based company Ball Horticulture. The five-year agreement (which continues to be renewed on a year to year basis), is the first North-South bioprospecting agreement in the horti- and flori-culture sector, and involves SANBI using its expertise to select South African plants of horticultural interest for Ball, both from its living collections and from the wild. SANBI is a public institution that aims to promote the sustainable use, conservation, appreciation and enjoyment of the exceptionally rich biodiversity of South Africa for the benefit of all people, and also to promote the economic use and potential of indigenous plants[12]. This it does through, *inter alia*, managing the various botanical gardens and herbaria in South Africa, conducting environmental education and outreach programmes, developing bioregional programmes, policies and plans, undertaking biosystematic research and biodiversity collections, conducting ecosystem rehabilitation, and maintaining and developing databases about southern African flora. The bulk of operational funding comes from the Department of Environmental Affairs and Tourism (DEAT) operational grant of R95 million, covering all salaries and the basic running costs of the Institute (SANBI, 2007). Ball is one of the world's largest multinational horticultural companies, holding 40% of the US market in bedding plants and pot plants, 25% of the European market, and 10% of the Japanese market. Ball Horticulture operates globally, in North America, South America, Europe, Asia, Africa, and Oceania[13].

4.2 NEGOTIATIONS AND PRIOR INFORMED CONSENT

The process of developing and negotiating the agreement was a long and arduous one, initiated in 1996 and finalised in 1999, after 14 iterations. In 1998, the proposed joint venture was tabled at a meeting of the Board of the NBI, who resolved to inform DEAT about the proposed deal and also to go ahead with the agreement subject to it being within the guidelines of government policy (Glazewski *et al,* 2001). However, none of the specifics of the contract were developed in the context of an institutional policy, nor through consultation with interest groups or NBI staff. Within the Institute, suspicion and concern about the agreement grew to the point where "people were getting ready to take the story to the newspapers" (Huntley, 1999). In response, two stakeholder workshops were convened in 1999 in Cape Town and Pretoria with NGOs, academics, and various national and provincial government departments. Substantial media attention was also attracted through this process. Key concerns noted at these meetings focused on the benefit-sharing provisions of the proposed deal, which were perceived to be out of line with the CBD with regard to technology transfer and scientific co-operation. The proposed agreement was also considered to badly undervalue South Africa's national heritage, and to neglect national imperatives towards job creation and the reconstruction and development of South Africa (Henne and Fakir, 1999). Further concerns were raised about the use of public funds to develop material for

12 Forest Act 122 of 1984, and Forest Amendment Act 53 of 1991.

13 Locations Ball Breeders, Producers and Distributors across the World, Available at: www.ballhort.com, Accessed on: 13 December 2007.

commercial purposes, about the patenting of life, and about the weak role of the local horticultural industry in the agreement. A series of letters to DEAT from NBI requesting guidance and Ministerial approval on the Agreement met with no response and in August 1999 the Agreement was signed. Although earlier NBI press releases in June 1999 had announced the possibility of the agreement, final signature of the agreement was not followed by any public announcements.

In April 2001 the deal again captured the attention of the public through its coverage as a lead story in the *Cape Times* newspaper (Gosling, 2001a,b). This in turn led to a series of radio and press reports about the matter. The NBI, it was claimed, had sold off the patent rights to a US company for huge sections of South Africa's floral kingdom, through a deal signed behind closed doors. Critics argued that this had effectively stifled the potential of local companies to develop the floriculture export industry and, moreover, had been done without DEAT approval. In defending its position, the NBI pointed to the stakeholder workshops held before finalisation of the agreement, to the continued rights of other players in the floriculture industry to commercialise South African plants, and to the long-overdue opportunities for South Africa to obtain benefits from the country's diversity of indigenous plants (Huntley, 2001). In May 2001 an internal NBI Board review was commissioned to, *inter alia:* assess the Agreement as well as progress with its implementation; to review the process of governance leading up to the signing of the Agreement; and to review the legal standing of the NBI to enter into such an agreement. The final report, while recognising the agreement to be a positive development in principle, stressed the insignificant financial and non-monetary benefits derived by NBI from the agreement, included a recommendation that the agreement not be renewed unless renegotiated, and highlighted the urgency for national legislation on the matter (Glazewski *et al,* 2001).

One of the crucial issues in this case study concerns the way in which prior informed consent was obtained from national and provincial government. Ball delegated this responsibility to SANBI but, as described above, repeated requests for policy guidance to DEAT from SANBI met with neither acknowledgement nor response, in some cases due to "obstructions" from civil servants (Glazewski *et al,* 2001) but also because of the newness of the issue and SANBI "feeling its way around". At the provincial level, it would seem that after some consideration, all nine provinces were in agreement to issue collection permits to SANBI, although with reservations. The Western Cape Nature Conservation Board (WCNCB), for example, was reluctant to issue an open permit with no species listing and considered the requested amounts to be collected as excessive (Jangle, 2001). WCNCB was also of the opinion that the province should benefit in some way from the agreement for the privilege to collect in nature reserves, and that a contribution should be made towards covering management costs. While WCNCB issued a permit for collection purposes, it is pertinent to note that this agency instilled a further level of control by also requiring a permit for export beyond the boundaries of the Western Cape. Written consent of private landowners prior to collection is also a requirement.

What does this case tell us about the procedural aspects of bioprospecting and best practice? Importantly, it emphasises the need for transparency, and also underlines the importance of allocating time and resources to ensure adequate consultation, debate and clarification. More time spent *before* finalisation of the deal would almost certainly have brought in a wider spectrum of stakeholders and greater support, and through more thorough analysis may have enabled a more comprehensive and beneficial agreement to be developed. But, as Maureen Wolfson, Director of Biosystematics Research and Biodiversity Collections at SANBI notes, more effective stakeholder consultation is also linked to awareness of ABS issues, which was very limited at the time the agreement was negotiated (pers. comm., 2007). Even within government, most were fairly ignorant about ABS requirements of the CBD: "…there was a very small group of folk who had a good overall grasp of ABS matters but generally we met with apathy amongst the others that we tried to consult" (M. Wolfson, SANBI, pers. comm., 2007). Despite this, there is little to suggest that a more consultative process would have guaranteed support, nor that such analyses would have received adequate attention by the SANBI or Ball.

4.3 BENEFIT-SHARING, TECHNOLOGY TRANSFER AND INTELLECTUAL PROPERTY RIGHTS

Monetary Benefits

Considerable criticism also accompanied the benefit-sharing provisions of the Agreement. International trade in ornamental horticultural products is substantial, estimated at some US$14.4 billion for live trees, planst, bulbs, roots, cut flowers,and foliage. South African genetic material is estimated to contribute at least $1-billion to $2-billion to this trade—although virtually none of this profit is realised by South Africa. On the contrary, through import of horticultural material, South Africa likely pays royalties to foreign companies for products derived from its own flora. The SANBI-Ball agreement thus represented a significant effort by South Africa to control the use of indigenous genetic resources in the global horticultural trade.

In terms of the agreement, SANBI was to supply Ball with different categories of "live plant material", including all horticultural groups except for slow-growing woody perennials and succulents unless specifically requested, as well as research expertise and knowledge of the plants and their habitats. For providing this service, SANBI obtained a once-off research service fee of $125 000, to be used to acquire a greenhouse for the propagation of plants before being sent to the US, and a vehicle, for plant collection trips. An annual research service fee with a "minimum value of $50 000" was also provided, to be used for operating expenses and staff costs. Royalties would also be derived by the SANBI in the event of commercialisation, but these would be offset against the accumulated amount of the annual research fee. Thus, as is pointed out in the SANBI Board's Internal Review of the agreement, direct monetary benefits are limited, conditional, and dependent on royalties exceeding accumulated annual research fees (Glazewski *et al,* 2001). In the event of profits being derived from the deal, a Biodiversity Trust Fund was intended to be established by the SANBI, for the purpose of capacity-building in the local horticultural industry, and for conservation and community development projects. The Trust has, however, not yet been formally established as the royalties, which were generated three years after the project was initiated, are still only adequate to contribute to recouping and repaying the operating costs (M. Wolfson, pers. comm., 2008).

One of the more controversial and poorly understood aspects of the agreement concerns its scope, and the numbers of species to which the agreement applies. Glazewski *et al* (2001) point out that although the agreement specifies "25 items", this should not be interpreted to be 25 species, but rather 25 items of plant material that the NBI has selected at any one time following an intensive sifting and screening process. Through this process, Ball effectively has access not only to all South African species, but also to the wealth of botanical knowledge built up over the centuries by the SANBI and South African botanists (Glazewski *et al,* 2001). This has been confirmed by Ball, who understand the agreement to mean they have "access to as many South African species as they like". Further, they suggest reference to "25 items" to be "meaningless" and initially intended to guide the number of plants to be kept out of public gardens whilst under development, not the number of plants to be scrutinised for commercial potential (Brian Corr, Ball Horticulture, pers. comm., 2003).

Intellectual property rights (IPRs) form a major component of the agreement, and caused much consternation among stakeholders who (a) objected in principle to the patenting and privatisation of life; or (b) considered the agreement to have taken IPRs out of South African hands. In terms of the agreement, IPRs will, depending on the different levels of research, development and ownership on the part of each party, either be obtained in the name of SANBI, jointly with Ball, or in Ball's name alone[14]. Ball has the right to obtain a plant patent, utility patent and/or Plant Breeder's Rights certificate in any country, while SANBI retains the right to obtain such rights in South Africa for plants collected using SANBI's existing collections. Royalty rates are similarly structured around the seven categories of plant material stipulated in the agreement. Thus, material collected by SANBI, using SANBI's existing collections, or material collected from wild habitats using fees provided by Ball secures a 10% royalty for SANBI of net product sales; material identified as "genepool plant material", which is pollinated with Ball plant material, generates a 4% royalty for SANBI; whilst material that is "improved" by

14 Clause 10.

Ball through genetic engineering or other techniques results in a 2% royalty for SANBI[15]. Ball, moreover, is granted worldwide marketing rights and free use of the SANBI's logo and trademark "Kirstenbosch", a cause for concern for many critics of the agreement, although SANBI sees this as a way of giving the Kirstenbosch name access to international markets. In reflection eight years on, the Ball Chief Executive remarks that the IP components of the agreement were inadequate: "There are three different layers of royalties: one of which is implausible as it involves GMOs and this is unlikely to ever be done with wild plant material. The other two don't make sense—and we could bypass the co-ownership option if we wanted to". The contract was built up from scratch, which could, roleplayers agree, account for its unnecessary complexity. As Maureen Wolfson of SANBI notes: "…the contract was probably unnecessarily complex because there were no existing models of such an agreement to guide the process and I guess, in that case there is always a tendency to try and cover all bases".

The first plant to be successfully commercialised as part of the agreement was a hybrid of two *Plectranthus* species, developed by SANBI and thus securing a 10% royalty for the Institute. "Mono Lavender", the resulting variety, is now commercially available throughout Europe, the US and Japan. At a wholesale price of $0.10 to 15 cents/unit, projected sales of several million units per annum, and a 10% royalty, it is estimated that benefits to SANBI will be upwards of $20 000 per annum. Plant Breeder's Rights have been granted worldwide for the variety, and application has also been made in South Africa. As stated in the agreement, such applications have been made by Ball on behalf of SANBI. A concern that has arisen through this process is that the SANBI has not been active enough in terms of local licensing.

Other items commercialised in terms of the agreement include six *Jamesbrittenia* hybrids, ('Breeze Indigo', 'Breeze Lavender', 'Breeze Pink', 'Breeze Upright White', 'Breeze Upright Lavender', and 'Breeze Plum'), and a form of *Arctotis arctoides* called 'Lemon Drop'. The revenue generated from sales remains undisclosed but royalties generated have not yet surpassed the accrued running costs and returns have been disappointing. There were no new releases in 2005-2006 or 2006-2007 although a new *Crassula* variety is anticipated to be released soon. It is important to note that it has taken eight years to develop just a few products, emphasising the lengthy research and development process in this sector.

Plectrantus "Mona-lavender", *a variety of a South African plant, developed and commercialised under the Ball-SANBI bioprospecting* ADAM HARROWER, SOUTH AFRICAN NATIONAL BIODIVERSITY INSTITUTE

Technology Transfer and Non-Monetary Benefits

Non-monetary benefits arising from the agreement have been significant, ranging from an enhanced plant database through to extensive field collections, enlarged herbaria and living collections, and the construction of a greenhouse. Technology transfer components of the agreement are, however, 'soft' rather than direct investments technology transfer and product development within South Africa. Although the agreement specifies that South Africa will be given "special consideration" for product development and scaling up, this is not legally binding and is qualified by language to stipulate "where appropriate and feasible". Part of the agreement is for Ball to present one technical seminar on ornamental horticulture a year, and to host interns each year for up to four months[16]. Thus far, a number of local seminars have been held and eight young Kirstenbosch horticulturalists have been trained in Chicago by Ball in plant breeding, marketing and glasshouse management. All but one of these horticulturalists have stayed in the research community in South Africa, and six currently work at SANBI. A significant result of this training is that increasingly, selection and breeding is taking place in-house at SANBI, enabling improved material to be sent to Ball, which commands a higher royalty for SANBI and reduces the time the product will take to reach market (M. Wolfson, SANBI, pers. comm., 2008).

15 Clause 11.1.
16 Clause 12.

A major criticism of the agreement is that it contains no significant technology transfer requirements, and does not address national development imperatives for job creation and economic empowerment. On this basis the agreement was initially lambasted both by South Africa's development fraternity and by the local horticultural industry when knowledge about it became public in the late 1990s. In the case of the former, SANBI was considered to have "closed down a major economic opportunity for Namaqualanders instead of making them partners in this development opportunity" (Glover, 2001); to have excluded disenfranchised communities producing indigenous flowers in the Western Cape (Ehrhardt, 2001); and to have diminished opportunities for job creation in the country. In the case of the local horticultural industry, SANBI was accused of monopolising South Africa's floral heritage and making it unattainable to those interested in developing products. Whether or not these impacts have in fact materialised is, however, a moot point. Staff at SANBI have observed that seven years down the line there have been no recorded negative impacts on the local horticultural and cut-flower industries (M. Wolfson and A. Harrower, SANBI, pers. comm., 2008), although it is also fair to say that there has been no systematic study to analyse such trends.

At the time the acquisition by Ball of Straathof, a major South African seed company, added to these concerns by local industry and was perceived by some to be simply a way to allow Ball to conduct its own distribution in South Africa, on its own terms. In response, SANBI and others noted South Africa's lack of marketing networks and capital infrastructure in the development of new plant cultivars, insufficient local capacity to competitively develop products for international markets, the difficulties of engaging local companies in co-operative breeding programmes, and the continued rights of other players in the industry to commercialise South African plants (NBI, 2001). Remarks Adam Harrower, Ball project manager at SANBI, "…we don't have the expertise in terms of breeding, developing, marketing, mass propagation and distribution that Ball has. So the NBI-Ball agreement was drawn up because they have the ability to turn our "green ore" into "green gold". We unfortunately don't—nowhere/nobody in South Africa can do this—the raw material in South Africa has very little value, even in our own horticultural industry. Quite simply it has to be "mined and processed" before it becomes valuable..... unlike *Hoodia* which is a ready-made product." In contrast to opinions from critics, the 51% acquisition of Straathof by Ball was seen both by Ball and SANBI as a concrete product of the agreement, resulting in foreign investment and the creation of "hundreds of new jobs" in the horticultural industry (Huntley, 2001). In response to these criticisms Ball notes that "…people have unreasonable expectations of what we can do; it doesn't make economic sense to set up a Ball equivalent in South Africa: why would we set up a competitor?" (Brian Corr, Ball, pers. comm., 2007).

4.4 COMPLIANCE

Despite the existence of compliance clauses in the contract , it is acknowledged by Ball that there is little that South Africa could do in the event of contract violations other than "shaming us". Nonetheless, the SANBI-Ball contract is legally binding and could be challenged in a court of law if required. However, this would be a costly process that would severely stretch the financial resources of a public institution such as SANBI (M. Wolfson, SANBI, pers. comm., 2008). Monitoring and tracking are acknowledged by both parties to be especially problematic. Remarks the chief executive of Ball: "Once seed is sent out, the ability to do anything to ensure compliance is basically zero". SANBI similarly note the difficulties of monitoring material that leaves South Africa and comment that "..to some extent we have to trust in the ethical behaviour of our partners in the contract" (M. Wolfson, SANBI, pers. comm., 2008). However, while some countries may abide by the rules and act in good faith, there are many others who won't. This underpins the belief that an answer to transgressions, including a guarantee that biological resources will only be used in accordance with conditions set by the provider, will only be found multilaterally through the International Regime, the WTO, or an alternative internationally applied mechanism.

4.5 ENVIRONMENTAL IMPACT AND BIODIVERSITY CONSERVATION

A final point concerns the potential environmental impacts of collecting activities and implications of the deal for biodiversity conservation in South Africa. In the absence of specific detail, environmental impacts are difficult to assess although the WCNCB considered the requested amounts for collection to be "excessive", and limited the number of cuttings to 30 per species, and the amount of seed to be collected to not exceed 10% of seeds per plant, from no more than 10% of the population (Jangle, 2001). A general concern is the lack of attention given in the agreement to bolstering conservation efforts in South Africa through, for example, the inclusion of conservation authorities or specific nature reserves as direct beneficiaries in the contract. As is the situation in the *Hoodia* case, the biological resource base upon which the contract hinges is not accorded any tangible recognition, and thus remains undervalued. While the agreement may eventually lead to the establishment of conservation projects through the proposed Trust, this is not guaranteed.

4.6 CONCLUSIONS

Several lessons emerge from this case that are instructive. The difficulties that SANBI has faced in switching hats between being a public interest body and a commercial player are especially useful to learn from. These tensions have played themselves out in a number of ways—in the high levels of suspicion and concern amongst the public about the deal; in the weak agreement, which suggests poor negotiating and legal skills on the part of SANBI; and in the seemingly tardy implementation by SANBI of commercial aspects of the agreement, such as the licensing of products. The significance of these issues is reflected in the National Biodiversity Act (10 of 2004) which precludes SANBI from any regulatory or oversight role in bioprospecting.

More positively, there is now increasing recognition of the role that SANBI can play in initiatives to investigate the sustainable use of South Africa's indigenous plants. Especially noteworthy is the ongoing use by other institutions of the knowledge and expertise of SANBI in the identification of plant material, which can be used and developed into saleable products (M. Wolfson, SANBI, pers. comm., 2008).

The expectations of technology transfer are also significant. Clearly there are different interpretations of what is best practice in this regard, with Ball emphasising softer forms of knowledge and information transfer, and critics placing greater emphasis on joint economic ventures and local economic development.

The lack of experience in developing agreements of this nature by either SANBI or Ball also yields important lessons. Legal expertise was, and continues to be, limited in this field, and this significantly affects the effectiveness of negotiating and drawing up fair and equitable benefit-sharing agreements.

The case also demonstrates vividly the need for a structured and multi-stakeholder oversight of bioprospecting, and the importance of setting aside adequate resources and time to ensure effective consultation and dialogue.

Lastly, the partnership that has developed between SANBI and Ball is considered a useful model from which to develop other ABS arrangements in the horticultural sector and is believed by those involved to be a more ethical and sustainable approach than a once-off collection agreement.

CASE STUDY 5:

Australian Sandalwood: Aveda-Mount Romance-Aboriginal Community Sourcing Partnerships in Western Australia

Sarah Laird

5.1 SANDALWOOD IN WESTERN AUSTRALIA

Sandalwood is one of the oldest and most popular incense and perfume ingredients in the world. *Santalum album* is found in India, Nepal, and Indonesia, and has long been the accepted world standard for sandalwood, but it is endangered from over-harvesting. The oil is found in both stem and roots, so trees are uprooted as part of harvesting. Full maturity is reached when the tree is 60-80 years old, but pressure on *S. album* has meant younger trees are harvested, and the species is now endangered. Australian sandalwood, *Santalum spicatum*, is a small tree (up to 4m) that occurs naturally in the southern half of Western Australia (WA). While its properties are different from those of *S. album*, it has gained acceptance in the perfume and incense industries.

Western Australian sandalwood was first exported in 1845, and soon became Western Australia's biggest export earner. In the 1920s, improved extraction methods led to the essential oil's adoption as an antiseptic in the pharmacopoeias of several countries, including Britain, France, Japan and Belgium, until it was replaced by antibiotics (www.mtromance.com.au). Today, WA sandalwood is primarily exported to South-East Asia for the manufacture of incense, with Taiwan, China and Hong Kong accounting for more than 60% of annual production. Other major markets include Malaysia, Singapore, China and Thailand. The main company consuming sandalwood domestically is Mt Romance Australia (FPC, 2007). The sandalwood industry in WA is roughly $30-35 million AUD today, with every tree accounted for, and tracked from point of harvest through to end use (David Brocklehurst, Mt Romance, pers. comm., 2007).

There are more than 250,000 tonnes of 'green' sandalwood distributed throughout Western Australia, found wild, in plantations, and in reserves including Aboriginal heritage sites. At present, the total area of distribution is approximately 161 million ha, of which over half is protected from any form of harvesting. The government sets an annual harvest quota, currently of approximately 2,000 tonnes, which normally is half dead, and half green sandalwood. Harvesting contractors are full time and part time operators with contract quotas varying in size from between 10—300 tonnes/annum. Pastoralists and Aboriginal communities make up more than 30% of current contractors. Processing and marketing of all Crown land sandalwood is conducted by Wescorp International, a private company awarded the contract through a public process in 2004 for ten years (FPC, 2007).

Sandalwood is a protected species, and the Department of Environment and Conservation issues licenses to harvesters, as well as the Forest Products Commission (FPC) to harvest the wood. The FPC is a government trading enterprise established to develop and market Western Australia's renewable timber resources. The Department of Conservation and Land Management is responsible for the environmental management of the species (FPC, 2007).

Meeting with Mardu people to discuss sandalwood. Standing in front of a sandalwood tree in Kutkabubba, Australia: Dr Richard Walley (Nyoongar), Dusty Stevens, Dominique Conseil (President of Aveda), and Kenny Farmer D HIRCOCK

5.2 MT ROMANCE-AVEDA-ABORIGINAL COMMUNITY SOURCING

Founded in 1990 with a mission of social and environmental responsibility, and based in Albany, Western Australia, Mt Romance is a private company, with roughly 50 employees. It operates the single largest sandalwood processing plant in the world, with the capacity to produce up to 21,000 kgs of sandalwood oil every year, all from Western Australian sandalwood. In addition to producing oil for the perfume industry, the company uses resins and all other by-products from the wood for use as incense, and in shampoos, detergents and other personal care products. The material used today by the company is wild-harvested, but plantations of both Indian sandalwood (3000 ha) and Australian sandalwood (9000 ha) will be coming on line in the next decade. Mt Romance does not own plantations, and instead intends to rely on partnerships with indigenous communities for its raw material. Wild-harvested material is higher quality than that from plantations, is organic, and undertaken by indigenous peoples allows them to stay on, and make a decent living from, their land and resources (David Brocklehurst, Mt Romance, pers. comm., 2007; www.mtromance.com).

Founded in 1978, the Aveda Corporation is a wholly owned subsidiary of the Estee Lauder Companies, and is based in the US. It manufactures plant-based hair care, skin care, makeup, and lifestyle products with a commitment to protect the environment, conserve resources, and support indigenous communities. In the late-1990s, Aveda began to investigate alternative sources of sandalwood for its projects after reports of human rights abuses and poor harvesting associated with sandalwood in India. In 2003, they were introduced to Richard Walley of the Nyoongar Aboriginal peoples, and Stephen Birkbeck of Mt Romance. Aveda decided to move its sourcing of sandalwood to Australia, in partnership with Mt Romance and Aboriginal harvesters, since the trade there met the standards of the Department of Environment and Conservation. They found, however, that existing sourcing practices in Australia resulted in minimal benefits for Aboriginal harvesters—with Aboriginal harvesters paid on average $1300-$2000 AUD/tonne of wood. The state government (FPC) then sells the wood for $8,000–11,000 per tonne, since the State claims ownership over the sandalwood. On private lands the ownership of sandalwood resides with the title holder and they can sell their wood for $7000 per tonne (Peter Jones, Renew Environmental Services, pers. comm., 2008). As a result, Aveda entered into a partnership with Mt Romance and the Aboriginal Kutkabubba community of Wiluna to develop an alternative supply chain, and build capacity in Aboriginal communities. A series of on-going consultations with a range of communities has expanded the sourcing partnerships into three other communities in recent years (David Hircock, Aveda Corporation, pers. comm., 2007).

Aboriginal harvesters may work through the Forest Products Commission, or through their own private licenses. If harvesters work through the FPC, they supply unprocessed wood, and receive the going rate of $2,000 AUD/tonne. Mt Romance provides an "indigenous bonus" to harvesters of private wood, paying $3,600/tonne for unprocessed wood. If harvesters work through a private license, they receive approximately $8,000 AUD/tonne, but they must pay all harvesting, transport, and processing costs, with net revenues of $4500-5,000 AUD/tonne. All material purchased by Mt Romance from Aboriginal communities is certified by the Songman Circle of Wisdom (see below); the premium it pays to harvesters under this scheme is passed on to purchasers of the oil, including Aveda and Givaudan (David Brocklehurst, Mt Romance, pers. comm., 2007).

