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ACCESS AND BENEFIT-SHARING ARRANGEMENTS EXISTING IN SPECIFIC SECTORS

Note by the Executive Secretary

1. The Executive Secretary is pleased to circulate herewith, for the information of participants in the sixth meeting of the Ad Hoc Working Group on Access and Benefit-sharing, a study commissioned by the Secretariat on access and benefit-sharing arrangements and practices in different sectors of industry. This study, which was made possible in part through funding from the United Nations Environment Programme (UNEP), is intended to fill gaps in current understanding of access and benefit-sharing partnerships, collaborations and contractual agreements in the various sectors using genetic resources. The case-studies that contributed to the analysis and findings contained in the study will be made available on the website of the Convention www.cbd.int as of 17 January 2008.

2. The study is being circulated in the form and language in which they were submitted to the Secretariat by the authors. The present document supersedes and replaces the executive summary of the same study that was circulated as document UNEP/CBD/WG-ABS/6/INF/4 of 22 December 2007.

* UNEP/CBD/WG-ABS/6/1.

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STUDY ON ACCESS AND BENEFIT-SHARING ARRANGEMENTS

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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.

The study fills gaps in current understanding of access and benefit sharing 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; mutually-agreed terms, including benefit-sharing packages (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. 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. Seven case studies were selected for detailed analysis.

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.

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. Astra Zeneca-Griffith University, Queensland Australia
From 1993-2007, Astra Zeneca 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, Papua New Guinea, and India. Significant benefits accrued to Griffiths 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 Services, 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 Teff case

The cereal crop Teff (*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 Teff 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 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, Mt 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 explores Aveda's long-running partnership with the Yawanawa in Brazil, including an agreement for the use of images in marketing (a common practice in this sector), and a partnership formed in Nepal with community groups that make certified paper for the company's products. An analysis is also provided of how the company leverages commercial partnerships to realize broader social and environmental goals.

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

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
TOTAL TOP 10 COMPANIES: $282.1		**46.4%**

Source: IMS Health, 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 Convention on Biological Diversity (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 (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 (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 for key food crops.

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 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**

Company	2006 Seed Sales (US$ millions)	Nature of business
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.

US$ million	2006
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, is 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 note 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

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 low risk rather 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.

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). With some exceptions, the horticulture sector has very low awareness of the CBD and relies to a large extent on its interests being represented by larger seed companies that also have an ornamental horticulture focus.

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" (American Dietetic Association) 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). The development of Teff 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)

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 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

Company	**Sales (US$billion)**	**Growth**
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 a European natural products manager notes (pers. comm., 2007): "Natural products are under pressure within large pharmaceutical companies – our