5.3 SONGMAN CIRCLE OF WISDOM

During development of sourcing partnerships in Western Australia, Aveda and Mt Romance also supported creation of the **Songman Circle of Wisdom**, "a Western Australian based National Aboriginal Corporation owned, operated, managed and controlled by Aboriginal people" (Songman Circle of Wisdom, 2004). The Songman Circle of Wisdom is based on the belief "that by active participation in supporting and facilitating equitable commercial partnerships between the Indigenous and business communities, based on the sustainable use of natural resources and Indigenous cultural knowledge, positive change will occur" (Songman Circle of Wisdom, 2004). It was designed to meet the challenges faced by indigenous communities when seeking to establish sustainable business enterprises that respect the environment and traditional cultural knowledge, and to facilitate opportunities for the business community to work with and learn from indigenous peoples

on an equitable basis. As part of partnerships, companies must obtain prior informed consent, in writing, from involved communities or individuals, and, while recognizing the existence and legitimacy of two parallel systems of law, "customary rights and traditional law will have precedence for the purpose of this protocol" (SCW, 2004).

The Songman Circle of Wisdom certifies the sandalwood supplied to Mt Romance, and the oil supplied to Aveda, including tracking it from the field, coding, and processing it separately. By involving the Songman Circle of Wisdom in these partnerships, they reflect the views and priorities of indigenous peoples "who have an ongoing spiritual and social connection to the lands on which sandalwood occurs" (Peter Jones, Renew Environmental Services, pers. comm., 2008). Within Mt Romance there are distillation units that process only Aboriginal peoples' wood, and the oil is quarantined and kept separately in the oil cellar, until sold on to the customer.

5.4 BENEFITS FOR ABORIGINAL AND LOCAL COMMUNITIES

The Aboriginal and local communities sourcing sandalwood under the Songman Circle of Wisdom program receive a range of benefits associated with the supply of sandalwood. In addition to a more equitable price paid, an additional "royalty" of $500 is also set aside on each tonne of wood, paid half by Mt Romance, and half by Aveda. For Aveda, this amounts to paying approximately $25/kilo more for Australian sandalwood oil. These funds are placed in a revolving Capital Works Fund, held by Mt Romance. Funds are provided as interest-free loans, and allow communities to invest in local capacity and engage more effectively in the sandalwood trade, as well as address basic community needs. Examples include equipment such as de-barking machines, four wheel drive vehicles, and lifters to pull trees out of the ground with minimal environmental damage.

In the case of Albert and Norma Philips, who hold a lease on unallocated crown land, approximately 300 miles from Perth in the semi-arid Paynes Find region, supply of $9,000 worth of equipment to meet new harvesting and environmental requirements meant that their capacity, and license, was increased to 100 tonnes/year. The Kutkabubba community has secured a private property license on a larger area of land than previously possible, and the Yamatji and Bondini people have built jobs and training for youth into their sourcing, including building cultural awareness and promoting teaching by Elders and collectors. Support for the sandalwood trade within Aboriginal communities is also a way to help people to stay on their land, and make a decent living. Additional enterprise development is also supported by Mt Romance and Aveda. For example, a 500 ha project has been established with the Kutkabubba community in Wiluna to plant out sandalwood and other indigenous medicinal plants in order to develop other forms of local enterprise. Aveda also makes grants for basic needs in collaborating communities, including recently a mobile solar-powered de-salination plant.

Aveda works on a number of levels to create a wide range of benefits for communities and conservation. More equitable prices paid for raw or processed materials, capacity-building, and supply of equipment and other materials for sourcing or basic community needs, are part of a package of immediate benefits that result from sourcing. In addition, the company seeks to link producers with a wider range of companies/buyers and certifiers, providing them with a rare commodity for communities—market access. For example, in Nepal Aveda worked with the Federation of Community Forestry Users (FECOFUN), Asia Network for Sustainable Agriculture and Bioresources (ANSAB), Himalayan Bio Trade Private Limited (HBTL), Enterprise Works/VITA, and Smartwood/FSC, to facilitate community owned paper making from sustainable sources of Lokta bark, and trade in other certified natural products. (www.fecofun.org; www.enterpriseworks.org; www.asnab.org; www.himalayanbiotrade.com; www.rainforest-alliance.org). As one partner in the initiative comments: "Aveda's willingness to provide industry expertise, guidance in product development and linkages with the herbal products industry is a contribution that goes beyond a traditional seller/buyer relationship" (The Canopy, 2004).

Aveda also works with indigenous peoples and communities on broader land rights, and increasingly provides linkages between communities and groups working on carbon sequestration and ecosystem services. In Brazil, for example, Aveda has worked with the Yawanawa people for 15 years, and recently assisted them in demarcating and monitoring their land, and defending claims on their land by logging companies. They are also brokering links between the community and groups working on carbon conservation (David Hircock, Aveda, pers. comm., 2007).

Paper Making—Bajhang District Nepal FSC D HIRCOCk

5.5 USE OF IMAGES

The use of indigenous peoples' images and cultural property in commercial marketing, without their prior informed consent, is a common problem in the personal care and cosmetic, botanicals, and other sectors. To address this problem, and allow for the use of sandalwood harvesting (not cultural) images in its marketing, Aveda worked with the Kutkabubba community in Wiluna to get approval for the use of approximately 10 images that might, at some point, be used in marketing. In Brazil, Aveda has signed a more formal written agreement with the Yawanawa, setting terms for the use of their images in marketing.

5.6 BENEFITS FOR COMPANIES

In addition to fulfilling socially and environmentally responsible missions, and returning benefits to the lands and communities where sandalwood is sourced, Mt Romance and Aveda benefit from their partnerships with communities in a number of concrete, commercial ways: they secure access to biomass, and in the case of sandalwood a raw material in short supply; they provide customers with the certified products they seek; and they benefit from the story associated with community-based sourcing of raw materials, and the way this distinguishes products, and the company, in the marketplace.

5.7 CONCLUSION

This case does not address access and benefit-sharing as related to genetic resources, however it illustrates the application of access and benefit-sharing principles in a broader context, in the spirit of the Convention. Although sandalwood is a widely known and used species, and 'prospecting' did not occur, the web of partnerships that make up this case highlight important aspects of ABS 'best practice' associated with raw material ("biological material") sourcing in this sector. These include significant consultations with a range of communities and groups on the contours of proposed partnerships; provision of a range of monetary (eg more equitable prices, royalties into a fund) and non-monetary (eg equipment, training, access to markets) benefits; attention paid to state and national laws, as well as prominence given to customary law and decision-making practices; and prior informed consent associated with the use of cultural and other images in marketing.

Community-based partnerships for raw material sourcing remain the exception in all sectors, however, with large-scale commercial agriculture, or purchase of raw material on the open market, with no questions asked, representing cheaper, more reliable (in the short term), and easier alternatives. Even companies trying to "do the right thing" often source a large portion of raw material in this way. It is clear that incentives must be in place to allow companies to invest in these types of partnerships, including the ability to tell their story and position themselves as unique within the market, or to secure raw material in short supply. Critical to implementing best practice in the personal care and cosmetic, and botanicals, sectors (unlike the pharmaceutical, biotech, or seed, for the most part) is demand from educated consumers for sustainable and equitable raw materials in their 'natural' products, and the role of certifiers in ensuring that claims are accurate.

CASE STUDY 6:

Natura, Brazil: The Use of Traditional Knowledge and Community-Based Sourcing of "Biological Materials" in the Personal Care and Cosmetics Sector

Sarah Laird

6.1 NATURA

Natura was founded in 1969 in Sao Paulo Brazil. In 2006, net revenues were R$2,52 billion, the company had roughly 600 products on the market, and 5,100 employees. Investment in research and development in 2006 was roughly 3.2% of net revenue, totaling R$80 million. Natura products are sold throughout Latin America, and more recently in France. They include cosmetics, personal hygiene, and perfume products. In 2004, Natura went public, and was listed on the Sao Paulo stock exchange. This follows a pattern of socially-responsible companies founded in the 1960s and 1970s subsequently taken over by larger companies, or going public, beginning in the mid-1990s[17] (UNEP, 2005).

6.2 THE EKOS LINE

In 2000, Natura founded the EKOS Line, which "draws from the wealth of Brazil's biodiversity and is inspired by traditional uses of plant ingredients." The products include soaps, shampoos, conditioners, moisturizers, and perfumes, and the line is intended to "increase awareness of the richness of our environmental heritage for future generations and stimulate the development and quality of life of the communities that cultivate or extract those ingredients" (www.natura.com).

Cupuaçu harvesting from the Reca community PEDRO MARTINELLI

The EKOS line includes 14 ingredients/raw materials sourced sustainably, with the majority from communities around Brazil. The ingredients include Cumaru, Pariparoba, Copaíba, Mate Verde, Murumuru, Guaraná, Priprioca, Breu Branco, Cupuaçu, Pitanga, Maracujá, Andiroba, Castanha, and Buriti.

6.3 SUSTAINABLE SOURCING OF RAW MATERIALS IN PARTNERSHIP WITH COMMUNITIES

The EKOS line is based on a commitment to use local biodiversity, and sustainably source raw materials from communities. This means that the company has invested in a range of sourcing partnerships to develop sustainable supplies of raw materials. Communities from which materials are sourced, and the number of families involved in the sourcing of raw materials, is found in Table 1. Natura facilitates partnerships between communities and the local FSC-certifier, IMAFLORA, for certification of forest products, and considers certified raw materials an important element of the EKOS line, and a way to inform consumers about the sourcing practices associated with their products. Natura has also expanded collaborations with certifiers to include the Sustainable Agriculture Network (SAN) and the Institute of Biodynamics (IBD) for agricultural or plantation sources.

17 Mother Earth founded in 1975, taken over by Cadbury Schweppes in 2001; The Body Shop founded in 1976, and going public in 1984; Ben and Jerry's and Aveda founded in 1978, and taken over respectively by Unilever in 2000, and Estée Lauder in 1997; and Stonyfield Farm founded in 1983, and taken over by Danone in 2003 (UNEP, 2005).

TABLE 1: RAW MATERIAL SOURCING FOR THE EKOS LINE

COMMUNITY-REGION	INGREDIENTS/ RAW MATERIALS SOURCED	NUMBER OF FAMILIES INVOLVED IN SOURCING
MÉDIO JURUÁ —AMAZONAS	Andiroba (*Carapa guianensis*) Murumuru (*Astrocarium mururumu*)	378
IRATAPURU—AMAPÁ	Castanha (*Bertolethia excelsa*) Copaiba (*Copaifera spp*) Breu Branco (*Protium pallidum*)	32
ENTORNO DE BELÉM—PARÁ	Priprioca (*Cyperus artticulathus*)	50
RECA—ACRE	Cupuaçu (*Theobroma grandiflorum*)	340
ILHÉUS—BAHIA	Guaraná (*Paullinia cupana*) Cacau (*Theobroma cacao*)	xx
ERVATEIRA PUTINGUENSE—RIO GRANDE DO SUL	Mate (*Ilex paraguariensis*)	Private company
CHAMEL—PARANÁ	Camomila (*Matricaria recutita*)	Private company
FAZENDA ALPINA—SAO PAULO	Pitanga (*Eugenia uniflora*)	Private company
FLORA DO BRASIL—MINAS GERAIS	Maracujá (*Passiflora edulis*)	Private company
MIL MADEIREIRAS—AMAZONAS	Louro Rosa (*Aniva parviflora*)	Private company

Source: Pommez, 2005

6.4 USE OF TRADITIONAL KNOWLEDGE

Traditional knowledge is used by Natura to inspire the development of new ingredients (or, more commonly, new applications for existing ingredients), and to develop sustainable management and harvesting strategies for species. The company accesses traditional knowledge through collaborations with ethnobotanists or ethnopharmacologists within universities (eg University of Sao Paulo, University of Campinas, and University Federal of Santa Catarina) and through academic publications and databases. For example, the company incorporated an extract of the leaf of Pariparoba that grew from work with the University of Sao Paulo, and is now sourced through a community in the Atlantic Forest. The company also directly works with communities to access traditional knowledge (eg Iratapuru for Breu branco), and has collected widely-known traditional knowledge in markets such as Ver-o-Peso in Belem.

6.5 NATIONAL ABS MEASURES

Natura's partnerships with communities for the sustainable supply of raw materials, and its use of traditional knowledge to develop new ingredients or products, pre-dated Brazilian ABS legislation. Prior to any legal framework, the company established a package of benefits and equitable practices that included: 1. providing training and capacity-building in agricultural techniques, and equipment and other materials to add value to raw materials, in order to promote greater benefits within the community; 2. supporting and assisting with the development and administration of community associations; 3. seeking prior informed consent and payment before using any images of people from communities in marketing; and 4. setting up funds in communities through allocation of a percentage of net sales; this is seen as an investment Natura makes in particular communities, and has been established in only one community to date, Iratapuru, and another is pending. Natura also pays more equitable prices for raw and processed materials but explicitly does

Boa Vista community where extraction of palm oil for soap manufacturing takes place PEDRO MARTINELLI

not understand this as "benefit-sharing", as in "access and benefit-sharing" (Anita Campos- Jacob, Natura, pers. comm., 2008).

Intellectual property rights, whenever developed, have been held by "the developer"—which in all cases to date has been Natura, with the exception of joint product development with universities, in which case the IPRs are shared between the parties, or held by the university (eg Pariparoba) (Anita Campos-Jacob, Natura, pers. comm., 2007). Natura has a policy of not taking patents out on ingredients, and only patents the proprietary process of extraction, or cosmetic formulations (Philippe Pommez, pers. comm., 2007).

Natura's work helped to inform the development of national ABS measures. Once these measures were in place, however, Natura required consent from the administering body, Conselho de Gestao do Patrimonio Genetico—CGEN, for both existing and any new sourcing partnerships, and those that involve accessing traditional knowledge (including Natura's previous arrangement with the Ver-as-Ervas Association; see below). It is now a requirement that companies present proposals for accessing and commercializing biological resources (not just genetic resources), including sourcing partnerships for raw materials, and that a benefit-sharing plan be in place. The ABS legal framework continues to evolve, however. In December 2007, the Office of Chief of Staff launched a public consultation to review the effectiveness of the ABS measures, including minimizing the bureaucracy associated with the law.

Today, Natura has more authorized ABS agreements before the CGEN than any other company. The company also enters into agreements that address rights to use images of local groups in their marketing, as required under the Brazilian Federal Constitution, and—for the use of cultural expressions—as governed by UNESCO Conventions (Anita Campos-Jacob, pers. comm., 2007)

The company distinguishes between different types of relationships and benefits that result for local groups: 1. *Access Agreements* for genetic resources and traditional knowledge that include benefit sharing in non-monetary forms, as well as a percentage of net revenue; 2. *Local Development* projects that include investments made by Natura in specific communities to build local institutions and capacity, not tied directly to accessing genetic resources or traditional knowledge; 3. *Supply partnerships*, which do not involve ABS agreements but include support for production and harvesting of raw materials, and facilitation of links between communities and third-party processors, from whom Natura buys processed products such as oils or extracts. In these cases, communities are not required to exclusively sell raw materials to Natura, and the company encourages additional buyers.

6.6 THE NATURA—VER-AS-ERVAS AGREEMENT: THE COMMERCIAL USE OF TRADITIONAL KNOWLEDGE

In 2001, Natura staff collected information in the Ver-o-Peso market in Belem on a range of useful plants. Species incorporated into Natura products from this exchange included Breu branco, a resin produced from insect-damaged trees, used traditionally as incense and in art work and handicrafts, and extracted from the forest in Iratapuru; Breu branco became an ingredient in a fragrance. Priprioca, used traditionally as a perfume, and now grown in certified sustainable farms around Belem, is also used in a fragrance.

At the time, and still today, Brazilian legislation was not clear on how to address widely known and used traditional knowledge of the kind found in markets. As a result, Natura did not initially enter into an access and benefit-sharing agreement, although the company gave the market association—Ver-as-Ervas—acknowledgement in its materials, and a verbal agreement was reached. As the ABS policy environment evolved in Brazil, however, and awareness grew of the importance of compensating traditional knowledge holders for the use of their knowledge, the women of Ver-as-Ervas requested assistance from the competent authority in order to claim benefits associated with the use of knowledge they supplied. Natura negotiated an agreement with the Association, reaching agreement on ABS principles and benefits to be shared, including royalties and an up front payment to the Association. The agreement has been signed by Natura and Ver-as-Ervas, but has

not yet been approved by CGEN, given the complexity of the issue and lack of clear legal guidance on access and benefit-sharing associated with traditional knowledge, in particular that found in markets.

Through this process, Natura built its own internal capacity to deal with prior informed consent associated with traditional knowledge, and developed ways to engage with local groups to achieve truly informed consent, including explaining the Brazilian ABS legislation through theatrical performances, and hiring economists and lawyers selected by communities to work on their behalf (Philippe Pommez, pers. comm., 2007; Anita Campos-Jacob, pers. comm., 2007).

6.7 THE NATURA-IRATAPURU AGREEMENT: SUSTAINABLE SOURCING PARTNERSHIP

The Iratapuru community is found in Amapá State, and is comprised of 32 families, living in an 800,000 hectare extractive reserve. The community is made up of 32 caboclo (mixed ethnicity) families. Natura began working in Iratapuru in 1999 to source brazil nuts. Natura worked with the community for three years to support the process of acquiring FSC certification, and contacted an international company, Cognis, to purchase nuts from the community, process them into oil, and sell the oil to Natura (at a premium price shared with communities). In 2005, Natura set up a press within the village to add more value there. The community undertakes a first extraction of the oil, which it then sells to Cognis. In addition, Natura provides funds to the Iratapuru community association, set up in 2005, and fed by a percentage of net sales of products supplied by Iratapuru, including copaiba, brazil nuts, and breu branco.

6.8 LESSONS LEARNED BY NATURA

When it started the EKOS line, Natura used 12 ingredients from local biodiversity, and worked with 12 communities to source these materials. Over time, the company found that it is important to work with communities that are organized, with an association, and to not deal with an individual or small group within a community. They also learned that concentrating on a few communities initially made more sense, as did sourcing a number of different products from a single community, in order to diversify their livelihood sources and reduce their risk. The third key lesson was that the company had to change the way they do business in order to source raw materials from communities. This included changing expectations in terms of deliveries, particularly for products that might be available during a single period a year; and providing payment in advance to allow communities to purchase, for example, gas for the boat engine to get on the river or into the forest. The company also realized that it was not possible to incorporate any new and exciting ingredient without also developing a plan for the sustainable supply of the raw material (Philippe Pommez, pers. comm., 2007).

6.9 CONCLUSION

Like Aveda—and the handful of companies that have committed real resources and energy to developing sustainable and equitable community-based supplies of "biological materials" in the personal care and cosmetic, botanicals, fragrance and flavor, and food and beverage sectors—Natura's commitment to source raw materials for its EKOS line largely through communities required a dramatic shift in business practice. In order to support this shift, the role of certifiers was critical, providing confirmation of Natura's hard-earned claims, and thereby real distinction in the marketplace, in contrast to the often inflated or inaccurate claims of competitors in this sector to have "sustainable" and culturally-appropriate sourcing practices.

In this case, Natura also addressed the use of traditional knowledge as a starting point for new product development, within the framework of an evolving ABS regime. In a short period of time the company—and the private sector at large—experienced a dramatic shift in how traditional (even common and widespread) knowledge was viewed, and the appropriate ways to receive consent and compensate for its use. Most companies in these sectors have yet to catch up to new ethical and legal realities. Natura adjusted its agreement with Ver-as-Ervas in light of these changes, but national ABS measures are still in flux. Regulating the use of TK is a far more complex undertaking—and one with few examples to provide guidance—compared with regulating genetic or biological resources.

CASE STUDY 7:

Access and Benefit-Sharing Agreements in the Commercial Development of *Hoodia*[18]

Rachel Wynberg

7.1 INTRODUCTION AND BACKGROUND

The complexities of access and benefit-sharing (ABS) and its scope, the challenges of partnerships, and the difficulties of regulating and implementing ABS when the same resource is used in different ways, are vividly demonstrated in the case of *Hoodia* species, succulent plants indigenous to southern Africa and long used to stave off hunger and thirst by the indigenous San peoples, the oldest human inhabitants in Africa (White and Sloane, 1937).

Wild Hoodia *plant* RACHEL WYNBERG

This knowledge was published by colonial botanists and led to the inclusion of *Hoodia* in a 1963 project on edible wild plants of the region undertaken by the South African-based Council for Scientific and Industrial Research (CSIR), one of the largest research organisations in Africa[19]. In 1995, after a lengthy period of development, the CSIR patented use of the active constituents of the plant responsible for suppressing appetite, without the consent of the San[20]. CSIR proceeded in 1998 to grant a license for the further development and commercialization of the patent to the U.K.-based company Phytopharm.

Through a programme dubbed "P57" Phytopharm developed the lead to a more advanced stage, leading to a license and royalty agreement with Pfizer, the US-based based pharmaceutical giant. However, the closure of Pfizer's Natureceuticals group led to the later withdrawal of Pfizer from the agreement. In 2004 a joint development agreement was negotiated between Phytopharm and the consumer giant Unilever. Unilever intends to develop extracts from the active ingredients of the plant and incorporate these into a functional weight-loss food for the mass market. Developments are at an advanced stage and have included clinical safety trials, manufacturing and the cultivation of some 300 ha of *Hoodia* in South Africa and Namibia. Recently, Phytopharm announced the initiation of Stage 3 activities, including supply chain expansion and the inclusion of consumer studies. Much is at stake: the global value of functional foods, meaning "any modified food or food ingredient that may provide a health benefit beyond the traditional nutrients it contain" (Bloch and Thomson, 1995) or, more popularly, "better for you" applications, is estimated at US$65 billion (Phytopharm, 2007). The market value for the dietary control of obesity is over US$3 billion per annum in the United States alone (Phytopharm, 2003).

A parallel *Hoodia* market, has also emerged in the past 3-4 years, based on trade in raw material. The publicity generated by the CSIR-Phytopharm-Unilever agreements, the marketing opportunities of San use of the plant, and the patent awarded to the CSIR led to a frenzied interest in *Hoodia* amongst plant traders. By 2004 concerns about the threats posed to natural populations through unregulated collection led to the inclusion of *Hoodia* spp. in Appendix II of the Convention on International Trade in Endangered Species of Wild Flora and Flora (CITES) (CITES, 2004). By 2006 trade had escalated exponentially—in many cases illegally—from just a few tons to more than 600 tons of wet, harvested material per year, sold as ground powder for incorporation into non-patented dietary supplements. In North America in particular, dozens of *Hoodia* products were sold as diet bars, pills, drinks, and juice, traded by a myriad of companies "free-riding" on the publicity and clinical trials of Phytopharm and Unilever. The CSIR patent was focused on the *Hoodia* extract, and nothing

18 This case study draws substantially from Wynberg (2004) and Wynberg and Chennells (2008).

19 See www.csir.co.za

20 South African Patent No. 983170. This was followed by the granting of international patents in 1998, GB2338235 and WO9846243: Pharmaceutical compositions having an appetite-suppressant activity.

prevented other companies from simply selling the raw material for incorporation into herbal supplements. Most products were of dubious authenticity, contained unsubstantiated quantities of Hoodia, made unfounded claims, and in many cases implied association with the San, who received no benefits. Concerns led to closer analysis of products by the Food and Drug Administration (FDA), which revealed many to have little or no *Hoodia*, and to lack adequate evidence of safety (FDA, 2004). The US Federal Trade Commission (FTC) also brought action against spammers sending e-mail messages about *Hoodia* weight-loss products, alleging that the claims made for the products were false and unsubstantiated (FTC, 2007). In South Africa and Namibia, illegal trade and harvesting of *Hoodia* resulted in a number of prosecutions and arrests; the high prices commanded for the dry product of up to US$200 per kilogram had led to the incorporation of the plant into a global underground network of diamonds, drugs and abalone.

Increasingly, however concerns about the quality and safety of material sold as *Hoodia*, joined with over-harvesting concerns and recognition of the need to ensure the sustainability of *Hoodia* supply have led to a more regulated industry based on cultivated material. Greater vigilance on the part of the FDA and FTC as well as the American Herbal Products Association is rapidly reducing the number of illegitimate products on the US market, and regulators in South Africa, Namibia and Botswana have introduced permitting procedures which prohibit wild harvesting of *Hoodia*, require its transparent cultivation, and set in place mechanisms to track trade across borders.

7.2 THE TYPES OF RESOURCES UTILISED: DIVERSE APPROACHES TO COMMERCIALISATION

As described above, the commercial development of *Hoodia* is based on two approaches: (1) a patented *Hoodia* extract, under development by Phytopharm and Unilever as a functional food; and (2) commercialisation of *Hoodia* as a raw, ground up material through incorporation into herbal supplements.

The industry sectors that develop and commercialise *Hoodia* material are thus very different, the former representing the food industry, represented by the largest consumer company in the world; and the latter the herbal supplements market, which is characterised by a large number of relatively small players with extremely divergent policies and ethics.

The economics between these sectors are also vastly different. For Unilever, the focus is on safety and efficacy and the company places emphasis on having sufficient active material to achieve effective weight loss. This is estimated by Unilever to be orders of magnitude greater the amounts currently sold in herbal supplements (K. Povey, Unilever, pers. comm., 2007). Thus Unilever requires vast amounts of material, and has already planted several hundred hectares of *Hoodia* material, with plans to significantly expand these volumes. Far less material is used for the herbal supplement market, and this combined with the fact that it comprises a much larger group of smaller growers and traders, means that the *Hoodia* industry operates using different economies of scale. This could lead to the emergence of two price structures for consumers, as has emerged for plant sterols: (1) a higher price for supplements, based on low volumes; and (2) a lower price for food, based on high volumes (K. Povey, Unilever, pers. comm., 2007). For *Hoodia*, much will depend on how much active ingredient is needed for efficacy, and consumer demand for the product.

7.3 NAVIGATING PRIOR INFORMED CONSENT AND THE ACCESS AND TRANSFER OF GENETIC RESOURCES

Obtaining PIC from government

Although access arrangements vary between these two approaches to commercialisation, there are similarities. Both approaches, at least initially, required access to wild *Hoodia* material, and thus the permission of government departments. The first accessions by the CSIR of *Hoodia* material would have taken place in the 1960s, however, long before any CBD requirements and involved a local research institution (the CSIR) partly

Wild-harvested Hoodia in the Western Cape, South Africa
RACHEL WYNBERG

funded by government. Later acquisitions of wild material would also have been done by the CSIR, collecting directly from private or public lands for research purposes in South Africa and Namibia, requiring collection permits. The involvement of Phytopharm as a license holder occurred only after the lodging of a patent by the CSIR, and thus the CSIR took primary responsibility both for collecting and negotiating consent with landowners and government at the research stage, prior to the development of a licensing agreement. In South Africa this was done initially at provincial level through request to the Northern Cape Directorate of Nature Conservation to collect *Hoodia* species for their intended commercialisation. In this case, a conventional permitting process led to the CSIR being granted permits for the collection of *Hoodia gordonii*, subject to resource assessments being undertaken and various environmental conditions being met (E. Powell, Northern Cape Nature Conservation, pers. comm., 2002).[21]

At the commencement of the contract between CSIR and Phytopharm for the commercial development of *Hoodia* in 1998, requests were made to the Department of Environmental Affairs and Tourism (DEAT)—the South Africa 'national focal point' for bioprospecting—for permission to develop a bioprospecting agreement. According to the CSIR, the response from DEAT was to acknowledge the lack of legislation in place to govern bioprospecting, but to suggest that the intended commercial collaboration be pursued through law of contract, so as to have case studies from which to learn for future policy development (M. Horak, CSIR, pers. comm., 2002).

Obtaining PIC from traditional knowledge holders

While certain administrative procedures were followed by the CSIR to obtain the consent of government bodies responsible for regulating bioprospecting and the collection of biological material, the CSIR was clearly remiss in following similar procedures with the San, holders of traditional knowledge about the appetite suppressing properties of Hoodia. In fact, until 2001, agreements for the further development and commercialisation of the *Hoodia* drug had proceeded apace without acknowledgement of the contribution of the San, let alone their prior informed consent. Indeed, a newspaper report quotes Phytopharm having been told by the CSIR that the 100 000-strong San "no longer existed" (Barnett, 2001). In defence of its position, the CSIR linked its initial reluctance in engaging with the San to a concern that "expectations would be raised with promises that could not be met" (Barnett, 2001) and insisted that the organisational policy on bioprospecting was to eventually share benefits of research based on traditional knowledge. How, it was argued by the CSIR and Phytopharm, could the real owners of traditional knowledge be identified, and what if one group had historically stolen the knowledge from another group? The potential complexities and scenarios seemed endless.

While such concerns were undoubtedly valid they were clearly also in flagrant disregard of the International Labour Organisation (ILO) Convention 169—an international agreement for the protection of indigenous peoples' rights, the letter and spirit of the CBD, the African Union's Model Law on Access and Benefit Sharing (Ekpere, 2001), and the Bonn Guidelines, a voluntary guide to assist governments to develop an access and benefit-sharing strategy, as well as necessary legal, administrative or policy measures (CBD, 2002). Although not overtly stated by the San, who to a large degree remain on the fringes of international indigenous peoples' movements, they also ignored numerous indigenous peoples' declarations and statements which explicitly refer to the importance of obtaining prior informed consent from holders of traditional knowledge before

21 As the Hoodia industry has evolved and matured, a more sophisticated permitting system has developed for the harvesting and cultivation of Hoodia, and in parallel, government departments in provider countries have engaged more actively in ensuring compliance with ABS requirements. Phytopharm, Unilever and Hoodia growers have also taken a more active role in overseeing permits and working directly with the South African, and more recently, Namibian governments.

commercialisation of this knowledge; and ensuring that benefits derived from commercialisation are equitably shared with original holders of the knowledge (see Dutfield, 2002 for a review of such statements).

But in 2001, ongoing vigilance by a South Africa-based NGO Biowatch, combined with assistance from the international NGO Action Aid, alerted the foreign media to the potentially exploitative nature of the CSIR/Phytopharm agreement and a leading story was published in a British newspaper. This catalysed a flurry of media interest, which pressurised the CSIR to enter into negotiations with the San, who had remained oblivious to the fact that their knowledge of *Hoodia* had commercial application and that this knowledge had led to research, scientific validation, and the filing of international patents.

On the part of the San, the following three organisations played—and continue to play—significant roles throughout the case:

- the Working Group of Indigenous Minorities in Southern Africa (WIMSA), the San networking and advocacy organisation established in 1996 at the request of San groups in the region to lobby for San rights;

- the South African San Council, a voluntary association established as part of WIMSA by the three San communities of South Africa (the=Khomani, !Xun and Khwe) in November 2001; and

- the Cape Town-based South African San Institute (SASI), a San service NGO facilitating access of San-based organisations to funding and expertise.

As a South African state institution, the CSIR was reluctant to negotiate with parties outside the country, and through WIMSA, the South African San Council was formally mandated to represent the San in Namibia and Botswana as well as South Africa in all benefit-sharing negotiations about *Hoodia*. With this arrangement in place, recognition was given to the fact that knowledge about the plant crossed national borders, and that the details of sharing benefits between San in different countries needed further consideration. WIMSA and SASI instructed their lawyer to negotiate with the CSIR on behalf of the San, and discussions between the two parties began in earnest.

7.4 NEGOTIATING A BENEFIT-SHARING AGREEMENT WITH THE CSIR

Negotiating a Memorandum of Understanding

Early on in the negotiations, the San were faced with a difficult choice. Should they oppose or even challenge the patent, based on ethical considerations and lack of novelty, or should they adopt a more practical approach and become active partners in negotiating a share of royalties from the patent? This was a critical moral dilemma. In communities such as the San, the sharing of knowledge is a culture-defining attribute and is basic to their way of life. Traditional knowledge of plants is viewed as a collective and the idea of 'owning' life abhorrent. The patenting of active compounds of *Hoodia* by the CSIR ran counter to this belief, yet brought with it lucrative opportunities for financial benefits. Ultimately, however, the principle of 'no patents on life' was considered 'too expensive' (Chennells, 2003) and the poverty-stricken San opted to obtain a share of royalties. Writing to the CSIR President in 2001, the CSIR was informed by San lawyers that a legal challenge of any nature did 'not form part of our clients' plans', but emphasised that the San looked on their traditional knowledge regarding *Hoodia,* as well as other plant uses, as being collective San intellectual property that should not morally be able to be owned by any individual or entity (Chennells, 2001)[22].

22 Of interest, is the subsequent appeal against the patent by the European Patent Office, on the basis of it lacking novelty and being based on prior art. The appeal was subsequently overturned, however.

Three months after formal commencement of negotiations, in February 2002, a Memorandum of Understanding (MOU) was reached between the CSIR and the South African San Council. Key aspects of this agreement included:

- an acknowledgement by the CSIR that the San are the 'custodians of an ancient body of traditional knowledge and cultural values, related *inter alia* to human uses of the *Hoodia* plant', and recognition that such knowledge pre-dated scientific knowledge developed by Western civilization over the past century;
- a commitment by the CSIR to (1) recognise the role of indigenous peoples as custodians of their own knowledge, innovations and practices; and (2) provide for fair and equitable benefit sharing;
- an acknowledgement and acceptance by the San of the explanation of the CSIR, which provided the 'context' in which the CSIR first registered the P57 patent, without having first engaged the San in negotiations with respect to material transfer, information transfer and associated benefit sharing;
- recognition by the CSIR of the San as originators of the body of traditional knowledge associated with human uses of *Hoodia*;
- a specification that any intellectual property arising from the traditional use of Hoodia and related to the CSIR patents for P57 remains vested exclusively with the CSIR. The San Council has no right to claim any co-ownership of the patents or products derived from the patents; and
- a commitment, on the part of both the CSIR and the San, to a process of negotiating with one another in good faith, in order to arrive at a comprehensive benefit-sharing agreement.

It was also agreed that both parties would provide each other with full disclosure of any 'matters of significance' relating to the agreement, and that all relevant disclosable information held by the CSIR relating to the P57 patent and subsequent licensing agreements would be made available to the San.

An additional understanding considered the San and the CSIR to be the primary parties with regard to benefit sharing. This latter point is especially significant because it effectively excluded other groups—genuine or opportunist—from claiming benefits through prior knowledge about *Hoodia.* While this helped to address earlier concerns expressed by the CSIR and Phytopharm of the need to identify genuine holders of traditional knowledge about the plant, it also raised new concerns from some commentators about excluding non-San groups, such as the Nama, Damara, and Topnaar, who had historically occupied, and still occupy, areas where *Hoodia* grows, and had undoubtedly used the plant as a medicinal remedy and as a food and water substitute.

Developing positions and identifying key issues of concern

While the MOU represented an important first step, negotiation of a concrete benefit-sharing agreement was still some way off. At a series of CSIR-funded workshops and meetings, representatives of the San, the CSIR, and in some cases certain government departments and NGOs, were brought together to further articulate concerns and positions (e.g. Spies, 2002). Key issues arising from these discussions focused on three main themes:

1) building trust between the parties;

2) identifying genuine holders of traditional knowledge about *Hoodia* and potential beneficiaries; and

3) ensuring the broader protection and promotion of San cultures and knowledge.

Building trust

The development of trust between the CSIR and the San emerged initially as a major concern (e.g. Spies, 2002), more especially given the CSIR's history as an institution shaped by the *apartheid* regime, and serving the interests of a repressive government for nearly 40 years. While transformation of this state institution is now well underway, its initial inertia in drawing the San into the project created mistrust and negative impressions amongst the San. Questions raised during this process focused on how the San could be assured that they would receive appropriate royalties and other benefits, and how they could trust that they would have access to all the necessary information. At an early stage in the negotiations the South African San Council alluded in writing to the CSIR's alleged collusion with the *apartheid* regime, as a potential problem in their building of trust. This was met with an outraged response from the CSIR Board, but the frank exchanges that ensued enabled the parties to clear the air and thereafter develop a more trusting relationship as they moved towards a final agreement (Private notes, R. Chennells).

Identifying holders of traditional knowledge and beneficiaries

The San immediately commenced a process amongst communities represented by WIMSA to establish the extent to which *Hoodia* was known and used. Responses from far flung communities in South Africa, Namibia and Botswana confirmed published records that *Hoodia*, known as *!Xhoba* to the San, was still well known and used for a number of purposes, and chiefly as a sustaining *veld*[23] food that also reduced hunger and thirst (Private notes, R. Chennells). Some informants cautioned about the danger of feeding the plant to small children for sustained periods, but otherwise it was confirmed to have a safe and ancient history. This bolstered the belief of the San, as the first peoples on the subcontinent, that their traditional knowledge of *Hoodia* had predated that of pastoralists who had subsequently entered and settled in Southern Africa. The San view was that they had shared knowledge with all subsequent migratory groups, and were thus the primary holders of traditional knowledge relating to *Hoodia*.

Despite this opinion, parties were anxious of the potential conflict that could arise between the San and other groups such as the Nama and Damara. Because both the plant and traditional knowledge about its use extend across Namibia, South Africa and Botswana, this matter was potentially especially complex and fraught. How could a system be created that ensured fairness and equity across the three countries, and within the relatively new organisational structures set up by different San groups in different countries? The restricted distribution of *Hoodia* suggested that not all groups of the San had utilised the plant within living memory. But identifying those groups that did have a clear record of historical use was near impossible, given the San's history of resettlement and dislocation over millennia, and also the manner in which the San have historically moved about the landscape, aggregating and dispersing according to season and resource availability (Hitchcock & Biesele, 2001). Moreover, thousands of people in southern Africa currently claim San descent, and are able to claim a recent history of use of *Hoodia.* Knowledge about the appetite-suppressant properties of *Hoodia* is shared among a broad spectrum of communities in the region, including the Nama, Damara, and other Khoe speaking peoples, who share the same linguistic roots with the San and have during the past centuries suffered a similar history of persecution and marginalisation.

Resolving these uncertainties presented difficult challenges but there was agreement amongst the San that a nit-picking exercise to link benefit sharing to specific communities using *Hoodia* would be futile and potentially divisive. WIMSA had taken a binding decision at an annual general meeting in 2001, after years of discussions, to the effect that heritage is indivisible, and that benefits resulting from shared heritage, such as *Hoodia*, must thus be shared equally amongst all San peoples. This decision led to a shared formula, decided collectively by the San during the negotiation process, for the equal division of financial benefits between the countries that WIMSA represents.

23 An Afrikaans word meaning uncultivated lands or grassland.

Protecting San culture and knowledge

More generally, the San sought further clarity about how they could more effectively protect their cultural heritage, including their world-renowned rock art, as well as their rich ethnobotanical and environmental knowledge. In the years preceding the benefit-sharing agreement, the San-affiliated non-governmental organisation the South African San Institute (SASI) had begun to assist WIMSA to establish a code of conduct for research and researchers, and to ensure the control and protection of all San intellectual property (WIMSA, 2001; WIMSA, 2003). There was growing sensitisation and awareness amongst the San about the past appropriation of their knowledge over centuries, without acknowledgement or compensation. How, it was asked, had the CSIR obtained local knowledge of *Hoodia* without the San knowing, and how could such knowledge be protected from future exploitation? Although legislation to protect and promote indigenous knowledge systems was under development in South Africa at the time of the negotiations (and had been for at least five years), there had been no consultation with the San about its content and scope. The absence of legislation to protect holders of traditional and/or indigenous knowledge presented a major stumbling block, requiring the San to negotiate in the absence of any legal requirement for benefit-sharing agreements to be developed with owners of knowledge and/or biological resources. This gap in the South African legislature was subsequently filled by the introduction of the Biodiversity Act (10 of 2004) (Republic of South Africa, 2004) and recently promulgated regulations to give effect to the Act (Republic of South Africa, 2008). A similar situation pertained in other countries of origin, such as Namibia and Botswana, where no law was yet in place requiring benefit-sharing agreements.

On the part of the CSIR and government, the absence of legislation created uncertainties as to who should be party to the benefit-sharing agreement, and exactly how traditional or indigenous knowledge should be obtained or used. The CSIR stepped gingerly, unsure (and undoubtedly reluctant) about 'shedding their white coats' and entering into protracted negotiations, but politically obliged to do so. A primary concern for the CSIR was to ensure that the San leadership they engaged with was genuine and representative, and that their agreement with the San would not lead to a flurry of claims to the knowledge from third parties.

Represented by Petrus Vaalbooi, chair of the South African San Council, and one of the authors (Roger Chennells), acting as legal representative, a series of meetings ensued between the San and the CSIR. In March 2003, less than two years after commencing discussions, negotiations concluded on the specifics of a mutually acceptable benefit-sharing agreement. Announcing the deal, Ben Ngubane, then South African Minister of Arts, Culture, Science and Technology, referred to its historical significance in 'symbolising the restoration of the dignity of indigenous societies', and in unleashing benefits by joining together owners of traditional knowledge and local scientists to add value to the biodiversity and indigenous knowledge systems of southern Africa. It was the 'right thing' to do, he said (Ngubane, 2003).

7.5 BENEFIT SHARING

The CSIR-San benefit-sharing agreement

The parties negotiated at arm's length for eighteen months, the San initially claiming ten percent of the royalties, in response to the CSIR's early offer of three percent. Both parties argued strongly in favour of their positions, each listening to the other's position, reconsidering implications, moving steadily to ensure progress, and finally, reluctantly, settling on an agreed amount. In terms of the agreement[24], the San would receive six percent of all royalties received by the CSIR from Phytopharm as a result of the successful exploitation of products (Figure 1). This would be for the duration of the royalty period or for as long as the CSIR received financial benefits from commercial sales of the products (Provisions 1.5 and 2). The San would also receive eight percent of the milestone income received by the CSIR from Phytopharm when certain performance targets were reached during the product development period. In the event of successful commercialisation, these monies would be payable into a trust set up jointly by the CSIR and the South African San Council to

24 Benefit-sharing Agreement between the CSIR and the South African San Council, March 2003.

raise the standard of living and well-being of the San peoples of southern Africa[25] (Figure 1). Monies received by the San would be extracted from royalty and milestone payments obtained by the CSIR, whereas profits received by Phytopharm and Pfizer would remain unchanged. Overall, therefore, the San would receive less than 0.03% of net sales of the product (Wynberg, 2004) although if successful this would still translate into millions of dollars.

Clear and transparent accounting procedures were required to be in place on the part of both the CSIR and the San Trust with regard to financial benefits paid by the CSIR and used by the San Trust. The Trust would include representatives of the CSIR, the=Khomani, !Xun and Khwe, other San stakeholders in southern Africa, WIMSA, a South African lawyer nominated by the South African San Council, and the Department of Science and Technology, with strict rules determining the distribution of funds to beneficiaries. Payments would not be made to individuals and would need to be used to attain the aims and objectives of the Trust. No distribution of funds would be made to a beneficiary community or institution unless a request, approved formally by the Trust, set out a detailed budget and coherent plan, identified a bank account opened by elected representatives, with a proper constitution, and indicated the capacity to account fully for the proper expenditure of funds.

It is noteworthy that the CSIR-San benefit-sharing agreement is confined almost exclusively to monetary benefits, which hinge on product sales and successful commercialisation, although there are general provisions relating to non-monetary benefits. These include a commitment by parties to conserve biodiversity and to undertake best-practice procedures for plant collection (Provision 3.6), required the CSIR to grant the San access to existing study bursaries (Provision 3.7), and, significantly, laid the ground for further collaboration in bioprospecting (Provision 3.8).

In addition to spelling out the details with respect to benefit sharing and administrative aspects such as accounting, the agreement also broadly covered intellectual property issues and, importantly, set out comprehensive measures to protect and indemnify the CSIR. 'Knowledge' was defined as 'the traditional knowledge on the uses of the *Hoodia* plant that occurs in Southern Africa, originally in the hands of the San people'. Provision 4 of the Agreement specified that 'any intellectual property that may be developed or created by the CSIR, including any patent, trade mark or plant breeder's right, as a result of any use of the traditional knowledge, shall be and remain vested in the CSIR'. Moreover, the San Council had no right to claim any co-ownership of the patents or products derived from the patents.

Provision 6, Warranties and Indemnity, included an undertaking and warranty by the San that, *inter alia,* it is the legal custodian of traditional indigenous knowledge on the use of *Hoodia;* that it would not assist or enter into an agreement with any third party for the development, research and exploitation of any competing products or patents; that it would not approach Phytopharm or Pfizer to obtain additional financial benefits; and that it would not contest the enforceability or validity of the CSIR's right, title and interest in the P57 patent and related products.

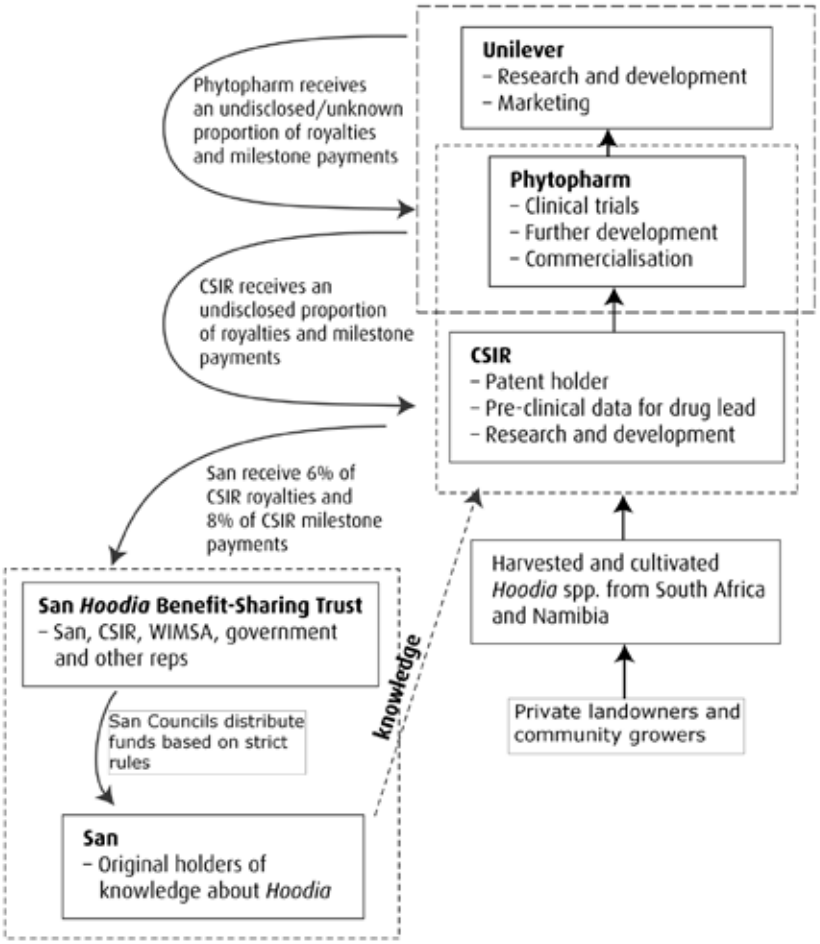
A further provision on Third Party Claims (Provision 9) set out various measures to protect the CSIR against claims by any third party for intellectual property infringement and stipulated that a successful third party claim against the CSIR could lead to a review of the agreement to accommodate claimants in the sharing of financial benefits. It also required the San Council to share financial benefits with a third party if the latter were successful in proving a claim.

In February 2005, the San Trust, formally named the San *Hoodia* Benefit-Sharing Trust, was registered. The content of the Trust document was discussed over several meetings, including a consultative conference at Upington, South Africa, in October 2003, during which San delegates from South Africa, Namibia and Botswana debated issues and agreed upon guiding principles relating to benefit sharing. There was unanimous agreement that 75 percent of all Trust income would be equally distributed to the then constituted San

25 Deed of Trust of the San *Hoodia* Benefit-Sharing Trust.

Councils of Namibia, Botswana and South Africa; that 10 percent would be retained by the Trust for internal and administration purposes; that 10 percent would be allocated to WIMSA as an emergency reserve fund; and that 5 percent would be allocated to WIMSA to cover administration of the San networks. Priorities within the region, such as education, leadership empowerment, and land security, were agreed upon as non-binding recommendations to the Councils. Principles for benefit sharing that would bind the Trust were unanimously endorsed by the WIMSA Annual General Meeting in December 2003 (WIMSA, 2004). The Trust began its work in earnest, electing a Chair, Secretary and Treasurer, and started engaging with the practical challenges of distributing milestone income received from the CSIR, at that time a total of R560,000.

FIGURE 1: BENEFIT-SHARING AND VALUE-ADDING UNDER THE SAN-CSIR-PHYTOPHARM-UNILEVER AGREEMENTS. AFTER WYNBERG (2006).



CSIR-Phytopharm-Unilever license agreements

What of the benefits for the CSIR? At the national level, these are purportedly substantial, although difficult to specify or verify owing to the confidentiality of the agreement and reluctance on the part of CSIR and Phytopharm to divulge these details. While CSIR and Phytopharm have been reimbursed for their continuing roles in research and development (R&D), these funds have been allocated largely to cover R&D costs and are not considered by the CSIR as income. Through licensing the technology, the CSIR is likely to earn $10-million in milestone payments, linked to success of the drug during different stages of the clinical trials. The specific royalty percentage has not been divulged publicly but is considered by the CSIR to "be substantial" compared to international norms (M. Horak, CSIR, pers. comm., April 2002). Typically, royalty percentages for pharmaceuticals range from 0.5% to 5% of total sales (Laird and ten Kate, 1999). If successful, commercialisation of P57 is likely to amount to hundreds of millions of Rand *per annum* for the lifetime of the patent. In

this regard many consider South Africa to have reached an important turning point in bioprospecting. Patent rights to the active constituents of Hoodia responsible for suppressing appetite have been successfully retained by South Africa through the CSIR (although notably, other *Hoodia*-related patents remain foreign-owned), with foreign drug firms attaining licences for the further development and commercialisation of the drug.

In terms of non-monetary benefits, some of the more significant benefits to emanate from the agreement have been the construction of the Food & Drug Administration (FDA) approvable medicinal plant extraction facility at the CSIR for the manufacture of material for use in clinical trials on P57, as well as the establishment of a Botanical Supplies Unit—both the first of their kind in the world. South Africa is also considered a preferential site for cultivation and the production of material, although Phytopharm does have the right to establish plantations outside of South Africa. Already, up to 300ha of *Hoodia* is cultivated in South Africa and Namibia, generating substantial jobs and investment, and a €30 million extraction facility for *Hoodia* is planned for development in the region.

Benefit Sharing and the Southern African *Hoodia* Growers Association

Cultivated Hoodia *in southern Namibia* RACHEL WYNBERG

Benefit streams have also emerged from those involved in growing *Hoodia* as a *raw material* for the herbal and dietary supplement market, with South African growers recently negotiating another benefit-sharing agreement with the San, based on a levy on processed *Hoodia*.[26] This process was initiated in late 2005 when the San were approached by a group of South African *Hoodia* growers who were cognisant of their obligations to share benefits with the San under the 2004 Biodiversity Act. The San realised that the new market for *Hoodia* as a food additive or dietary supplement was likely to grow over the years, and that they had a right to share in benefits. Because these products did not relate directly to the P57 patent and the use of *Hoodia* extracts, the San were legally able to sign an additional benefit-sharing agreement with *Hoodia* growers that was not in breach of their prior agreement with the CSIR. Negotiations commenced between the South African San Council (again acting on behalf of WIMSA), and the South African *Hoodia* Growers Pty Ltd (SAHG), which represented the interests of some commercial growers of *Hoodia* in South Africa who had agreed to comply with certain standards of best practice, safety, fair trade and benefit sharing. In March 2006 a preliminary benefit- sharing agreement was concluded with the SAHG. In terms of the agreement 6% of the gross value of *Hoodia* sold would be allocated to WIMSA—4% into a Trust for the San, and 2% to WIMSA or the South

26 Benefit sharing agreement and joint venture between the Southern African Hoodia Growers Association and the Working Group of Indigenous Minorities in Southern Africa, March 2007. Unpublished signed legal agreement

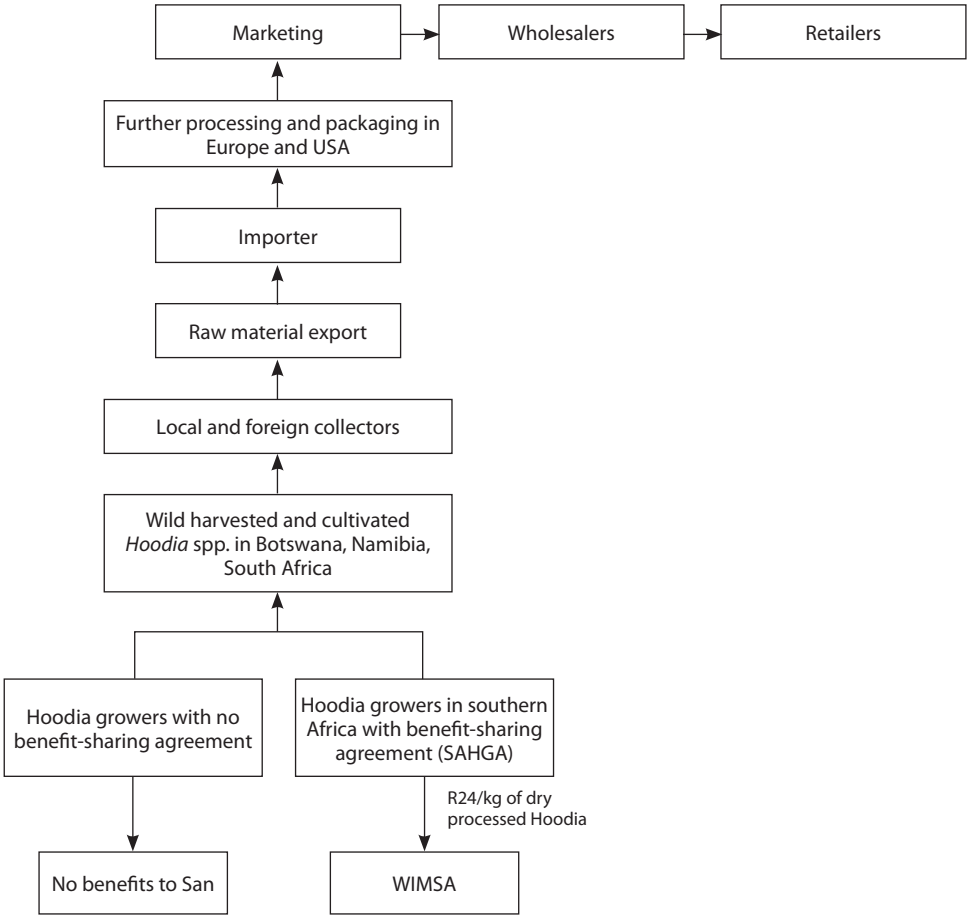
African San Council. No member was permitted to sell to vendors engaged with the production or marketing of illegal *Hoodia* products.

Royalties of R176,000 trickled in from this agreement, but it was soon replaced with another more comprehensive initiative that included the majority of South African *Hoodia* growers as well as South African provincial environmental government agencies responsible for ensuring sustainable use of *Hoodia* and administering permits. After a year of negotiations, during which the different realities and negotiating positions of the respective parties emerged in an increasingly mature climate of transparency, a benefit-sharing agreement was concluded in March 2007 between the San and the newly formed Southern African *Hoodia* Growers Association (SAHGA). This had been preceded by the signing of a Memorandum of Understanding in January 2007 between the San (represented by WIMSA), *Hoodia* growers, and the Western Cape and Northern Cape environmental departments[27] which captured the intention of the parties as they entered negotiations.

The benefit-sharing agreement, drafted to be compliant with the provisions of the Biodiversity Act, acknowledged the San to be the primary traditional knowledge holders of *Hoodia*, having a legal right to share benefits arising from its harvesting, growing and marketing. It also recognised the urgent need for regulation to minimise impacts on wild populations and to ensure attainment of standards of legality, safety and fair trade. Stated objectives of the non-profit SAHGA were *inter alia* to regulate the legal production and harvesting of *Hoodia* by its members; to promote a sustainable *Hoodia* industry in southern Africa; to liaise with all roleplayers; to gather and exchange relevant information relating to permits, quality control, sales and compliance; and to promote research. Two San representatives were elected to be members of the Board of Directors, and an additional two San representatives were designated as observers. WIMSA in turn was to ensure the proper administration of financial benefits, and to further the objectives of SAHGA and help with effective marketing of *Hoodia*. Although the stated intention of the parties was to create an exclusive joint venture and benefit-sharing agreement, WIMSA was entitled, on good cause, to motivate to SAHGA for the signing of another, separate agreement. Parties additionally agreed to promote SAHGA as the only legitimate source of *Hoodia* for the food, food additive, and dietary supplement market, outside of the CSIR/Unilever agreement, and to 'inform the world' that *Hoodia* products outside of the two benefit-sharing agreements were illegal. The agreement also, significantly, acknowledged other groups holding traditional knowledge of *Hoodia*, such as the Nama and Damara, and provided an opening for further discussions and possible agreements with such groups.

27 Signed unpublished legal agreement.

FIGURE 2: BENEFIT-SHARING THROUGH THE SOUTHERN AFRICAN *HOODIA* GROWERS ASSOCIATION, AND THE *HOODIA* VALUE CHAIN BASED ON TRADE OF RAW MATERIAL



Financial benefits for the San were formulated based on a ZAR 24 levy charged on each kilogram of dry, processed *Hoodia*, paid prior to the issue of CITES export permits and to be revisited on an annual basis. Calculation of the levy was based on a number of factors including the previous SAHG levy of six percent of the sale from the farm, as well as conditions in the world *Hoodia* market—recognising its high levels of fluctuation, the need for the levy to be affordable for growers, and other equity considerations. The agreement also provided for re-evaluation after one year, in recognition of the need for the eventual amount to be fair to both sides. Parties were fully aware that the original figure of six percent had been agreed upon with SAHG without the benefit of adequate knowledge about trade volumes, without extensive calculation of likely implications of percentages for all parties, and without sufficient reliable information to fix an appropriate percentage with surety. Conflict resolution was proposed through mediation or, failing this, through arbitration. The agreement, whilst negotiated in South Africa, was drafted in such a way as to welcome and enable the participation of *Hoodia* growers from neighbouring Namibia and Botswana in due course.

7.6 IMPLEMENTATION CHALLENGES

The conclusion of two benefit-sharing agreements represents a major achievement. Indeed, these agreements characterise some of the most unique examples in the world of where the much-touted benefits from bioprospecting have had practical realisation. Nonetheless, a number of implementation challenges are now faced by the San, by those involved in the *Hoodia* industry, and by regulators and policy-makers.

Decision-making and the distribution of benefits

Signatories to a second agreement to share benefits from Hoodia with the San. Pictured are from the left: Robby Gass (Chair of the South African Hoodia Growers Association), Tasneem Essop (Minister for Environment and Tourism, Western Cape), Andries Steenkamp (Chair of the South African San Council), and Volker Miros (SAHGA) RACHEL WYNBERG

One of the key challenges concerns the way in which decisions will now be made about the sharing of benefits. The CSIR/San agreement will pay six percent of royalties into the San *Hoodia* Trust, which as described above, has begun the task of preparing the policies and structures necessary to distribute the significant flows of money anticipated within the next two years. The fair and equitable distribution of large sums of money to beneficiaries in three different countries would be an enormous challenge for any organisation. The fact that these beneficiaries are impoverished indigenous peoples, wrestling with problems of organisational cohesion and under-development, introduces a heightened degree of complexity to this challenge. The SAHGA benefit-sharing agreement also promises to deliver millions of Rands within the next few years, this income flow being channelled directly to the San regional organisation WIMSA. This money does not have any prior allocations that have been earmarked, and its wise distribution will similarly present the relatively inexperienced Board with major challenges.

The burden on San individuals on the San *Hoodia* Trust as well as on the WIMSA Board to meet heightened expectations, and to act wisely and transparently in the eyes of the watching world, will be heavy indeed. NGOs entrusted with providing support will be expected to shoulder part of this responsibility. The objective will be to minimise the negative social and economic impacts, and the intra-community conflicts that may arise following the introduction of large sums of money into San communities. Limited international and local experience exists in the administration and implementation of such agreements, and few, if any, cases address the sharing of benefits within communities. As Barrett and Lybbert (2000) point out, thus far benefit-sharing questions have remained issues of distribution between the community in aggregate and outsiders, whilst at a local and intra-community level there has been little practical experience. Early experiences, however, suggest the potentially divisive impact that natural product trade can have in indigenous communities. In India, for example, the commercialisation of Jeevani *(Trychopus Zeylanicus*) a wild plant with anti-fatigue properties, has led to divisions amongst the tribal community, the Kanis, as to how their knowledge should be used (Tobin, 2002; Gupta, 2004). In Peru, a 1996 agreement of the International Cooperative Biodiversity Group also led to conflict between organisations representing local Aguarana communities, as well as at a national level (Tobin, 2002; Greene, 2004).

In the case of the San, intra-community issues are especially complex. The organisations set up to politically represent the San are relatively new and the introduction of Western values and economies into supposedly traditional communities, already fractured and 'hybridised', presents a suite of difficult social and economic problems. Robins (2002) describes the social complexities of contemporary San identity, knowledge and practice, and charts the intra-community divisions and conflict that emerged between self-designated 'traditionalists' and 'western bushmen' when San land claims were lodged in the Northern Cape Province of South Africa. While these claims resulted in significant benefits for the San, they also had unintended consequences in terms of generating conflict. Robins (2002) points out the contradictions between San 'cultural survival' and the promotion of the values of 'civil society' and 'liberal individualism', a conclusion that holds particular resonance for the *Hoodia* case, contextualised as it is within the international discourse of indigenous peo-

ples, a vigilant NGO community alert to biopiracy cases, and a new policy framework that requires fair and equitable benefit sharing for use of traditional knowledge.

The possible compensation of other groups that use *Hoodia* and have traditional knowledge of the plant such as the Nama, Damara and Topnaar also represents a major challenge that will demand resolution, especially once Unilever products emerge, other *Hoodia* markets mature, and significant profits begin to flow. Already, Namibia has articulated a position that supports the inclusion of the Nama and other groups in benefit-sharing arrangements, bolstered by the fact that *Hoodia* wild and cultivated populations occur in areas occupied by Nama communities. However, these communities, even more than the San, lack organisational structures and cohesion and will require substantial support to enable them to get to the point at which they can negotiate their rights, and manage and disburse incoming funds. In the interim, structures have emerged through the Hoodia Growers Association of Namibia, to raise and manage funds for the inclusion of the Nama and other indigenous groups in the Hoodia industry with the intention to build organisational and technical capacity within such groups in the medium to long term.

Regional differences in benefit-sharing policies

One of the more interesting aspects of the case lies in its regional implications. *Hoodia* is a biological resource that is shared across national political boundaries, and knowledge of the plant is similarly shared by communities straddling these boundaries. Thus far, however, South Africa has played a leading role—in lodging the patent, developing commercial partnerships with multinational companies, negotiating benefit-sharing arrangements with the San, and facilitating legal trade in the plant. Botswana and Namibia by comparison, although involved in harvesting and cultivating *Hoodia*, have not yet legalised trade in the plant, nor developed commercial partnerships. Moreover, South Africa has adopted ABS legislation requiring benefit-sharing agreements, and is supportive of recognising the San as a community with clear rights to benefit from *Hoodia*, but Namibian and Botswanan policies have been more ambivalent. Neither Namibia nor Botswana have ABS legislation in place and in both countries benefits from *Hoodia* are considered to belong to the state, rather than the San or other traditional knowledge holders. Unsurprisingly, these divergent policy approaches have led to concerns.

A central concern relates to the difficulties of controlling trade. Numerous reports exist of illegal material entering South Africa from Namibia, and being exported from South Africa under permit. The areas in which the plant occurs are typically very remote and illegal harvesting is difficult to monitor and enforce. While steps could be taken to address these concerns, their efficacy would be questionable without a regionally coherent position on *Hoodia* use. Strategic approaches to value adding and the use of marketing tools such as Geographical Indications would also be undermined in the absence of strong regional collaboration—needed at government, industry, farmer and community level.

Although the San-*Hoodia* Trust that is set up to disburse benefits already implements benefit-sharing across regional boundaries, based on an acknowledgment of the shared knowledge of *Hoodia*, there is clearly a need for benefit-sharing strategies to be developed at regional and national levels in cases where genetic resources are shared across boundaries. The added requirement of the South Africa Biodiversity Act for all funds arising from benefit-sharing agreements to be channelled via a Trust Fund adds to these complications.

Hoodia trade and markets

Without the development of a sustainable and viable industry, no benefits will emerge and a set of complex challenges also confronts those involved in trading and growing *Hoodia.* Like other agricultural commodities, *Hoodia* markets follow the law of supply and demand, which determines the prices, quantities and allocation of resources (Wall, 2001). In line with the classical model described by Homma (1992) *Hoodia* has moved through a rapid expansion phase, followed by a stabilisation phase, where an equilibrium has been reached between the supply and demand of the product, supposedly close to the maximum capacity of extraction. Prices have consequently risen because of the inability to meet a growth in demand, which have lead to the adoption of policies to protect the sector or stimulate sustainable production of the resource. Shrinkage of

the resource, restrictive policies on wild harvesting, and incentives to cultivate have stimulated a substantial increase in cultivated *Hoodia* with the challenge now to secure markets for this material. Similarly, although Unilever markets are secure, there remain questions as to whether a product can be developed that is safe and efficacious and desirable to consumers.

Further challenges lie in the monitoring of compliance to the benefit-sharing agreements. While this is relatively straightforward and effective for the CSIR-San benefit-sharing agreement, which has clear milestones, reporting mechanisms and traceability mechanisms, it is less so for the SAHGA benefit-sharing agreement. Because of the nature of *Hoodia* trade by the myriad of companies trading it as a herbal supplement, it is difficult to track the way in which *Hoodia* material is used. Moreover, many *Hoodia* traders wish their trade volumes to remain confidential, yet this information is vital to calculate the agreed levy to the San. The SAHGA agreement depends to a large extent on good faith and the proactive declaration by growers of volumes traded and monies owed. After close to one year of the agreement's existence, and in the absence of long-awaited (but recently promulgated) regulations which will make benefit-sharing agreements compulsory, many growers have proved reluctant to provide the necessary information. *Hoodia* sales are also currently severely depressed as a result of increased crackdown by compliance institutions on new and unregulated products. Currently the environmental government agencies responsible for issuing permits are not legally required to provide SAHGA with this vital information, however with the promulgation of the regulations and with an amendment of the SAHGA constitution, it is anticipated that the intended benefit sharing payments will flow to the San within the next year.

Some of the greatest threats to benefit-sharing lie outside of the region. Although no conclusive figures exist, it is well known that extensive *Hoodia* populations have been established elsewhere in the world. Some of this genetic material may have been acquired before the entry into force of the Convention on Biological Diversity, and some could just as easily have been smuggled out of the region without the required permission. It is therefore possible that a *Hoodia* industry could thrive outside of southern Africa, without channelling benefits to the original knowledge holders. This concern accounts for a newly-implemented regional decision to prohibit export of live *Hoodia* genetic material outside of those countries with wild populations (South Africa, Botswana, and Namibia).

7.7 CONCLUSION

The *Hoodia* case study tells a complex story of many strands, and from it a number of important lessons and conclusions can be drawn that are important to integrate into ongoing debates about ways in which benefit sharing for communities can be made more equitable. One of the most crucial lessons to emerge from the case is the need to get it right from the start. Obtaining the prior informed consent of communities holding knowledge about biodiversity from the very outset of a project—and engaging them as active partners—is an absolutely fundamental principle of benefit sharing. The *Hoodia* case study illustrates what can go wrong when this principle is ignored. Recent adoption of this principle in South African legislation is likely to set new ways in which communities are consulted about use of their knowledge about biodiversity.

The negotiating process between the CSIR and the San has demonstrated the importance of building trust between role players and of having in place a political climate conducive to fair deliberations. It has also reaffirmed the importance of having community-based institutions through which holders of traditional knowledge can be represented in negotiations, and benefits channelled. The process has highlighted the prominent role played by NGOs, legal representatives, and intermediaries in benefit sharing—in this case not only in assisting the San to attain their rights but also in shaping San politics and economic development.

One of the major impacts arising from the commercialisation of *Hoodia* has been the wide-ranging interest it has aroused about the importance of protecting traditional knowledge and ensuring that holders of such knowledge receive fair compensation. Amongst the San, the *Hoodia* case is considered an important empowering tool to enable more informed decisions to be made about their intellectual property and ways to protect

it. At government level, the case has led directly to an increased focus and prominence for biodiversity and its potential value, and in South Africa, the inclusion of prior informed consent and benefit sharing within new biodiversity legislation and the requirement of disclosure of origin prior to the granting of patents. At the international level, the case is widely considered to set precedents about the ways in which holders of traditional knowledge should be compensated for their knowledge.

There is clearly an urgent need to introduce new forms of protection for traditional knowledge that not only give communities rights over their knowledge but also enable the wider preservation and promotion of such knowledge systems. The *Hoodia* case demonstrates not only the value of having an integrated system to protect and promote traditional knowledge, but also the importance of so-called 'defensive protection', to prevent the misappropriation of traditional knowledge.

Some of the lessons are still to be learnt and some are only unfolding. If significant monies are eventually received by the San there will be extremely difficult issues to deal with in terms of determining who benefits and how benefits are spread across geographical boundaries and within communities, and of minimising the negative social and economic impacts and conflicts that could arise with the introduction of large sums of money into impoverished communities. The due compensation of other communities such as the Nama, Damara and Topnaar will also require careful consideration. Overwhelmingly, there will be a need for continued legal, administrative and technical support to enable beneficiaries to claim what is rightfully theirs, and to do so in a manner that consciously and cautiously brings tangible and effective benefits to the original holders of *Hoodia* knowledge.

Typical landscape in which Hoodia *is found in southern Namibia* RACHEL WYNBERG

VOLUME III

The Commercial Use of Biodiversity: An Update on Recent Trends in Demand for Access to Genetic Resources and Benefit-Sharing, and Industry Perspectives on ABS Policy and Implementation

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December 2005

CONTENTS

1. INTRODUCTION

This paper was prepared for the ABS Working Group in 2005 (UNEP/CBD/WGABS/4/INF/5), in order to provide an overview of market and research trends that impact industry demand for genetic resources, trends in benefit-sharing, and—13 years after the CBD entered into force—the impact the CBD, and national ABS policies and regulations, had on industry demand for and research on genetic resources. The paper also reported on industry and researcher perspectives on the strengths and weaknesses of the CBD, and ABS measures in particular. It is included here as Volume 3 because much of the information and analysis provides useful background for the preceding volumes, and key elements—including that on industry and researcher perspectives—have changed little in the last few years, and are important context for an analysis of ABS arrangements today.

As part of the research for this paper, approximately 40 interviews were undertaken in 2005 with a wide range of academic and industry researchers, as well as company executives, government officials, and individuals working on ABS issues for NGOs and other groups. The breakdown of interviews with researchers and industry representatives by sector is as follows: pharmaceuticals: 7; biotechnology: 4 ; seed and crop protection: 5; horticulture: 3; personal care and cosmetic (including fragrance): 4; botanicals: 4; food and beverage: 1.

The paper is an overview of the state of the field in 2005, and in no way can be considered comprehensive. While it identifies the broad parameters of current trends that should impact the design, development, and implementation of effective ABS measures, a far more comprehensive study, or an on-going effort on behalf of the Parties to the CBD to track these developments and perspectives, is warranted.

The paper begins with a review of trends in markets, research and development, and demand for access to genetic resources in five sectors: pharmaceuticals, biotechnology, seed, crop protection, and horticulture. Drawing on perspectives from a broader range of industries—including the cosmetic and personal care, botanical, fragrance, and food and beverage—it then reviews trends in benefit-sharing across sectors and reports on the impact of the CBD, and national ABS policies and regulations, on industry demand for genetic resources. It concludes with recommendations for more effective ABS policy.

2. INDUSTRY PROFILES

A wide range of sectors undertake research and develop commercial products from genetic resources. They include the pharmaceutical, biotechnology, seed, crop protection, horticulture, cosmetic and personal care, fragrance and flavor, botanicals, and food and beverage industries. Each sector is part of a unique market, undertakes research and development in distinct ways, and uses genetic resources and demands access to these resources very differently. Incorporation of these factors into ABS regulatory frameworks is essential.

Following is a brief overview of five sectors—pharmaceuticals, biotechnology, seed, crop protection and horticulture—that highlights some of the recent market and scientific and technological trends, and the ways they impact demand for access.

2.1 THE PHARMACEUTICAL INDUSTRY

Market Trends

Pharmaceutical industry global revenues in 2004 topped $500 billion, dominated by sales in North America, Europe and Japan. The industry is also concentrated in the US and Europe, followed by Japan. Despite poor research and development productivity, the loss of patent protection for some major products in recent years, and pressures for containment of drug costs, the industry grew around 9% in 2004 (Class, 2004). Companies are adapting to changes in the market and regulatory environment in a number of ways, including moving

away from the 'blockbuster' model to smaller niche markets with still significant sales, although 85 blockbusters are expected to account for 30% of global sales in 2005, up from 69 in 1993 (Lewis et al, 2005).

The top 10 companies in 2003 accounted for half of all worldwide sales, but their relative contribution to overall industry growth declined to 41% in 2003 from 53% in 2001. The greatest rates of growth were seen in generic and biotechnology companies (Class, 2004). Biotechnology products account for an increasing share of the market, with 17% growth in 2004. Eighty percent of the biotechnology market was held by just ten firms, with Amgen the leading player (Lewis et al, 2005). [28]

There is continued consolidation in the pharmaceutical industry, although the rate of mergers and acquisitions has slowed in the last few years. Recent 'megamergers' have produced mixed results, with many of the top companies having lower actual market shares in 2003 than the sum of their components in 1998. It has become evident that mergers can actually have a negative impact on R&D productivity, previously cited as a one of the main drivers of mergers and acquisitions. Many analysts now believe that the optimal number of scientists for a successful R&D program is 300-800, with any more being unmanageable. Large companies like Glaxo SmithKline and Lilly are breaking their research teams into therapy areas to promote an 'independent, entrepreneurial spirit' (Class, 2004).

Targeted acquisitions of small biotechnology firms to gain access to a specific product or technology are increasing in importance, as are licensing deals, to make up for unproductive R&D programs in large companies. In 2001, in-licensed products accounted for 16-20% of the top 20 companies' revenue; by 2007 this figure is expected to reach 40%. Some predict that the industry will divide into two, with small R&D boutiques providing candidates for large companies that focus on development, sales and marketing (Class, 2004). This means that smaller companies may be more likely than the largest to seek access to genetic resources for their discovery programs, and that promising compounds will then be licensed to the larger companies for development.

Trends in Research and Development

Pharmaceutical R&D falls into *discovery*—the process by which a lead is found, including the acquisition of materials for screening—and *development*—which includes chemical improvements to a drug molecule and animal and clinical studies. It takes roughly 10-15 years for a compound to make its way through discovery and development into commercialization, and roughly one in 10,000 compounds screened are commercialized (Table 1; see Laird and ten Kate, 1999 for a discussion of the components of R&D).

TABLE 1: DRUG DISCOVERY AND DEVELOPMENT

	AVERAGE TIME (YEARS)	AVERAGE # COMPOUNDS	PhRMA MEMBER COMPANY INVESTMENTS ($BN)
DRUG DISCOVERY	5 years	10,000	$11.0 billion
PRE-CLINICAL	1.5	250	
IND SUBMITTED			
CLINICAL TRIALS PHASE I, II, III	6	5	14.1
NDA SUBMITTED			
FDA REVIEW	2	1	4.1
LARGE SCALE MANUFACTURING/ PHASE IV	2	1	3.7

Source: PhRMA, 2005

28 In 2004 Amgen saw 30% growth and has five of the ten biotechnology blockbusters—Epogen (erythropoietin), Aranesp (darbepoietin alpha), Enbrel (etanercept), Neulasta (pegfilgrastim), and Neupogen (filgrastim) (Lewis et al, 2005).

Despite continual increases in R&D expenditures, including the highest-ever investment in R&D in 2004[29], pharmaceutical industry productivity is significantly lower than in recent years. The number of new chemical entities (NCEs) launched worldwide in 2004 was the lowest for 10 years (Lewis et al, 2005). Of the New Drug Applications approved by the FDA in 2002, only 22% were for NCEs, with the majority being 'me-too' drugs that are new formulations or line extensions of existing products. Biotechnology is making an increasing contribution to the industry's bottom line, and biotechnology research tools and techniques are central features of pharmaceutical discovery and development today. Eight of the thirty NCEs launched in 2003 were biotechnology-derived, and 27% of active compounds in industry's pipeline were biotechnology-based[30] (Class, 2004).

Advances in molecular biology, cellular biology and genomics in the 1990s deconstructed disease pathways and processes into their molecular and genetic components to identify the exact point of malfunction, and the point in need of therapeutic intervention. The result was an increase of molecular targets that may be applied to the discovery of novel tools for the diagnosis, prevention and treatment of human diseases from approximately 500 to more than 10,000 targets (Class, 2004; Newman et al, 2003; Bio, 2005).

The development of high-throughput screens based on molecular targets led to demand for large libraries of compounds that might inhibit or activate a specific biological target, such as a cell-surface receptor or enzyme. For much of the 1990s, scientists thought the best way to generate compounds for the screens was through mass-produced combinatorial libraries (Newman et al, 2003; Koehn and Carter, 2005). The importance of natural products as a source of molecular diversity for drug discovery and development was overshadowed by chemical approaches that use combinatorial chemistry and biological approaches such as the manipulation of biosynthetic pathways of microbial metabolites through combinatorial biosynthetic techniques (Cragg et al, 2005). Natural products were considered too slow, too costly, and too problematic from both a scientific perspective (for example, the additional steps needed to identify and isolate active components in mixtures), and for the legal and public relations uncertainties associated with gaining access to genetic resources as a result of the Convention on Biological Diversity. This latter point is dealt with in Section 4.

BOX 1. REASONS FOR THE DECLINE IN PHARMACEUTICAL INDUSTRY NATURAL PRODUCTS RESEARCH IN THE LAST DECADE

(Koehn and Carter, 2005)

1. Introduction of high-throughput screening against defined molecular targets (and the move from natural products extract libraries to 'screen-friendly' synthetic libraries);

2. Development of combinatorial chemistry, which appeared to offer more drug-like screening libraries of wide chemical diversity;

3. Advances in molecular biology, cellular biology, and genomics, which increased the number of molecular targets and prompted shorter drug discovery timelines;

4. Declining emphasis among major pharmaceutical companies on infectious disease therapy, a traditional strength of natural products;

5. Possibly uncertainties with regard to collection of biomaterials as a result of the Convention on Biological Diversity.

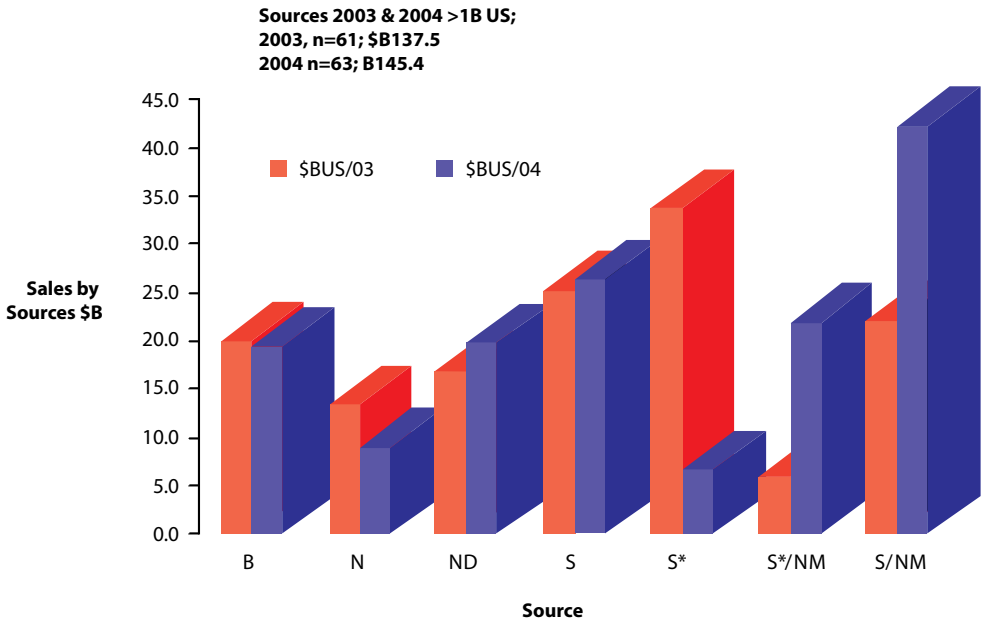
29 2004 R&D investment was $49.3 billion for PhRMA member companies alone (www.PhRMA.org).

30 Biotechnology is transforming drug discovery and development, including high-throughput screening that has revolutionized the process of target identification, DNA sequencing machines that shaved years off the mapping of the human genome, and monoclonal antibodies that transformed the diagnostics industry and are now used in treatments (Ernst and Young, 2005). Biotechnology techniques used in drug discovery and development include: bioprocessing (using living cells to manufacture products such as human insulin); monoclonal antibody technology (using immune system cells that make antibodies to target treatments to specific cells); molecular cloning (creating genetically identical DNA molecules); and recombinant DNA technology (combining and modifying genes to create new therapies) (PhRMA, 2005).

Despite the contributions of natural products to industry's bottom line[31] (see Chart 1), particularly in categories like infectious disease and cancer[32], natural products experienced a slow decline over the past two decades due to both scientific and commercial considerations (Koehn and Carter, 2005; See box 1). Disease categories for which natural products are well suited—in particular infectious disease—lost ground within companies (Koehn and Carter, 2005; Handelsman, 2005). The US pharmaceutical industry essentially abandoned antibiotic discovery around 1990, even as resistance problems were emerging. Antibiotics have limited profitability (compared with those taken over long periods of time for chronic conditions) and there was a misplaced belief of having conquered infectious diseases. Wyeth's tigecy-cline released in 2005 is the first new class of antibiotics to be introduced to the market in 20 years (Handelsman, 2005).

After a multi-billion dollar investment in combinatorial chemistry since the late 1980s, however, large pharmaceutical companies have found very little in the way of new structurally diverse entities, and their pipelines are all but empty. The percentage of synthetics as new chemical entities (NCEs) has remained roughly the same (see Chart 2; Newman, 2005). It is now widely agreed that while combinatorial chemistry is a valuable development tool for optimization of leads, including those from natural products, it does not yield much in the way of new molecular diversity.

CHART 1: SALES BY ALL CATEGORIES, DRUGS >$1 BILLION, 2003 AND 2004



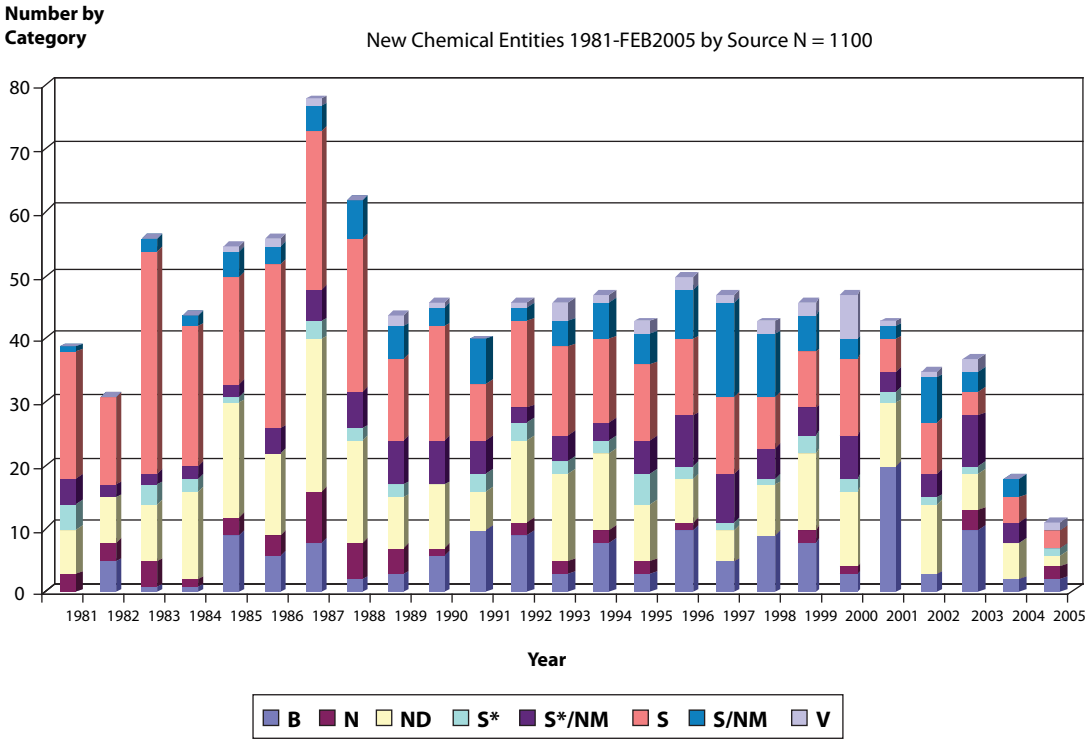
Source: Newman, 2005

B=biologicals; N = natural products without modification; ND = modified natural products; S= synthetic; S/NM= synthetic by natural product mimic; S*=natural product pharmacophore; S*/NM=natural product pharmacophore or mimic

31 See, for example, Newman et al, 2003; Newman, 2005; Newman and Laird, 1999.

32 In addition to infectious diseases, cancer drugs draw heavily upon natural products, and companies with aggressive oncology programs, like Novartis and Bristol Myers Squibb, maintain natural products R&D programs in this area. Newman et al (2003) undertook a study of natural products as sources of new drugs from 1981-2002 and found drugs of natural origin predominate in certain disease categories like cancer and infectious disease, despite the expansion of combinatorial chemistry in the 1990s.

CHART 2: NEW CHEMICAL ENTITIES 1981–2005



Source: Newman, 2005

At the same time the limitations of combinatorial chemistry have become evident, breakthroughs in technologies (eg in separation and structure-determination) have made screening mixtures of structurally complex natural product molecules easier, and have expanded the potential role of natural chemical diversity in the drug discovery process (Koehn and Carter, 2005). Expanded understanding of the genes involved in secondary metabolite biosynthesis also mean that researchers can now discern the complex chemical structure of a secondary metabolite which will result from the enzymes produced following expression of a particular set of genomic sequences. This makes "genome mining" of even well-known natural products a potentially powerful new approach to natural product discovery (McAlpine et al, 2005). Advances in synthetic chemistry have revolutionized the process of material supply, making it possible to recreate almost any compound in the laboratory, and addressing one of the fundamental concerns in natural product discovery, the 'supply issue' (Koehn and Carter, 2005). The result of these developments is renewed interest in natural products as a source of chemical diversity and lead generation, and a view of natural products and combinatorial synthesis as complementary rather than stand-alone approaches (Koehn and Carter, 2005). [33]

Demand for Access to Genetic Resources

Despite renewed interest in natural products, most large companies are not at present expanding their in-house natural products programs, but they are licensing in, or forming partnerships, with small companies and universities that generate interesting leads from natural products discovery research. However, the same technological and scientific developments that make natural products more interesting again, also mean that a great deal of research can be done in laboratories or on a computer looking at the genomes of already known organisms. Analysis, using new scientific and technological tools, of the genome of the well-characterized microorganism *Streptomyces aizunensis*, for example, produced novel and highly defined structures (McAlpine et al, 2005). Demand for access to 'new' natural products is therefore different in approach and character to that of previous cycles of natural products research.

33 Newman et al (2003) suggest the best solution to the current productivity crisis is "…a multidisciplinary approach to drug discovery that involves the generation of truly novel molecular diversity from natural product sources, combined with total and combinatorial synthetic methodologies, and including the manipulation of biosynthetic pathways (so-called combinatorial biosynthesis)." (p 1036).

MICROORGANISMS

While plants, insects, marine and other organisms are still of interest to natural products researchers, the trend over the last 5-10 years is towards microorganisms. Metagenomic technology allows researchers to extract DNA directly from microorganisms found in environmental samples, making available the 99% of microbial diversity previously inaccessible through traditional cultures, while at the same time discovering a far greater number of secondary metabolities in a given organism by 'genome mining' (Handelsman, 2005; McAlpine et al, 2005; see section 2.2 for a discussion of micororganisms). The genomes of micoroganisms can be more easily sequenced than those of plants or insects, and can be grown in culture, rather than collected (eg plants), which makes it easier for companies to deal with supply issues as research progresses (although synthetic chemistry is making it possible to produce most compounds in the laboratory).

MARINE ORGANISMS

The last 10 years have also seen a surge of interest in marine organisms. Marine chemistry is new to natural products chemists, but already approximately 20 marine natural products are in clinical trials, and 34 of the 36 phyla of our planet's biodiversity is found in oceans (only 17 are found on land) (William Fenical, SCRIPPS, pers.comm., 2005). The US National Cancer Institute has reduced its interest in plants and is now focusing its collections on marine organisms. Although plants can still provide invaluable leads for other disease categories, they have not been as promising for anti-cancer agents. Marine organisms live in extremely hostile environments, and in a perpetual state of 'chemical warfare' that produces potent toxins, and a number of novel compounds that work in a way similar to existing anti-cancer agents have been found (David Newman, NCI, pers. comm., 2005).

COMPLEX ASSOCIATIONS BETWEEN ORGANISMS

It is also increasingly recognized that distinctions between organisms—plant, marine, invertebrate, microorganism—are not always clear-cut, and that promising compounds may in fact be produced by symbiotic microbial species (Cragg et al, 2005). For example, in 1972 researchers working with the US National Cancer Institute isolated maytansines from an extract of *Maytenus serrata* collected in Ethiopia, and subsequently found them in other *Maytenus* and *Putterlickia* species. However, recollections of the plants, cell cultures, and greenhouse-grown plants did not yield the active compounds. In recent years, it was found that microorganisms isolated from the rhizophere appear to be responsible for producing the active compounds, perhaps with plants playing a role in determining the final chemical structures (Yu and Floss, 2005). Toxins in birds feathers or secreted by reptiles have been found to originate in insects they eat; promising compounds from insects are traced back to the microorganisms living in their gut; and marine invertebrates have been found to undertake the bulk of the chemistry that produces an interesting compound, which is then modified by associated microorganisms, or vice-versa. Through co-evolution a spectrum of complex community associations, rather than single organisms, appear to be the source of many promising compounds.

DEMAND FOR DIVERSITY

These associations get to the heart of another on-going discussion within natural products research: the need for accessing 'new' biological diversity to fuel discovery. New research tools mean that diversity found in one's 'backyard', particularly that found in the previously inaccessible genomes of microorganisms, and even those of known microorganisms (eg McAlpine et al, 2005), can keep researchers busy. A number of researchers feel that for microorganisms "every species is everywhere" and that there is enough at home, or in a few provider countries, to fuel research for many years to come. But as Jo Handelsman of the University of Wisconsin-Madison put it (pers. comm., 2005): "Until very recently I used to think that 'everything is everywhere', and it is true that going into any backyard is like going to Mars. But even if every species is everywhere, members of the same species will produce different secondary metabolites in different places, and I think it is unlikely that all species are indeed everywhere. Insects, for example, have highly specific associations with microorganisms,

with some microorganisms known only to exist inside one species of insect. No one would argue that insect diversity in the tropics is not unique, so if macrodiversity is unique, it is likely that the associated microdiversity is as well. We really don't know, and it is premature to make those judgements, because we are so far from having a complete census of the microbial world. It is very possible that most microorganism species are everywhere, but that the most interesting strains are not." The same advances in science and technology that currently make many research programs focus on existing collections or materials easily available at home, may very well lead to expanded interest once again in a broader range of biological diversity.

SUPPLY ISSUES

A decade ago, the unknown associations between organisms created issues with re-supply, and researchers at times faced difficulties re-locating individual plants or marine organisms that produced the active compounds. However, today DNA is isolated and expressed in an external host for mass production, so this circumvents that element of the supply issue. The technology is still developing, and all genes cannot be expressed in this way, so there is still some demand for re-supply along a continuum from full synthesis, to semi-synthesis from a precursor taken from the raw material produced in culture, and so on. However, the need for re-supply of material for research and development, and in some cases commercialization, was until recently an important component of the relationship between providers and users, and served as a useful incentive for users to establish solid partnerships with providers. While advances in technologies also make it easier to trace plant, marine and other compounds back to the source, it is much more difficult to do this with microorganisms. The need for providers and users to develop strong partnerships as a way of monitoring development of natural product compounds is far greater today than even a few years ago, and will continue to grow in importance.

DEMAND FOR TRADITIONAL KNOWLEDGE

The role of traditional knowledge in pharmaceutical discovery has been relatively small in recent decades (see Laird and ten Kate, 1999), but appears to be growing smaller. In part this is due to the emphasis of pharmaceutical drug development on disease categories that do not feature prominently in traditional medicine, but it is also due to the increasing role of microorganisms, and the diminished role of plants, in discovery.[34] It is also the case that new research approaches do not easily integrate the type of information available through traditional knowledge, however companies will still consult the literature and databases following a promising lead.

THE CONVENTION ON BIOLOGICAL DIVERSITY

Although scientific and technological developments, and commercial considerations, have resulted in increased interest in microorganisms, and marine organisms, it also appears that the CBD and concerns associated with gaining access and legal title to material, and re-supply of raw material for research, have played a role. We will discuss these issues further in Section 4, but it is important to note that many researchers include difficulties in gaining access to materials as a factor driving research away from the bioprospecting models of the 1980s and 1990s (see Koehn and Carter, 2005; Box 1).

2.2 THE BIOTECHNOLOGY INDUSTRY

Biotechnology is the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods, and services (OECD, 2005). It includes a diverse collection of technologies that manipulate cellular, sub-cellular, or molecular components in living things to make products or discover new knowledge about the molecular and genetic basis of life, or to modify plants, animals, and micro-organisms (US Department of Commerce, 2003).

34 However, many traditional healers collect from very precise locations and make distinctions between individual plants that do not correspond to taxonomic differences. Individual plants found in a particular location, for example, will have properties that are not found in other locations, quite possibly due to microorganism associations.

The biotechnology industry spans a wide range of sectors, and can be broken down into industrial, agricultural, and healthcare biotechnology. Agricultural biotechnology (see section 2.3) comprises 7% of European and 5% of US biotechnology companies (EuropaBio, 2005). Health care biotechnology (see section 2.1) is the largest and most profitable sector, comprising 51% of European and 60% of US biotechnology companies, and accounting for a majority of industry revenues (EuropaBio, 2005). Following a discussion of market trends for all elements of the biotechnology industry, this section focuses on industrial biotechnology, which uses living cells like moulds, yeasts or bacteria, as well as enzymes, to produce goods and services. Industrial biotechnology applications may create more efficient and cost-effective industrial processes that produce less waste, and use less energy and water in such sectors as chemicals, pulp and paper, textiles, food, energy, and metals and minerals (Bio, 2005; EuropaBio, 2005). In some cases, environmental biotechnology products make it possible to clean up hazardous waste more efficiently by harnessing pollution-eating microbes without the use of caustic chemicals. (Bio, 2005).[35]

Market Trends

The global biotechnology industry had revenues of $54.6 billion in 2004, a 17% increase over 2003. The US dominates the industry, accounting for 78% of global public company revenues, followed by Europe at 14%, Canada at 4% and the Asia-Pacific region at 4% (Ernst and Young, 2005). In 2005, the top 12 biotechnology countries, ranked by number of biotechnology companies (private and public), were: the US, Canada, Germany, UK, Australia, France, Sweden, Israel, China and Hong King, Switzerland, India and The Netherlands (Ernst and Young, 2005). The largest companies are primarily found in the US.

Biotechnology firms vary greatly in size and scope, ranging from small, dedicated biotechnology companies that are R&D-intensive to large, diversified companies that have greater in-house resources and well-established production and distribution systems. In a survey undertaken of the US biotechnology industry, 90% of firms had 500 or fewer employees, and only 19 (2%) had more than 15,000 (US Department of Commerce, 2003).

The majority of biotechnology companies operate primarily on venture capital, grants, initial public offerings and collaborative agreements, and the state of this research-intensive industry depends heavily upon the availability of these forms of financing (US Department of Commerce, 2003). Biotechnology companies need external capital to act as a catalyst for growth in early years, fund R&D, and allow them to build on their intellectual property without the need to develop a separate infrastructure to generate revenues to fuel the business (EuropaBio, 2005).[36]

After the collapse of the boom market for biotechnology companies in 2001, the investment cycle entered a 'bust' phase and investors stayed away from the sector. Companies responded by restructuring, spinning off assets, reducing cash burn rates, refocusing their business models to place more emphasis on product development and commercialization and less on technology platforms, and forming alliances with other companies (EuropaBio, 2005; Ernst and Young, 2005).[37] By 2004, a surge of products in the late-stage pipeline and product approvals[38], as well as better-articulated company paths to products and profitability, had drawn

35 Industrial and specialty enzymes produced an estimated $3.6 billion in revenue in 2000 (www.Diversa.org, 2005).

36 A study by EuropaBio found that the biggest barrier to development of the European biotechnology industry was the lack of a suitable financial infrastructure later in the business cycle. While US companies raised $2.4 billion in venture capital in 2004, sold an additional $3.3 billion worth of equity in 2004, and raised a further $3.3 billion in debt in 2004, European companies raised $771 million in venture capital, $1.3 billion through equity, and $820 million in debt financing in the same year (EuropaBio, 2005).

37 Examples of biotechnology/biotechnology deals includes Idec Pharmaceuticals $4.2 billion all-share merger with Biogen, Amgen's $7.8 billion acquisition of Immunex, and the range of acquisitions made by Genzyme Corp in recent years. Pharmaceutical giants such as Novartis, Pfizer and Johnson & Johnson have also acquired biotechnology companies in recent years, but the most common relationship between pharmaceutical and biotechnology companies remains discreet biopartnerships (EuropaBio, 2005).

38 In the US, 365 products were in Phase II clinical trials in December 2004, compared with 290 the previous year, and as of early 2005 there were 55 new drug application submissions under review at the FDA. European companies brought 9 products to market in 2004, compared with 6 in 2003 (Ernst and Young, 2005).

investors back to what is now considered a more mature industry (Ernst and Young, 2005).[39] At the same time, partnerships between biotechnology companies, and between biotechnology and pharmaceutical companies, continue. Biotechnology companies need capital and pharmaceutical companies, concerned about the effect their innovation deficits will have on future earnings, need products (EuropaBio, 2005).

Trends in Research and Development

Biotechnology is one of the most research-intensive industries in the world. In the US, biotechnology-related R&D accounted for roughly 10% of all US industry R&D in 2001 (US Department of Commerce, 2003). New biotechnology research tools have enabled researchers to tease apart cellular and genetic processes, and to understand biological systems at the molecular level. Biotechnology research tools have changed the research questions scientists ask, the problems they tackle, and the methods they use to get answers (Bio, 2005). Biotechnology includes bioprocessing technology, monoclonal antibodies, cell culture, recombinant DNA technology, cloning, protein engineering, biosensors, nanobiotechnology, and microarrays. The need to integrate the pieces of data generated by biotechnology into an understanding of whole systems and organisms has given rise to other new information technologies called the "omics"—genomics, proteomics, metabolomics, immunomics, and transcriptomics. At the same time, new bioinformatics technology uses computational tools provided by the information technology revolution—such as statistical software, graphics simulation, algorithms and database management—to consistently organize, access, process, and integrate data from different sources (Bio, 2005). [40]

These new technologies have changed new product discovery, and identified new uses for existing products, by helping researchers understand the basic biology of the processes they want to control or change, and manage vast quantities of data. They have also made product development quicker and often cheaper. For example, pharmaceutical companies can better identify molecular targets, pinpoint winning compounds far earlier in the discovery process, and use cell culture and microarray technology to test the safety and efficacy of drugs and observe adverse side effects early in the drug development process; agricultural biotechnology companies developing insect-resistant plants can measure the amount of protective protein that a plant cell produces and avoid having to raise the plants to maturity (Bio, 2005). Combined, these technologies are leading to synthesis of living organisms from scratch. Venter (2005) notes how science is moving from "reading the genetic code to writing it", predicting that within 2 years it will be possible to synthesize bacteria, and within 10 years single-cell eukaryotes. Increasingly, technological changes are enabling biological materials to exist in a 'virtual' as well as an actual state (Parry, 1999).

The Role of Genetic Resources in Biotechnology R&D

The ways biotechnology companies use genetic resources vary significantly by sector. Some companies develop specialty enzymes, enhanced genes, or small molecules for use in crop protection and drug development; others develop enzymes that act as biological catalysts in the production of polymers and specialty chemicals, or for use in industrial processing; and others might insert genes that impart desirable traits into crops. The pharmaceutical, crop protection, and seed industries are dealt with in other sections. The remaining biotechnology market is primarily focused on the use of enzymes, which we will review here.

Enzymes are proteins found in every living organism and are the 'tools of nature", ie they cut and paste products and speed up vital biological processes in cells. They have been used for more than 60 years by textile, detergent, food, feed and other industries, to make higher-quality products and make production processes more cost-effective and efficient, and therefore more environmentally-sound by minimizing the use of water,

39 The global biotechnology industry raised $21.2 billion in venture capital in 2004, a 15% increase over the capital raised in 2003, and IPOs raised $2 billion in the US, Europe, and Canada in 2004, compared with $450 million in 2003. Asia-Pacific companies raised about $500 million through Initial Public Offerings in 2004, led by offerings in Australia, Japan, and India (Ernst and Young, 2005).

40 For a full description of these technologies and their applications, see: Guide to Biotechnology, Biotechnology Industry Association, www.bio.org, 2005.

raw materials and energy. Since they are biodegradable, enzymes are also a more environmentally-sound substitute for synthetic chemicals (Novozymes.org, 2005).

Enzymes used by industry are usually found in microorganisms, in particular bacteria and fungi. Microorganisms are the world's most genetically diverse organisms, and include bacteria, archae, fungi, yeasts, and viruses. Through billions of years of natural selection in dissimilar environments, microbes have developed broader and more varied characteristics than those observed in plants or animals, while silently enabling and supporting life for larger plants and animals (Mathur et al, 2004).

Microorganisms called extremophiles are of particular interest to researchers today because they live in environments similar to those required by industrial processes, and reflect the necessary range of conditions—for example, extreme hot or cold temperatures, or acidic or salty conditions. For example, starch and baking require high temperatures and low pH; textiles, pulp and paper, and detergents a high temperature and high pH; and dairy and food a low temperature and low pH (Lange, 2004). As technologies to collect and study extremophiles advance, commercialization of processes and products derived from extremophiles is likely to increase (Arice and Salpin, 2005).

Recent advances in bio- and information technologies allow target compounds from environmental samples to be identified much more rapidly. Microorganisms were traditionally isolated and cultured in laboratories, a process that requires scientists to recreate the environments in which the target microbe lives, and as a result less than 1% of the billion plus microbial species have been studied (Mathur et al, 2004). Today, using metagenomics—the culture-independent analysis of assemblages of uncultured microorganisms—DNA is extracted directly from a soil, water or other environmental sample, it is cut with restriction enzymes, and cloned into a culturable host such as *Escherichia coli* (Handelsman, 2005). The host organism will then produce the biochemicals from which commercially valuable enzymes and other biomolecules are developed. Using computer-assisted techniques such as massive parallelism and randomness, genome sequencing can now occur at a speed previously unheard of. In 1995, for example the first genome sequence was described (for *E. coli*)—a task that then took 15 years and today could be done in less than a day (Venter, 2005).

Demand for Access to Genetic Resources

A striking trend over the past five years has been the vigorous attention given to micro-organisms. The astounding numbers and diversity of microbes, combined with their all-pervasive existence—from thermal vents to the subglacial environments of Antarctica—and advances in technological development, have led to renewed interest in their use for energy saving, climate control, pollution control, biomaterials, and many other applications.

Biotechnology companies continue to demand access to genetic resources, which are either collected from nature or acquired through external collections. Microorganism samples needed for biotechnology research tend to be small—typically a few grams of soil or milliliters of water—and recollection is not usually necessary. The majority of companies and research institutes maintain in-house collections of genetic resources, including microorganisms, plants, insects, human genetic material, animals, fungi, bacteria, and derivatives of these resources such as enzymes, purified compounds, and extracts. Researchers access *ex situ* materials from the collections of companies, universities, national culture collections, and international collections (eg the International Mycological Institute) (ten Kate, 1999).

Most collections made by biotechnology companies outside of pharmaceuticals and agriculture are microorganisms. Insects, plants, animals, marine organisms and others continue to hold interest, although often for their associated microorganisms. Biotechnology companies do not incorporate traditional knowledge into their collecting programs, in part due to their emphasis on microorganisms, but also because their research approaches and technologies do not lend themselves to incorporation of this type of information (Lange, 2004; Mathur, 2004).

When collecting from nature, companies are interested in samples from diverse and extreme environments and ecological niches (eg salt lakes, deserts, caves, hyrothermal vents, cold seeps in the deep seabed), as well as areas with microbial diversity associated with endemic flora (eg epiphytes, endophytes and pathogens) and fauna (eg insects, pathogens and endosymbionts) (Lange, 2004; Arico and Salpin, 2005). The objective of micro-organism collection is *biochemical* diversity, which can be found not only by collecting in areas with high species diversity, but also in extreme environments or unique ecological niches (Lange, 2004). To access regions high in microbial diversity, for example, Diversa, a publicly traded US biotechnology company whose business involves the discovery and evolution of novel genes and genetic pathways from unique environmental sources, has entered into 18 partnerships with groups providing access to genetic resources in 10 countries across six continents, and to all international waters around the world (Diversa, 2005).

The Venter Institute has likewise, through 'Sorcerer II', embarked upon a global expedition to sample microbial abundance and diversity in marine and coastal environments describing, in its initial findings a situation where 85% of data collected is unique to each site. Findings from the Sorcerer II's voyage will be used, among other things, to: design and engineer species to replace petro-chemicals; better understand reef health; analyze drinking water and air quality; track and avoid emerging viruses; and understand the effects of ballast water, where ships flush micro-organisms from one part of the world into the seas of another (Venter, 2005). The related 'Air Genome Project' of the Venter Institute aims to determine the numbers of new protein families from air-borne bacteria. Initiatives such as these throw up a host of new questions and challenges with regard to access and benefit-sharing, in particular relating to the sovereignty of microbes and the difficulties of ascribing ownership.

While initiatives such as these signify an accelerated increase in collecting microbes at a global scale, there are also companies that believe that new scientific and technological developments, coupled with the astounding diversity often found in their own 'backyards' or in existing collections, do not necessitate prospecting overseas.

Recent trends in science and technology have impacted demand for genetic resources from nature in both positive and negative ways. The poor showing of combinatorial chemistry and synthetic compounds over the last decade, limitations to protein engineering, and a realization that natural solutions to the pressures of evolution have come up with things that could not be engineered in the laboratory, have made genetic resources in nature more attractive candidates for discovery. The ability to isolate DNA directly from samples, without resorting to culturing, also means that the vast genetic diversity in microorganisms can be accessed. At the same time, however, new scientific and technological developments mean that more diversity can be generated in the laboratory through molecular biology, shuffling, and protein evolution, and tools like bioinformatics allow researchers to hunt, not in nature, but in existing genome sequences and databases, for novel proteins and enzymes. Bioinformatics and sophisticated molecular biology tools also mean that for each sample collected, a great deal more information is gleaned, and so only a few strains are needed to keep research programs busy in a given year.

Novozymes, the leader in biotechnology-based enzymes and microorganisms, with more than 700 different products, net turnover of DKK 6,024 million in 2004, and 4,000 employees, has long-standing partnerships in Thailand and other countries for sample collection (novozymes.org, 2005; Lange, 2004). Although patents have been filed on interesting developments, no new products have been developed from collections made since the CBD entered into force. The 5-6 new products that come out each year primarily derive from a handful of well-known strains that continue to yield valuable products (Lange, pers. comm., 2005).

Diversa, on the other hand, has developed a number of new products from its collections undertaken with partners overseas. For example, Luminase— which enhances the reactivity of pulp fiber to bleaching chemicals and reduces the need for chlorine dioxide and the cost of pulp processing—was developed from a microbe discovered in a thermal feature in Kamchatka, as part of a research partnership between the company and the Center for Ecological Research and BioResources Development (CERBRD) in Russia. Diversa estimates the

potential market for Luminase at $200 million. Another Diversa product, Cottonase, reduces the use of harsh chemicals, extreme temperatures and large volumes of water in cotton scouring (diversa.com, 2005). [41]

2.3 THE SEED, CROP PROTECTION AND PLANT BIOTECHNOLOGY INDUSTRIES

The seed, crop protection and plant biotechnology industries all use wild genetic resources, although their dependence on these resources varies considerably across and within each sector. The seed sector in general is far more reliant on breeding material from its own private collections or from genebanks than from that collected from the wild, whereas the crop protection sector has a greater interest in wild genetic resources for chemical protection or plant improvement. All however share a focus on the 130 species responsible for feeding humankind and in many cases those crops cultivated on a large scale. This needs to be considered in the context of just nine crops—wheat, rice, maize, barley, sorghum/millet, potato, sweet potato/yam, sugarcane and soybean—accounting for over three quarters of the plant kingdom's contribution to human energy, with wheat, rice and maize providing more than half of this amount (Fowler & Mooney, 1990).

Industry Overview and Market Trends

The use of genetic resources in the breeding and sale of agricultural products involves a diverse group of players, including the private sector, universities and other research institutions, public and private genebanks, farmers and a variety of other organisations. A notable trend since the 1930s has been a shift towards increased involvement of the commercial sector, culminating in the 1990s with the integration of the seed industry into food and agrichemical companies and the formation of the so-called 'life science giants' (ten Kate, 1999).

The seed industry is characterized by three levels of companies: life science giants, large multinational firms, and small and medium-sized enterprises. The first two tiers play a central role in the seed trade, but small and medium-sized seed companies, of which there are several thousand, are also significant and occupy different market niches. For larger companies, the emphasis is on high value seed such as maize, soybean, cotton and canola, and vegetables such as tomatoes, peppers and melons (Smolders, 2005). Smaller companies in contrast focus on vegetables, grasses and more marginal crops. Most of the larger companies also have active interests in agrichemicals and pharmaceuticals.

An intensifying trend over the past decade has been the continued consolidation of the seed, crop protection and plant biotechnology industries, and consequent increase in the available genepool (Bijman, 2001; ten Kate, 1999). Currently, just ten companies control 49% of the global seed market, with an increased trend towards acquisitions and mergers. There is a great deal of overlap between seed and agrichemical companies.

Higher levels of concentration are evident at the level of crop, region or trait. For example, Monsanto alone—through licensing or direct sales—accounted for 88% of total genetically modified (GM) crop area worldwide: 91% of GM soybeans, 97% of GM maize; 64% of GM cotton; and 59% of GM canola (ETC, 2005).

The crop protection industry likewise is concentrated in the hands of only a small number of multinational companies. They pursue a range of approaches to crop protection, including chemical control—which uses chemical compounds to kill pests; biological control—which uses living organisms; and genetic modification of the crop plant itself—which introduces diseases and herbicide resistance into crops through GM and traditional crop breeding techniques. As ten Kate (1999) notes, all three approaches require access to genetic resources.

In 2004, global commercial seed sales were estimated at between $21 billion (ETC, 2005) and $30 billion (International Seed Federation, 2005a). GM seed—predominantly soya, maize, cotton and canola—comprises about 16% of this trade, based on a total trade figure of $30 billion (James, 2004). Major seed companies report

41 Cottonase grew from the companies' collaboration with the National Institute of Biodiversity (InBio) in Costa Rica (Leif Christofferson, pers. comm., 2005).

a gross profit of about 50% or higher and aim to have a mid-term EBITDA (Earnings before Interest, Taxes, Depreciation and Amortization) of 25% on sales or higher.

In the crop protection sector, sales were US$27.7 billion in 2002, representing an overall decline of 12% over five years (Agrow, 2003). Herbicide sales constitute the bulk of sales, accounting for almost 50% of the total crop protection market in 2002, with insecticides comprising 25.3%, fungicides 21.6% and others about 3.4% (CropLife International, 2002). In 2003, genetically modified crops represented 15% of the global crop protection market (James, 2004).

The rapid uptake of GM crops has been one of the most profound industry trends over the past 5-10 years, escalating at a rate that surpasses than of any new technology ever embraced by the agricultural industry. From 1996 (the first year of commercial plantings) to 2004, the global area of GM crops increased more than 47 fold, from 1.7 million hectares in 1996 to 81 million hectares in 2004 (James, 2004). Leading growers of GM crops are dominated in the main by the United States (59% of the global total) and Argentina (20% of the global total). The most commonly planted GM crop is soya, and 55 per cent of the world's soya crop, covering 48.4 million hectares, is now genetically modified (James, 2004). GM maize was planted on 19.3 million hectares worldwide in 2004, an increase of a quarter over the previous year; GM cotton was grown on 9 million hectares; and GM canola occupied 4.3 million hectares.

In 2004, the global market value of genetically modified crops was $4.70 billion, calculated on the basis of the sale price of GM seed plus any technology fees that apply (James, 2004). The value of GM crops since they were first commercialized in 1996, is an estimated $24 billion (James,2004).

Trends in Research and Development

In common with other areas of the life sciences, there have been substantial scientific and technological changes in the seed and crop protection industries over the past 5-10 years, stimulated in the main by advances in genomics, combinatorial chemistry, information technology and DNA technology.

Traits that improve performance and farming efficiency for major crops have comprised a major focus area for large seed companies, with the development of high value commercial lines through advanced marker-assisted selection and breeding techniques (Smolders, 2005). For smaller seed companies, levels of technological investment have in contrast been much lower, with the development of DNA markers, for example, not being pursued for varieties where margins are low (eg grasses) (Noome, Advanta Seeds, pers. comm., 2005).

In the crop protection industry, chemical discovery has been aided significantly through the use of genomics to identify suitable product candidates, and combinatorial chemistry which has increased the number of products subject to biological screening. A key trend has a shift in expenditure from conventional agrichemical research to an expansion of in-house R&D efforts on transgenic crops (Phillips McDougall, 2005). Rising R&D costs in combination with a stagnant market for crop protection products have also led to a continued focus on major crops that are cultivated on a large scale, like cereals, oilseed crops, and cotton (Bijman, 2001)

Agronomic traits such as herbicide resistance—guaranteed to bring high returns when used—have dominated R&D efforts for GM crops, and in 2004 over 70% of all hectares planted to GM crops, including soybean, maize, canola and cotton included this trait. Insect resistance has also comprised a major focus, with 19% of GM crops in 2004 planted to insect resistant crops. An important trend is the continued development and introduction of second generation traits (plant varieties that have one or more output characteristic modified), as well as combined or stacked traits, intended to improve the performance of transgenic crops. Stacked genes for herbicide tolerance and insect resistance, used in both cotton and maize, now account for 9% of all GM crops (James, 2004).

Breeding efforts reflect an emerging division of labour between the public and private sector, with the former largely devoted to open-pollinated crops and the latter tending to work predominantly on hybrid crops (Rangnekar, 2005). However, this is not the case all over the world. For example, in Europe, much breeding work is done by the public sector on cereal seed, whereas almost all work on soybean and cotton is private (Le Buanec, International Seed Federation, pers. comm., 2005). A striking trend has been the escalation of private sector interest in agricultural research and associated decline in public sector research. In the US, for example, private sector spending on crop variety R&D increased 14-fold between 1960 and 1996, with research focused predominantly on marketable input and output traits of corn, soybeans, and cotton (Fernandez-Cornejo & Schimmelpfennig, 2004). In the public sector, this same period saw a change in research focus towards minor crops and public goods such as environmental protection and food safety, areas less attractive to the private sector because of lower profit potential (Fernandez-Cornejo & Schimmelpfennig, 2004).

Although there has been private sector interest in agricultural research for decades, its accelerated development has arisen in part because of the advent of genetic engineering, and also because many of the technologies used can receive patent protection. Companies are therefore able to earn higher returns from their agricultural research than they could from conventional plant breeding. However, IFPRI (2005) and others note that nearly all R&D done by the private sector has been based on crops and traits important to developed-country farmers, with little attention paid to crops important to poor farmers[42].

A growing trend towards increased public-private partnerships aims to address these divergences. One example is a partnership between Syngenta and various universities and public research institutions to develop *GoldenRice*™, a GM crop manipulated to deliver Vitamin A to its consumers (IFPRI, 2005).

Increased attention is also being given to improving old varieties, using the new tools of genomics and modern biotechnology. The improved flavouring of crops such as tomatoes, for example, has received renewed attention, and old varieties with a long history of research and development are now being considered anew.

Despite growth trends in GM crops, many European-based companies have reported a decline in biotechnology research, linked predominantly to consumer resistance and environmental concerns. One opinion voiced is that modern biotechnology may provide an advantage for specific crops with particular problem diseases, but that its application is limited and is often not cost-effective. However, opinions on this matter are widely conflicting.

Technological change and patents have been major drivers of the consolidation of the global seed and crop protection industries and, through achieving vertical and horizontal integration, companies have been enabled to consolidate research efforts and enhance control of distribution channels and agricultural inputs (CIPR, 2002; Rangnekar, 2005). In the 1980s, for example, the university and public sector accounted for 50% of US patents relating to genes encoding various forms of insect toxins from the bacteria *Bacillus thuringuensis* ("Bt"), now used widely in GM crops to confer insect resistance. By 1994, 77% of patents in this area were held by small biotechnology start-up companies. By 2004, consolidation in this sector and acquisition of small biotechnology start-ups, resulted in over 65% of patents relating to the insect-resistant trait incorporated into GM crops being held by the top five biotechnology companies (Rangnekar, 2005).

Some analysts suggest that due to reduced threats of competition, increased consolidation and increases in market concentration have reduced the incentives to invest in research, and have led to surviving firms devoting fewer resources to innovation. Others note that seed companies are increasingly doing less or no basic research and that exotic germplasm and landraces are perceived as having little practical value for a seed company, with their introgression into breeding lines being time-consuming and risky (Smolders, 2005). Currently R&D investments in leading seed companies stand at about 10 (+/- 2)% on sales, compared to 23.2% recorded in the "euphoric" period for biotechnology in 1988/89 (Smolders, 2005). R&D investment

42 An alternative viewpoint is that crops such as soybean, maize and cotton and traits such as herbicide and insect resistance are not exclusively tailored towards developed countries (Le Buanec, International Seed Federation, pers. comm., 2005).

varies by crop and is typically higher for fruity vegetables and substantially lower for open-pollinated small grains, peas and beans.

Budget allocations for the exploration of wild genetic resources vary considerably depending on the crop. Sugar beet, for example, requires no wild collection whereas vegetables may have an allocation as high as 10%, especially for crops where traits such as insect resistance are paramount. Typically, about 1-3 % of the total research budget is applied to exploratory breeding, equalling about 0.1-0.3% of the overall turnover of the company.

Investments in new product discovery are substantially higher for the crop protection industry. A recent survey of R&D in ten leading crop protection companies indicates an overall R&D expenditure of $2250 million, equivalent to 7.5% of sales for these companies in 2004 (Phillips McDougall, 2005). About 54%—or 4% of sales—of the total industry R&D budget is devoted to the process of new product discovery and development, most of this due to expenditures in chemistry- and biology-based research programmes, with the discovery process alone accounting for 31% of the R&D budget. A growing trend is towards greater expenditures in environmental risk assessment and human health risk assessment, driven predominantly by consumer concerns and regulatory requirements (Short, 2005). However, several companies have only limited new product discovery programmes, and use methods such as product acquisition and licensing, joint ventures and generic product manufacture to enhance their product portfolios.

Demand for Access to Genetic Resources

Although a prevalent trend within the seed industry, and particularly for commodity crops, seems to be reduced dependence on wild genetic resources, this varies considerably depending on the size and nature of the company, and the type of resources under investigation. High levels of interest in wild genetic resources are still evident for example where new inputs are needed on quality, to meet consumer demands, and to reduce vulnerability to pests and diseases. Demand for wild genetic resources for vegetables and flowers (and for plant genetic resources not covered by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture) is also greater than for commodity crops.

A central question is the extent to which the industry is dependent upon diversity. Crop varieties and animal breeds, for example, are often selected for domestication characteristics, which are typically contrary to those characteristics that enable their survival in the wild. Much of this diversity is now conserved *ex situ* in gene banks or breeders' materials although coverage of 'minor' crops such as root crops, fruits and vegetables remains incomplete (Rubenstein *et al*, 2005). As Stannard (2005) notes, in wild resources most value lies at the species level.but for agricultural resources, the value lies *within* crop and animal species, and in the complexity of their genepools that have been built up by farmers over thousands of years.

Several seed industry representatives have commented on the fact that DNA technology, genomics and other technologies have given greater insight as to what is available, leading to the in-depth use of genetic resources already existing in breeding programmes and genebanks, rather than requiring new collection: "We are looking at old material with new eyes; existing material has aspects that were not recognised before". However, as Rubenstein et al (2005) remark, agricultural production increasingly relies on 'temporal diversity', requiring varieties to be changed more frequently to maintain resistance to pests and diseases.

The crop protection industry in contrast has increasing interest in wild genetic resources to improve the plant or to produce chemical protection. This increased interest in natural compounds is predominantly driven by environmental concerns and consumer demand for reduced use of chemicals. "Because of the consequences of chemical use, we are looking at new options and ways to improve the product itself", commented a representative from a multinational crop protection industry.

A crucial factor determining the demand for genetic resources in the seed and crop protection industries is the effort required to turn them into usable resources. Genetic resources that widen a company's genepool but without identified properties of interest are typically considered to have little commercial value as they require considerable investment, and the return on the investment is often risky (Smolders, 2005). Although new technology can assist in the search for a specific trait, the expense of doing so is generally prohibitive for smaller companies.

Because of these factors, several industry commentators suggest there to be little pricing advantage for having genetic variability. Therefore diversity is not considered to add value. "The market is not asking for diversity to be made available to the farmer", stated one representative of a major seed company. Moreover, much material, including pre-bred material, is available free from the public sector, and payment if any for exotic and unadapted material, and even pre-bred materials, will normally not exceed a nominal fee, such as US$5-20 (Smolders, 2005). However, the value of material increases with characterisation and evaluation, if there is an indication of a trait or characteristic of potential commercialisation. Upfront payments in these circumstances may vary from US$5,000-50,000 (Smolders, 2005).

Although breeders royalties typically fall in the 5-10% range these vary considerably from case to case although are ultimately market-determined. The value of a trait will also vary depending upon whether the trait originates from plant genetic resources or from another source such as bacteria. Across the board, however, there would appear to be little data available regarding the local use and potential future values of genetic resources, and in the absence of this data, an assumption from genetic resource providers that the genes, gene sequences, and related material have maximum potential value.

2.4 THE HORTICULTURAL INDUSTRY[43]

Industry Overview and Market Trends

All plants used in ornamental horticulture, and the diversity of cultivars derived through selection and breeding, originally came from wild plants, with first records of their use for ornament from the Xia dynasty in China in 2100BC (Heywood, 2003). However, like the seed sector, the modern-day horticultural industry has relatively low reliance on wild genetic resources, and many of the genetic resources it uses have been developed over decades and exist within industry collections. Presently, about 100-200 species are used intensively in commercial floriculture (eg carnations, chrysanthemums, gerbera, narcissus, orchids, tulips, lilies, roses, pansies etc) and up to 500 species as house plants, and these represent the mainstay of the industry. Several thousand species of herbs, shrubs and trees are also traded commercially by nurseries and garden centres as ornamentals, many introduced from the wild with little selection or breeding (Heywood, 2003).

Overall, ornamental horticulture is growing both in size and worth, and the sector is characterised by high levels of competition, dynamism and entrepreneurship (Hall, 2004). Statistics reported to the United Nations[44] from more than 100 countries show the world import trade value in horticulture (live trees, plants, bulbs, roots, cut flowers and foliage) in 2004 was US$12,425 million—an increase of 28% since 2001. Of this amount:

- US$5,417 million (43,6%) was attributed to fresh cut flowers,
- US$5,128 million (41,3%) to live plants,
- US$1,056 million (8,5%) to bulbs, tubers and corms; and

43 The definition of 'horticulture' is notoriously ambiguous, embracing the large-scale commercial production of vegetables and fruit through to cut flowers and ornamental plants. For the purposes of this section, the focus is on herbaceous ornamental horticulture.

44 Note that market data for horticulture is not definitive due *inter alia* to the differing definitions that are used, the fluidity of trade between importing and exporting countries, their frequent exclusion of developing country statistics, and the difficulties of distinguishing between different products (ten Kate, 1999).

- US$880 million (7%) to fresh cut foliage (UN Comtrade, 2005).

A variety of different sized companies are engaged in breeding ornamental plant varieties. Ten Kate (1999) describes three main categories: (a) a small group of multinationals accounting for the majority of sales worldwide; (b) a larger group of mainly national companies; and (c) hundreds of small and medium-sized enterprises.

About 55% of the import value of the live plant trade is accounted for by five countries: Germany (20%), France (11%), the United Kingdom (8,8%) United States (8,5%), and the Netherlands (6,5%). The export trade of live plants is dominated by the Netherlands (41%), with Denmark, Belgium, Italy and Germany comprising 32% of exports, and other countries the balance of 27%.

Current growth trends are expected to persist, and these are pitched closely to projected income earnings of consumers in the North (European Commission, 2003). Heywood (2003) notes two antagonistic trends with regard to the products offered by ornamental horticulture. On the one hand, the streamlining of operations by commercial nurseries is leading to simplification and a reduction in the number of cultivars grown and offered for sale. On the other hand, market saturation by traditional materials is leading to increasing interest in cultivars or new introductions from the wild, and greater interest among countries in their native flora as a source of such introductions. This has clear implications both for industries wishing to access these genetic materials, and for countries of origin wishing to derive benefits from their use.

Trends in Research and Development

Technological developments over the past decade have impacted the horticultural industry significantly. The advent of tissue culture biotechnology and plug production has provided growers with uniform, consistent plantlets or cuttings that may offer disease resistance; slow-release and soluble fertilisation and irrigation technology has improved production; and automation technology and climate control systems have increased the efficiency of many commercial nurseries and greenhouses (Hall, 2004). The adoption of information technology has also led to fundamental changes in business practices. Some examples include the capability to improve supply chain management through 'just-in-time' delivery; the ability to develop targeted relationships with customers through practices such as Efficient Consumer Response; improved business-to-business ('B2B') collaborations through the Internet; and increased on-line transactions (Hall, 2004). An important trend appears to be greater institutional collaboration, and the initiation of long-term partnerships, rather than reliance on more ad hoc approaches to collaboration such as student internships (Kopse, Syngenta International, pers. comm., 2005).

Despite these technological advances, the fundamentals of horticultural science remain paramount: "Much of what we do today hasn't changed since Mendel", remarked one Chief Executive of a major horticulture company, referring to the industry's continued reliance on traditional breeding, yet acknowledging that major advancements had been made through enhanced ability to do broad crosses. Improved understanding of plants and their genetics is a major factor that has affected horticultural developments, enabling old cultivars and varieties to be looked at with new eyes. Commented one industry representative: " … we understand plants much better now and can discern specific traits more easily. Faster breeding is now possible and is more focused—even without using genetic modification".

Indeed, it would seem that there has not been a wholehearted adoption of genetic modification in ornamental horticulture, one respondent commenting that there is no need and that costs are out of proportion to the benefits gained, more especially in light of societal concerns: "We don't need Petunias or other flowers that are Round Up Ready". In contrast, other horticultural companies are focusing solely on genetic modification. Florigene, for example, an Australian-founded company which in 2003 became part of the Suntory group, does research exclusively on colour modification of important flower species using genes of the anthocyanin

biosynthesis pathway. In 1997 this company marketed the first blue carnations, and in 2004 announced the world's first biotechnology-driven 'blue rose' (Florigene, 2005).

Demand for Access to Genetic Resources

For the bulk of plants traded, the ornamental horticultural industry has a low dependence on wild genetic resources, and is instead reliant on the creative use of existing germplasm, much of which already exists in collections. One example is the introduction of a new Begonia cultivar ('dragon fly'), which has been in collections for decades but is now being put together in new ways (Corr, Ball Horticulture, pers. comm., 2005). However, as ten Kate (1999) notes, while the search for new materials is immaterial to some companies, for others especially those wishing to enter the market with new species, it comprises an important component of their work. For some smaller companies—particularly those who sell material on to firms for use in breeding programmes—the hunt for new material comprises the main focus of their work. And for some companies involved in breeding, the reliance on wild germplasm—and the associated variations of colour and other character traits—is paramount, because clonal germplasm from nurseries and collections has little of these critical variations. New germplasm is thus highly desired and much sought after by these companies.

There is also increased interest in new introductions and native plants, with a major advantage of wild genetic resources being their novelty. Where wild material is collected, however, it is seldom 'plucked' out of the wild and introduced but rather is accompanied by a long process of research and development—more especially where new products are involved. The time and cost of this process vary considerably—from a breeding programme that may use highly sophisticated technologies and cost several million dollars, through to the introduction of ornamentals that require little selection or breeding (ten Kate, 1999). Overall, however, it would seem that most of the larger companies allocate relatively low proportions (less than 10%) of their research budgets to investigating wild genetic resources.

It is envisaged that interest in wild genetic resources will peak once the market is saturated with existing material. There is thus a crucial need by the industry to ensure continued long-term access to wild germplasm. In some cases this is being done through benefit-sharing agreements with countries of origin (eg Ball Horticulture and the South African National Biodiversity Institute—see below). In other cases, collaborations have been struck between horticultural companies and those specialising in wild plant collections. And in other instances the illicit collection of material seems to be the norm.

Low reliance of the industry on wild material, combined with the difficulties of 'proving' the origin of germplasm[45], has led to the sector, with some exceptions, still having low levels of awareness about the CBD and its ABS requirements. Indeed, it appears that in many cases germplasm acquisition via the 'cowboy approach' is still prevalent with many plant collectors working outside of government approval systems to supply nurseries and horticultural firms. Commentators have mentioned the ease with which the horticultural industry can 'hide its tracks' with regard to the origin of these resources, especially in cases where freshly collected germplasm is incorporated into existing genetic resources. This is a key difference between the horticultural and, for example, the pharmaceutical industry.

3. TRENDS IN BENEFIT-SHARING AND PARTNERSHIPS

BENEFIT-SHARING AS STANDARD PRACTICE IN INDUSTRY

Benefit sharing varies by sector, but since adoption of the CBD standards for best practice in benefit-sharing have become widely accepted. This is a significant and positive achievement of the CBD and ABS policy dialogue. Although unscrupulous and ill-informed companies continue to by-pass these standards, the larger or

45 Wolfson (South African National Botanical Institute, pers. comm., 2005) notes the possibility of exploring the potential of the 'Barcode of Life' project to deal with this issue, through a DNA-based system of species identification.

more socially responsible companies today would not consider genetic resources freely available, or the 'common heritage of mankind'. The package of benefits typically includes a mix of monetary benefits like fees per sample, milestone payments, royalties on net sales, and licensing agreements, as well as non-monetary benefits like training, capacity-building, research exchanges, supply of equipment, technology transfer[46], and joint publications[47]. Groups with the most experience in benefit-sharing generally emphasize the importance of non-monetary benefits and 'front-loading' benefit-sharing packages. 'Front-loading' benefit-sharing packages ensures that provider countries receive a stream of benefits through the discovery and development phases, given the small odds of any one partnership yielding a commercial product and the fact that all products will not necessarily be billion-dollar 'blockbusters', generating large royalties, or that in most industries products rarely, if ever, achieve this status[48].

Concerns continue to be raised about the quality of prior informed consent and benefit-sharing arrangements in particular cases, and there are many companies and indeed some sectors (eg cosmetic, fragrance, botanical, horticulture) that have not fully grasped the new legal and ethical obligations that arise from the Convention on Biological Diversity. In general, however, companies now see benefit-sharing as a necessary business practice associated with accessing genetic resources. For example, the European biotechnology firm Novozymes has developed a partnership with BIOTEC, Bangkok. BIOTEC collects, isolates, identifies and screens samples, with Novozymes sponsoring the research and providing training at BIOTEC, while transferring enzyme technologies and libraries, bioinformatics, providing training, and royalties if products are commercialized (Lange, 2004). A three year access and benefit sharing partnership between Syngenta and the Hubei Biopesticide Engineering Research Centre in China aims to discover natural chemicals that can be used as starting points for the development of novel crop protection agents. Under the terms of this agreement, HBERC will collect micro-organisms from natural habitats in China, screen them for interesting biological activity and produce information on their chemical properties. Syngenta will provide technological and financial support and will pay HBERC royalties on any products derived from the research (Syngenta, 2005).

Horticulture is a sector characterized by ignorance of the CBD, but even here new access and benefit-sharing agreements have been developed. A Research and Licensing Agreement between the Chicago-based Ball Horticulture and the South African-based National Botanical Institute (now the South African National Biodiversity Institute), was entered into in 1999. The five-year agreement, which is the first North-South bioprospecting agreement in the horti- and flori-culture sector, involved the NBI using its expertise to select South African plants of horticultural interest for Ball, both from its living collections and from the wild. Thus far three varieties have been introduced, based on South African species, although royalties, despite being substantial, have yet to surpass costs of the project (Brian Corr, Ball Horticulture, pers. comm., 2005). While the agreement has raised concerns about the adequacy of benefits and the role of public institutions (Wynberg, 2003), the process of negotiation and revision in response to public concerns has helped to refine expectations and stimulate discussion about standards for benefit-sharing within South Africa, which will eventually be incorporated in a re-negotiated contract between the parties.

BENEFIT-SHARING IN SECTORS THAT CONSUME LARGE QUANTITIES OF RAW MATERIAL

An important trend observed is that many companies in sectors reliant on bulk trading of raw material (rather than genetic resources) are becoming more socially and environmentally responsible and are considering benefit-sharing measures. The nature of benefits reflects the different research and business practices of particular industries. For example, in ornamental horticulture a vast amount of material is already in the public

46 The International Seed Federation (ISF), for example, reports that technology transfer as it relates to the maintenance of plant genetic resources for food and agriculture is common practice, with more than 40% of ISF members granting licenses free of charge to developing countries and some members also participating in programmes for technology transfer (International Seed Federation, 2005b).

47 As part of their roughly 125 agreements since 1993, the ICBGS have provided formal training for 2,800 individuals from 12 countries, with 90% of these from developing countries. Associated with training and research efforts, a substantial amount of equipment and infrastructure enhancement for both US and developing country institutions is carried out, and capacity-building to undertake research. Other benefits address the direct needs of collaborating communities, and include water tanks, fencing for gardens, shade cloth, boats, and refrigerators (Rosenthal and Katz, 2004).

48 As noted in Section 2.1, even within the pharmaceutical industry, companies are moving away from the 'blockbuster' model to smaller niche markets with still significant sales (Lewis et al, 2005).

domain, but many developing countries do not have the funds to develop cultivars for IPR registration, the primary mechanism for benefit-sharing (Coetzee, 2002). An alternative approach proposed for generating benefits for local communities and rural producers is to promote fair trade certified horticultural products[49]. Socially–responsible personal care and cosmetic, and botanical companies, similarly emphasize a range of benefits associated with raw material sourcing following product development. Aveda, for example, seeks to develop sourcing partnerships with local groups that include long term agreements and fair prices, as well as contributions to community development funds, bringing in certifiers to broaden the market appeal of the products, and helping communities link with other buyers (Waddington and Laird, 1999; David Hircock, Aveda, pers. comm., 2005). But it takes a great deal of time and money to do this, including staff dedicated to following and monitoring these activities, so most companies do not invest in these activities.

Increasingly, non-governmental organizations are adopting the role of intermediary or facilitator in these deals. PhytoTrade Africa, for example, is a non-profit organization that links rural producers, industry and consumers, developing new products for the personal care and cosmetic, botanicals and other industries. PhytoTrade works to ensure that benefits result from the discovery and development of new commercial ingredients and products (see www.phytotradeafrica.com) through innovative applications of intellectual property and trust funds. However, they consider the most significant benefits for rural producers to be those associated with improving livelihoods through long-term sourcing partnerships for raw materials (Aldivia and Phytotrade, 2005; Cyril Lombard, 2004).

QUESTIONS REMAIN ABOUT WHO SHOULD BENEFIT

Difficulties remain about who should benefit, with many in industry feeling that scientific research institutions and partners, rather than governments, should receive the lion's share of benefits, as a way to build local capacity in this area.[50] Many acknowledge that indigenous peoples and local communities should clearly benefit from the use of their traditional knowledge, but this has presented challenges in a number of sectors, depending upon: how knowledge is accessed (eg field collections, literature, databases, botanic gardens, genebanks); how 'communities' are defined and represented, and knowledge is 'owned'; and levels of awareness within industry of their obligations to seek prior informed consent and share benefits with communities (eg numerous botanical and personal care and cosmetic products are developed without appropriate agreements with communities, and little or no return of benefits).

A case that reflects many of these difficulties concerns the development of the succulent plant *Hoodia* by Phytopharm and Unilever as an anti-obesity product. The plant has a long history of use by indigenous San communities in southern Africa and this, catalyzed by public pressure, led to their eventual inclusion in a benefit-sharing agreement with the South African-based patent holder, the Council for Scientific and Industrial Research. Initial reluctance to engage the San as partners was due to concern that expectations would be raised, that the genuine holders of traditional knowledge about *Hoodia* could not be identified, and that this would be challenged by other groups holding this knowledge. Ultimately, however, it was agreed by the San that a nit-picking exercise to link benefit-sharing to specific communities using *Hoodia* was divisive, and that benefits must be shared equally amongst all San peoples. Moreover, the agreement sets out mechanisms to resolve any 'third party' claims that may arise (Wynberg, 2004). The initiative has demonstrated the importance of moving forward, even in the absence of full certainty, and 'learning from doing' rather than waiting for complete resolution of often intractable issues.

49 For example, Fair Trade certified cut flowers were launched in 2001, and are now sold widely in European supermarkets. Fair trade roses have since gained a market share of 8% of imported roses (Jorgensen, 2004; Lawrence, 2005).

50 The seed industry presents particular problems with benefit-sharing because of the cumulative nature of plant breeding, because the entire chain of development leading to the final product may not take place within one company, and because intermediate products themselves are sometimes marketed (Stannard, 2005). As Stannard (2005) observes, this raises questions as to where the values are captured, and how the benefits are shared: on the first commercial product, on all marketed products throughout the development cycle, or only when a final product enters the market?

LACK OF RESOLUTION ON APPROPRIATE MONETARY BENEFITS

While responsible users of genetic resources understand that providers must benefit, the scale of those benefits remains unresolved in some cases. Non-monetary benefits are not generally a source of much controversy or confusion, although some provider countries appear to undervalue the importance of this type of benefit for their scientific and technological institutions and domestic industry. There remains much concern on the part of both providers and users, however, about appropriate monetary benefits, in particular up front payments and royalties. For the most part, companies are loathe to provide significant advance benefits unless they are attached to an agreed-upon workplan. Fees for samples and milestone payments, attached to progress in the research collaboration and a product's development, are familiar components of most industry R&D programs. Royalties are also standard practice, and the vast majority of companies agree that should a product be commercialized, provider countries should receive financial benefits, but the scale and nature of these benefits is often in dispute.

The greatest controversy remains the appropriate range for royalty rates. At the heart of this debate are different concepts of the value of genetic resources to commercial product discovery and development. A regular feature in current industry commentary on the CBD and ABS measures is the need to match expectations of value with commercial realities, and to appropriately value genetic resources in negotiations with companies. Lange (2004) refers to this as a 'mismatch of expectations' which she says grows from provider country inexperience with industry, and a lack of awareness on the part of national focal points and negotiators about the higher risks and costs involved in development, compared with discovery. In the absence of information on possible commercial values for genetic resources, providers make the assumption that genetic and biochemical resources have significant value for companies (See further discussion of this point in Sections 3.and 4.4).

Companies feel that the different research and development approaches and profit margins of industries, and existing practices in paying royalties for samples or leads, must inform the negotiation of royalties for genetic resources. The relative contribution of the partners to discovery and development, the information provided with samples, the degree of derivation of the final product from the original sample, and the novelty or rarity of samples all affect where in an established industry range a royalty rate will fall. [51]

In addition, provider countries should consider the time and cost it takes to develop a product; the volumes sold and average profit; and the likelihood that a product will be developed from a given collaboration. For example, industrial enzymes have a much lower profit margin than pharmaceuticals, and generally a lower royalty range (0.5–2% compared with 3-5%), but they cost between $2–20 million to develop compared with around $1 billion, and can yield commercial products in half or less the time (3-5 years compared with 10-15 years, with markets of $200 million compared with possibly $1 billion) (ten Kate, 1999; Laird and ten Kate, 1999; Ernst and Young, 2005).

A debate also exists about when royalty negotiations should take place. Cragg et al (in press) propose a two phase process of agreements between providers and users based on their experience with drug discovery and development at the US National Cancer Institute. The first stage is a research agreement that covers the discovery phase, and the second a commercial agreement that includes benefits related to drug development and royalties, triggered by a patent or selection of an agent for Phase II development. They feel that negotiation of these latter types of benefits are better left to the second stage, once a promising drug candidate has been identified and fully characterized, the breadth of any intellectual property determination is made, the disease category with known markets is clear, and resulting appropriate levels of benefit-sharing can more reasonably be discussed. It is not common practice within industry to lock down these terms in the earliest stages of a research collaboration, and they feel that requiring this serves to dampen demand for access. However, in industries where the likelihood of commercial product development is high, such as horticulture, it is common practice to merge discovery and commercial agreements, and in such cases royalties may be specified.[52]

51 See ten Kate and Laird (1999) for a review of the factors influencing royalties for genetic resources.

52 For example, see the Ball-NBI agreement in South Africa.

The stakes for coming to agreement on the ways genetic resources are valued as part of commercial product discovery and development are quite high. A significant number of companies in the pharmaceutical, biotechnology, seed and other industries voiced the opinion that if provider countries set the bar too high, for example demanding royalties well outside of what is considered standard commercial practice, companies will withdraw from collection and research partnerships. Even if higher than normal royalties are agreed upon, some in industry feel that products with these conditions attached would fare poorly within the company and would not be developed. Products derived from genetic resources must compete with those originating from other research programs for development support, and they may look less financially promising if attached to large financial obligations.

THE IMPORTANCE OF PARTNERSHIPS

Many companies seek the benefits of better-developed and longer-term partnerships with source country institutions. Partnerships allow companies to access local expertise and resources in areas of interest, and in some cases companies build research capacity to undertake a greater share of discovery, more affordably, in provider countries. Partnerships also provide more insurance to companies that the resources they access are legally obtained. Because these more involved partnerships require a large investment of time and resources, however, companies tend to work in fewer countries than in earlier years, a trend further encouraged by developments associated with the CBD and ABS measures (see Section 3). The US biotechnology company Diversa has developed criteria by which it selects partners that include: the legal framework and political will within a country to support research and commercial activities; the scientific and institutional strength of potential partners; and the presence of unique and protected habitats (Mathur et al, 2004).

Partnerships also enhance the benefits accruing to provider countries and their institutions, particularly those that build the scientific and technological capacity of countries to undertake research on their own biological diversity[53]. Because provider country scientists play a larger role in discovery when part of partnerships, it also means that financial benefits derived from any commercial product will be more significant. Better-established partnerships also help provider countries monitor the ways samples are collected and used. This is of increasing importance as microorganisms come to dominate many natural products research programs, re-collection of samples becomes unnecessary with expression of DNA in the laboratory, and improvements in synthetic chemistry make it possible to create almost any compound in the laboratory (Koehn and Carter, 2005; Bull, 2004). As one US academic researcher that has brokered access and benefit sharing agreements in a number of countries put it: "This highlights again the value and importance of partnerships—for the benefit of everybody. People need to develop relationships so that they are comfortable working with each other. This kind of research is a difficult thing to regulate, and is becoming more so. Trust is a huge issue, and paramount to the process working. It is not enough to get a permit from a government agency that doesn't really know what the research is about—it is much better for all involved to also have full partnerships."

4. INDUSTRY AND THE CONVENTION ON BIOLOGICAL DIVERSITY

Industry and researcher perceptions of the Convention on Biological Diversity, and ABS in particular, have become increasingly negative in the last decade. Some continue to cite the positive role the CBD can play in promoting equitable relationships, conservation and best practices in industry, but many more consider the negative impacts to far outweigh the positive. In 1999, ten Kate and Laird reported that over the course of the previous two years of their study many of the companies they interviewed had come to believe that implementation of the CBD had gone badly wrong. They cited lack of clarity in the regulatory framework; bureaucracy and delays in receiving permits; lack of understanding of business; confusion about national focal points; unrealistic expectations and transaction costs; restriction of scientific traditions of collaboration and exchange; and the pressures these new regulatory frameworks place on already taxed natural product

53 For example, Diversa's 18 partners have received more than $2 million in financial payments and $2 million in third-party grants to support research collaborations. Diversa has also supplied a range of non-monetary benefits, including training more than 100 scientists and students, and providing equipment and infrastructure improvements (Mathur et al, 2004).

research programs (ten Kate and Laird, 1999, p296). These concerns continue today, but are also increasingly accompanied by an underlying unease with what are characterized as "dangerous" and "political" minefields of fickle regulatory processes, and an absence of goodwill.

INCREASED MISTRUST AND THE ABSENCE OF GOODWILL

From its inception, the CBD brought together a complex mix of scientific, conservation, trade, and legal elements that fit uneasily into a regulatory whole. ABS regulations exist at the juncture of many inter-lacing bodies of law, which "criss-cross" the same biological material, including international agreements on trade, environment, biological diversity, agriculture, IPR, and so on (Thornstrom, 2005). The ethical, legal and political implications of new biotechnologies, commercialization and ownership of life forms, patenting of gene sequences, the Human Genome Project, and broader concerns about globalization and corporate behavior, have found expression in the ABS policy process (Parry, 2004; Rosenthal and Katz, 2004; Dutfield, 2002; Laird, 2002). These are critical issues to debate and resolve as part of international and national policy processes, but their effect on ABS policy has been divisive and has drained it of the goodwill necessary to come to agreement. Rather than coming together over the last 13 years to create simple, workable legal and regulatory frameworks for access and benefit-sharing, providers and users of genetic resources are increasingly estranged. [54]

The commercial activities upon which ABS is predicated are not sufficient in scope or scale to adequately support, or allow practical prescriptions, for a policy process that incorporates so many pressing but diverse ethical, political and legal issues[55]. The result is that ABS is all but stalled in practice, with only a small minority of governments enacting regulations that meet their obligations under the CBD, and companies being increasingly loathe to access genetic resources, or undertake research partnerships, in more than a handful of 'safe' countries that have strong institutions and relatively clear approaches to ABS. Industry involvement in the CBD has been erratic, in some cases becoming much stronger—as, for example, in the development of ABS guidelines by the biotechnology industry[56]—whilst in other sectors interest has waned. In general, however, involvement of industry and academic researchers in the ABS policy process has declined in recent years.

CHARGES OF BIOPIRACY AND 'IMAGE PROBLEMS'

As a result of an environment characterized by misunderstanding and mistrust, in recent years researchers and companies have become increasingly concerned about negative attacks and bad press associated with accessing genetic resources. In addition to the practical hurdles of gaining access, companies and researchers now consider the threat of 'biopiracy' charges a serious impediment to research (this concern did not feature prominently in the study undertaken by ten Kate and Laird (1999) in the late 1990s). One problem regularly cited is the broad definition of 'biopiracy'. Whereas its initial meaning focused on the patenting of genetic resources based on traditional knowledge without the consent of the knowledge holders, today it is popularly used to describe any commercial activity associated with genetic resources.

In a study of German companies using genetic resources, it was found that 'image' problems associated with accessing genetic resources were a major concern for companies from a range of sectors, and influenced their decision-making about whether and how to undertake collections (Holm-Muller et al, 2005). An academic researcher in the US said that both academic researchers and companies today are reluctant to access genetic resources overseas for fear of "…becoming part of a very dangerous socio-political environment in which anyone can claim they are biopirates at any time, and slander them without any legal recourse." An executive at a cosmetics and personal care company in the US similarly characterized research on 'new' ingredients or products as "very dangerous", and in the on-going absence of solid laws they currently avoid this research.

54 As Rosenthal and Katz (2004) put it: "… suspicion, resentment, and misunderstanding, fueled by colonial history and the politics of trade and intellectual property rights, have frequently brought discussion of the issues to a stand-off in both multi-lateral and project-specific fora … In the policy vacuum that characterizes the current ABS situation in most countries, it is easy for anxiety and suspicion to proliferate."

55 Finston (2005) describes a rush to "solutions" within the ABS policy process, without having adequately defined the "problem".

56 In June 2005 BIO, the world's largest biotechnology industry association issued *Guidelines for Bioprospecting* for its members (www.bio.org/ip/international/200507guide.asp)

The rise in concerns about biopiracy is occurring at the same time most in industry have come to accept the need to negotiate access and benefit-sharing agreements. As one biotechnology company executive put it: " The agreements are not onerous; they [companies] can afford royalties. Furthermore, the parties to the CBD can seek some form of reprisal with any firm they feel has gathered samples without permission… I can't imagine any reasonably sized company trying to build a business on hidden material."

Leif Christofferson of Diversa notes that attacks on companies for 'biopiracy' almost always focus on the companies that are most transparent, which has the effect of encouraging greater secrecy on the part of industry. He cites the case of Diversa in Yellowstone National Park in the US, because in this case both the Park and the company felt that their agreement was a 'win-win' and presented it to the public with the expectation that others would share their views. The firestorm that erupted and put their collaboration on hold for many years has served as a warning to other companies, he says.

Rosenthal and Katz (2004), reporting on the work of the ICBGs, note: "Sometimes, regardless of how thoughtfully, transparently, or collaboratively a collection-based project and its approach to ABS are formulated, the political context in which it operates may ultimately make certain partnerships controversial. This is particularly the case when working with indigenous peoples."

Sometimes, however, charges of biopiracy have been necessary stimulants towards attaining equitable agreements and persuading reluctant parties to negotiate. For example, public outrage was expressed about the filing by the South African-based Council for Scientific and Industrial Research of a patent for active constituents of *Hoodia* spp. responsible for suppressing appetite. The indigenous San had long used the plant for these purposes yet did not give consent to the use of their knowledge and were not acknowledged by the inventors. International media coverage forced a turn-about of the situation, and the development of an agreement and partnership of mutual benefit to the CSIR and the San (South African San Council and CSIR, 2003; Wynberg, 2004).

In some cases, claims of biopiracy also have positive commercial spin-offs. For example, an agreement between Chicago-based Ball Horticulture and the South Africa-based National Botanical Institute was the subject of much publicity and controversy (Wynberg, 2003). However, greater profile for the agreement is believed to have led to an improved image for Ball and increased interest from other provider countries in partnerships (Brian Corr, Ball Horticulture, pers. comm., 2005).

LACK OF AWARENESS OF THE CBD AND NEW ETHICAL AND LEGAL OBLIGATIONS

Other companies, however, appear to be unaware of the complexities of their obligations under the CBD, and attract attention because of deficiencies in their agreements, or the information made available to the public, rather than as a result of efforts at transparency. For example, the Netherlands and US biotechnology company, Genencor International, have been in discussions with the Kenyan government about claims that it developed enzymes from samples collected in the 1990s from alkaline lakes, which were subsequently licensed to Proctor and Gamble and used in Tide laundry detergent (Mbaria, 2004). This case was brought to public attention after a feature in Genencor's 2000 annual report suggested that the lakes served as a source of a useful enzyme—a powerful image in an annual report, perhaps, but bound to raise concerns on the part of provider countries.

Although many in industry are well-versed in the CBD and resulting obligations, other companies, and indeed entire sectors, remain largely ignorant of these issues. Ten Kate and Laird (1999) found awareness significantly lower in companies in botanical medicine, personal care and cosmetic, and horticulture than in pharmaceuticals, biotechnology, the seed industry and crop protection, and this continues today[57]. Holm-

57 Nutraceuticals and botanicals companies, which tend to be small, are often completely unaware of the CBD, and yet as a researcher at a French personal care and cosmetics company put it: "they prospect for leads and use traditional knowledge more directly in new product development". Ingredient suppliers in these sectors undertake a significant portion of the prospecting and new product development, but rarely see the CBD as relevant to their business model (Kodzo Gbewonyo, Bioresources International, pers. comm., 2005).

Muller et al (2005) found that only a small minority of the German companies they interviewed, including only 14% of those that access genetic resources, are aware of the CBD and its legal obligations, and fewer still are familiar with terms such as "access and benefit-sharing".

Ignorance of the CBD is not confined to industry, however. Many academic researchers continue to see the CBD as having no bearing on their work. For example, the Scientific Council for Biological Diversity of the Swedish Environment Protection Agency sent an enquiry to 39 universities about ABS provisions of the CBD. Of the 17 that responded, 50% said that ABS issues did not impact or relate to their work (Thornstrom, 2005). Some academic researchers express concern about colleagues that do not take the CBD seriously, and while paying lip service prefer in practice to "ask forgiveness rather than ask permission". Some see the new obligations as too burdensome and expensive in time and funds, and others say that whatever they do, they will be tarred 'biopirates'.

LACK OF UNDERSTANDING OF COMMERCIAL PRACTICES AND RISKS

Numerous researchers and companies expressed concern that few in government responsible for ABS are familiar with the rapid scientific and technological developments in industries that use genetic resources, or with the market, legal and other factors that influence corporate behavior. They see this as a serious impediment to the development of effective ABS frameworks.

Many thought government ministries dealing with trade and industry, or scientific research, should be the home for national focal points, rather than ministries of environment and natural resources. Some feel that the role of those with relevant scientific expertise in provider countries has diminished over the last ten years, and that the ABS policy process is now dominated by groups with little scientific or commercial experience.

For example, there are common misunderstandings about the value of genetic resources for R&D and commercialization, including the lower expenditure and risk associated with discovery compared with development, and the low odds of commercial product development from any one sample (although this varies by sector)[58]. Companies have also remarked that the internal competition genetic resources research programs (eg natural products in the pharmaceutical and cosmetics industries, and wild germplasm in seed) face from other research programs within companies is often poorly appreciated[59]. Overall there is a perception that the actual activities governments seek to regulate are unclear[60], and that standard, and largely non-negotiable, commercial practices like the premium placed on confidentiality associated with R&D and agreements[61], and the role of intellectual property is not well understood. One company representative said that when they work in countries with low levels of ABS capacity, the company "must sit on both sides of the negotiating table, explaining what a contract is, a patent, and so on," and that this process is "wearing" and "unsustainable".

INCREASINGLY CONTESTED INTELLECTUAL PROPERTY RIGHTS

There are sharp differences in perspective between groups about the positive and negative impacts of intellectual property rights (IPRs), and as a result this issue has been found at the center of much of the ABS dialogue. In particular, there are divergent perceptions about the role of intellectual property protection in stimulating innovation and revenue; the ethics of patenting life; and the effects of intellectual property protection on food security, and health service provision (CIPR, 2002; Oldham, 2004; GRAIN, 2005). Ongoing efforts to introduce 'disclosure of origin' requirements for IPR applications, the lodging of multi-genome patent claims,

58 It is estimated that one in 10,000 samples makes it into a commercial pharmaceutical product, and Cragg et al (in press) estimate that less than 4% of patented pharmaceutical drug candidates become commercial drugs.

59 As one researcher said of bioprospecting for fragrances: "…if it becomes too difficult to do this research from a legislative perspective then it will stop, which would be a terrible shame." (Roman Kaiser, Givaudan, pers. comm., 2005).

60 For example, in many instances policy makers confuse collection of samples for discovery (bioprospecting) with sourcing and export of bulk botanical raw materials—two very distinct activities raising very different legal and ethical issues regarding ABS (Kodzo Gbewonyo, BRI, pers. comm., 2005).

61 For example, a biotechnology company representative said: "…Some interest groups, such as journalists searching for a story, or environmental groups in need of controversy to help boost fundraising efforts, may find the mere fact that these benefit-sharing terms are confidential is unethical".

and differences of opinion as to the placement of genetic information in public databases have been three recent debates that illustrate these divergences.

The possibility of requiring applicants for patents or other IPRs to declare if any genetic resources or traditional knowledge have been utilized in their applications has been brought into focus in recent years. Although a number of countries have adopted these disclosures of origin measures, there are conflicting opinions about their introduction at the international level, with some making a strong calls for patents to be granted only on evidence of PIC and benefit-sharing, and others arguing that a contract-based system suffices for securing the ABS objectives of the CBD. An industry-wide survey in Germany revealed wide support for disclosure requirements amongst users, predominantly Holm-Muller et al (2005) remark because the requirement is without prejudice to the processing of patent applications or the validity of rights arising from granted patents. Although the debate has predominantly focused on moral and ethical issues, Tobin (2005) notes an important shift in focus towards the use of disclosure as an economic tool to promote facilitated access, reduced transaction costs for ABS and legal certainty. This could go a long way to resolving the 'biopiracy' claims described earlier.

Industry and researchers view IPRs as important elements of the research and commercialization process, but there are also differences in approaches to intellectual property protection and the publication of research findings. For example, Diversa has patented results of their research on microbial diversity, while the Venter Institute is working in similar areas and publishing a freely-shared genomics database even though this may "decrease a nation's benefits arising from potential commercial utilization" (Biological Resources Access Agreement, 2004). In Bermuda's Sargasso Sea, a six-year process by Diversa to develop a biodiversity research partnership with a local biological station is in contrast to the Venter Institute's open publication of 1.2 million gene fragments from the same area. This might mean that Diversa and other companies like it may now find it harder to justify to their shareholders that they should continue to pay for something that they can now initiate for free from a public database (Diversa, 2005).

Increasingly, genome mapping with its identification of key genetic material across varieties, species, and genera, and the increasing realization of relatedness between organisms, is resulting in a surge of very broad intellectual property claims (Oldham, 2004). With continued scientific and technological changes, an increased ability to turn genetic resources into new informational products, and reduced dependency on wild genetic resources in certain sectors, the ground for continued contestations of IPRs is fertile.

COMPETENT NATIONAL AUTHORITIES

The Bonn Guidelines recommend each country designate competent national authorities (CNAs) or focal points for ABS. Most countries have yet to designate or clearly define the tasks of CNAs, and companies and researchers regularly experience difficulties locating groups within government that can clearly explain and execute permitting for collections and research. German companies cited difficulties identifying an appropriate focal point with whom to negotiate and receive permits or prior informed consent as one of the most common problems associated with accessing genetic resources (Holm-Muller et al, 2005). As a researcher at a French personal care and cosmetics company said: " Companies need security and for things to be clear. We want to know what we can do, where we go to ask for authorization, what partners are allowed to work with us, who can collect and send plants to the company. We are happy to apply for authorization and share benefits, but it can be very difficult to know how to do this."

A biotechnology industry representative in Europe made the additional point that because many countries have not established effective PIC procedures or authorities, "… industries will have to choose their countries of CBD collaboration not only based on where the interesting biodiversity is, but also where PIC procedures and the CBD legislation are in place" (Lange, 2004).

Acquiring prior informed consent poses particular difficulties for companies. The CBD gives legal authority to national governments, however in practice there are a range of stakeholders in provider countries whose consent is required. Most companies consider it beyond their expertise to navigate the complex political and social issues that underlie seeking prior informed consent from many parties within a country[62]. Almost all companies prefer to negotiate with scientific research institutions that share their experiences and worldview[63], and many would prefer to work entirely through these groups for all permitting as well as PIC requirements, rather than having to work through complex government bureaucracies. Indeed, in most cases partnerships between companies and research institutes (both domestic and provider country) are still the most common model through which companies gain access to genetic resources.

While many governments remain ill-informed about the scientific and commercial realities of bioprospecting, some of the problems that have arisen in this regard are magnified by striking differences in experience and perspective in a new and evolving regulatory field. The ICBG program, for example, has found numerous challenges in bridging the expectations and practices of users and providers. Companies are typically concerned about losing their competitive edge if proprietary bioassays and related methodology, as well as the nature of any specific leads or the financial terms of an agreement, are shared with parties peripheral to the work. The unfamiliar concerns of indigenous peoples, conservationists and others raise concern among industrial partners that their needs for secrecy will not be respected, and vice versa (Rosenthal and Katz, 2004). However, the ICBG program has produced approximately 125 contracts, including research and benefit sharing, material transfer, confidentialty, know-how licenses, license option agreements, and trust funds, and has managed to build partnerships that address both provider and user expectations and priorities. While this has 'been a significant rate-limiting factor in some projects", the development of models for collaboration is considered perhaps the single most significant contribution of the program to date (Rosenthal and Katz, 2004).

REGULATORY CONFUSION, COMPLEXITY AND SHIFTING GOALPOSTS

Although more than 75 Contracting Parties have been involved in ABS law and policy development, only 26 of the 188 Contracting Parties to the CBD have adopted ABS laws and procedures. Development of national ABS measures has proven difficult for many countries due to a number of factors, including lack of technical expertise, budgetary constraints, weak government structures and political support, local social conflicts, and conflicts over ownership of genetic resources (UNEP/CBD/WG-ABS/3/2, 2004; Carrizosa et al 2004; Nnadozie et al, 2003). It is also the case that many governments are juggling competing priorities, and do not see bioprospecting as an area active enough to warrant allocating the resources necessary to develop ABS laws and institutions. At the same time, many countries have yet to identify the objectives ABS measures are intended to serve, and a strategy for achieving them[64]. The result is that even existing ABS measures are often sectoral and patchy.

But even in countries with well-developed ABS measures, and national focal points, there remains confusion associated with implementation. For example, in the Galapagos Islands, Thorstrom (2005) found that—despite Ecuador's membership in the Andean Pact and active participation in ABS policy dialogue over the last 15 years—negotiation of an agreement in line with current ABS norms was haphazard and imperfect, and "…the CBD's guidelines on ABS, coupled with the 391/96 provisions did not work very well in practice". (p3) This was due to a lack of awareness of new regulatory frameworks on the part of the local research institution and the company involved.

62 In the ICBG program, academic researchers tend to broker relationships between parties, but even they have run into problems obtaining prior informed consent in cases where the 'community' that can legitimately make decisions regarding the sharing of knowledge or resources is unclear, and where an "established, credible and politically representative governance system" does not exist for the indigenous communities involved (Rosenthal and Katz, 2004; Rosenthal, in press).

63 The US National Cancer Institute (NCI), for example, found that companies are reluctant to negotiate directly for PIC with local communities and indigenous peoples, and prefer to leave these to local partner institutions with the necessary experience in the country. NCI has found that it is most effective for local partners to obtain all necessary permits and PIC from relevant government authorities as well as local communities (Cragg et al, in press).

64 See ten Kate and Wells, 2000. Finston (2004) described it this way: "To paraphrase Lewis Carroll, if you do not know where you are going any road will get you there. Now more than ever, it is important for the developing country Members of the CBD to identify their destination in terms of their strategic commercial interests, and to map out a strategy for reaching their goals".

In other cases, countries with well-developed measures can fine-tune measures, in ways that shift goalposts and create uncertainty for users. For example, in the 1990s the University of Utah was the first group to enter into a commercial research agreement with the Philippine government under Executive Order 247. A process underway today to refine ABS laws has produced a framework that is at odds with the earlier agreement. New rules include, for example, royalties of 3% on gross sales to shareholders in the Philippines. At present, the University of Utah will split any royalties from their marine bioprospecting with the University of the Philippines, as an agent of the national government, and considers royalties of 3-5% of net sales the most likely range possible. Under this scenario, 2.5% of net sales possible for the University of the Philippines falls well below the 3% of gross sales anticipated in the new rules. It is extremely unlikely any company will agree to royalties based on gross, rather than net, sales, and it is unclear where this leaves the research programs. The Bureau of Fisheries and Aquatic Resources, in the Department of Agriculture (DA-BFAR) is willing to consider compromise language, however, and discussions for renewal are currently underway (Chris Ireland, University of Utah, pers. comm., 2005).

Another major problem with coherent implementation of ABS regulations appears to be what some in industry refer to as a lack of "political will" within governments (Mathur et al, 2004). Researchers and industry now widely believe that in many countries government officials are reluctant to grant access, even if regulatory procedures are in place. One US researcher described his unsuccessful efforts to gain access in one country over many years as follows: "People in government see this as a political hot potato, and are afraid to stick their neck out and even prepare an agreement for fear of the criticism that will result, and they will be fired… We finally came to realize that this is a political issue, and concerns had nothing to do with coming up with a fair and satisfactory agreement, or not. "

The cost and time required to develop partnerships within complex and evolving regulatory frameworks are significant, and many companies report a retraction of collections into fewer countries with more straightforward procedures. Countries like Brazil and India, for example, are regularly avoided; it takes 1-3 years to get a permit, and researchers fear both the hostility they find to any research on genetic resources, and what one observer called the "national regulatory labyrinths" (Thorstrom, 2005). In The Philippines, the University of Utah undertook negotiations for 3 years for their first commercial research agreement, and a year and a half for the first renewal (Chris Ireland, pers. comm., 2005). The US National Cancer Institute has found that it can take many years to reach agreements, and that delays have resulted in promising compounds or their derivatives being synthesized and partnerships stalling (Cragg and Newman, pers. comm., 2005). Syngenta, noting their frustration at finding a government body to give PIC, and a partner with whom to develop agreements, have remarked that "…if you don't move for two years, you lose interest and move on" (Alwin Kopse, Syngenta International, pers. comm., 2005).

LEGAL CERTAINTY CONCERNS

All of these factors combine to create concerns about 'legal certainty' for users of genetic resources, something a party would have regarding an instrument if "he was fully aware of all relevant laws, and certain that they were consistently and predictably in force and enforceable" (IUCN-Canada, 2005)[65]. Legal certainty grows from a broader body of law than ABS or biodiversity law, but confusion in the ABS regulatory process makes many companies very nervous. As one researcher put it, "…even if one comes to an agreement that is satisfactory to both researchers and governments, in a few years another individual with more political influence will come along and say the agreement is invalid." Companies want to know that during the course of the 10-15

65 In its analysis of legal certainty in ABS measures, IUCN-Canada (2005) focused on three elements: (1) process certainty (establishment and empowerment of competent national authorities, specifying the rights and duties of others (eg landowners and communities) who may be involved; clarity in procedures for applying for ABS rights, various deadlines, and appeal); (2) scope and nature of the grant (clearly defining the right granted, and enunciating mandatory provisions and conditions that must be included within 'mutually agreed terms'); and (3) legitimate expectations and vested rights (eg clear and specific statutory requirements and limitations regarding subsequent challenges to the user's activities after receiving ABS rights, and a clear delimitation of the nature of government's power to alter, cancel, repudiate, amend or suspend an ABS right, once it has been received).

years it takes to develop a pharmaceutical, for example, and following expenditures in the hundreds of millions of dollars, questions will not be raised about the company's rights to the original material.

Some companies find that through more involved partnerships with provider country research institutions they gain greater confidence in their legal title to resources. Others work only in countries with which they feel comfortable, whether through historical ties (eg French companies working in French territories under French law), or as a result of the legal framework meeting their needs for legal certainty (eg Costa Rica).

IMPACTS ON SCIENCE AND DEVELOPMENT

Researchers in both academia and industry express significant concern about the negative impact ABS is having upon basic science and upon traditions of trust and collaboration among scientists. Just as scientific and technological developments have dramatically improved our ability to study and use genetic and biochemical resources, the availability of organisms to research has diminished, including in countries with extremely threatened ecosystems where the future of these organisms is uncertain. Many felt that countries were shutting themselves behind an 'iron curtain' and setting back their own capacity and development. Craig Venter, Director of the Venter Institute, remarked at a recent public lecture, "If Darwin were alive today, he would not have been able to have done his research."

A marine researcher in the US feels that "… closing off collaboration and collegiality has very serious consequences for science worldwide. People don't seem to appreciate that it isn't just pharmaceutical companies that have an interest in natural products, it is also academic researchers. We used to work in many parts of the world from which we are now excluded, and train students from countries with which we no longer have working relationships. How is this a positive development?" (William Fenical, SCRIPPS, pers. comm.., 2005). Rosenthal and Katz (2004) consider the need to develop effective models for collaboration an urgent one. They argue that the research community must "demonstrate that this work can be done in a flexible and accommodating manner that recognizes the environmental and socioeconomic context in which these organisms exist, or we will lose access to them in the near term through politics, and eventually through extinction…".

A representative from the seed industry believes that the CBD and FAO agreements have led to a narrow band of collaboration between companies in the North who know and trust each other, and that new collaborations with new institutions are considered with increasing reluctance. The net effect is a stifling of research and innovation (Alwin Kopse, Syngenta International, pers. comm., 2005). Others have expressed concern about the effect of the CBD on collection of genetic material for agricultural genebanks, and the reduced *ex situ* conservation of agricultural diversity, as a result.

Another researcher is working on a project called "The Scent of the Vanishing Flora" as a way of educating people about the many reasons why nature conservation is important (Kaiser, 2004). A number of countries would not let him undertake research on the scents of extremely endangered species, although they were found in botanic gardens. "As soon as they know you are from industry, they become very suspicious… There are amazing things in nature, and this research should continue" (Roman Kaiser, Givaudan, pers. comm., 2005).

But it is not only negative impacts on science that has researchers and other worried about trends in ABS. Many groups also feel that local communities and rural producers suffer when opportunities for commercialization of local products are cut off. PhytoTrade Africa, for example, has established partnerships with companies in the cosmetic and personal care sector like Aldivia (France) around the commercialization of products from Southern Africa (Aldivia and PhytoTrade, 2005). In order to develop products, producers need to do research and development, and this requires funds. One option is through charitable donations and public support, and the other is through commercial partnerships. The former is limited, and the latter depends on companies benefiting from the arrangement. They have found that their association can best bring benefits to local producers through industry partnerships, including shared intellectual property and benefit-sharing

agreements. Although royalties are built into negotiations, the primary benefits they see are partnerships with reliable buyers, who sign long term supply contracts, paying a fair price. At the same time, PhytoTrade is working on innovative models for capturing benefits from intellectual property, including through a trust. But they see the most important goal as developing "long term supplementary income sources for poor rural people in the region from the sustainable exploitation of indigenous NTFP [non-timber forest products]" (Lombard, 2004; Lombard, PhytoTrade Africa, pers. comm., 2005).

5. RECOMMENDATIONS

During the course of this project, researchers and representatives from industry and academia were asked for their recommendations on ways to improve the ABS policy process. A range of invaluable recommendations relating to ABS in general, and ABS and industry in particular, have also emerged in the literature, but these will not be repeated here[66].

RECOMMENDATIONS FOR PROVIDERS

1. Undertake national consultations that comprehensively and overtly address the range of issues that touch upon or underlie ABS—eg patenting of life forms, relationships with external companies, implications of new biotechnology—and tease out the distinct concerns associated with each, and their relationship to ABS frameworks.

2. Define biopiracy and what would constitute acceptable bioprospecting activites.

3. Clarify the types of activities ABS measures regulate.

4. Identify the objectives ABS measures are intended to serve—eg biodiversity conservation, scientific and technological development—and develop a strategy for achieving them

5. Improve capacity within government to address these issues, including understanding of the scientific and technological, market, and legal aspects of bioprospecting and the industries of which it is a part.

6. Improve the capacity of national focal points, clarifying their roles and responsibilities, and ensure that individuals with relevant scientific, commercial and other expertise are part of the staff, and part of national ABS policy dialogues.

7. Clarify expectations for permitting (time to process, content of application, requests for additional information, criteria by which applications will be judged, etc.) and identify the ways PIC is to be sought from groups outside of government.

8. Promote the role of research institutions as intermediaries between companies and providers, and brokers of permitting and PIC procedures.

9. Build domestic capacity and infrastructure to support higher levels of scientific collaboration, and to maximize the gains from bioprospecting partnerships.

10. Create a legal and scientific environment receptive to research and commercial partnerships, including providing legal certainty to users adhering to national laws.

66 See, for example, IUCN-Canada, 2005; UNEP/CBD/WG-ABS/3/2, 2004; Carrizosa et al, 2004; Nnadozie et al, 2003; Rosenthal and Katz, 2004; Cragg et al, in press; Parry, 2004; Laird, 2002; ten Kate and Laird, 1999.

11. Avoid a 'one-size fits all' approach to ABS measures, taking into account the diversity in user industries, including differences in research and development, the value of genetic resources to industry R&D, the types of commercial products that result, and the profitability of products.

12. Retain flexibility to allow laws to adapt to the rapid scientific and technological change that characterize industries using genetic resources. Use a 'stepwise' approach to ABS law and development and keep the permitting and regulatory process simple and predictable.

13. Don't lock companies into a commercial agreement and a predetermined set of benefits at the earliest stages of discovery, but rather provide indicative benefits, or a package of benefits triggered by different stages in the R&D and commercialization process. A research agreement might cover the discovery phase, for example, followed by a commercial agreement triggered by patents or selection of an agent for development.

14. Distinguish between academic and commercial research in regulations, with different levels of complexity in agreements, and different expectations associated with benefit-sharing.

15. Do not sacrifice the invaluable benefits of scientific collaboration, or academic research on biodiversity, out of fear that commercial research cannot be adequately regulated or monitored.

16. Promote transparency and partnerships, rather than illegal collecting. Byzantine regulatory frameworks and mistrust do not appear to deter the more unscrupulous collectors and only serve to put off more responsible companies.

17. Promote more involved partnerships between domestic research institutions and companies, as a way of ensuring more significant benefits and—particularly in light of advances in synthetic chemistry and the increasing focus on microorganisms—more effectively monitoring commercial activities.

18. Bring more individuals from trade and industry, and academic scientists with experience in these fields, onto delegations to the CBD.

RECOMMENDATIONS FOR USER COUNTRY GOVERNMENTS

1. Build the capacity of national focal points to provide information (eg corporate policies, standardized contracts, information on ABS measures) and technical assistance to researchers and companies. National focal points might also collaborate across regions to ensure more effective use of limited resources.

2. Promote the involvement of companies and industry associations[67], and academic researchers working in these fields, in the CBD policy process. This might include actively soliciting their feedback and input on ABS issues prior to key meetings.

RECOMMENDATION FOR PARTIES TO THE CBD

1. Develop a regional or international clearing house for information on the commercial use of biodiversity. This would include information on the range of sectors undertaking research on genetic resources, including scientific and technological developments, demand for access, trends in benefit sharing, and new ABS agreements. The information would be regularly updated, and summaries of recent developments and emerging issues submitted to each meeting of the ABS Working Group, the COP, etc. In this way, Parties might be better able to stay abreast of the commercial activities they seek to regulate.

67 For example, a new industry association, the American BioIndustry Alliance, has been formed to represent a range of sectors involved in bioprospecting at the CBD, WIPO and other international policy processes (www.abialliance.com).

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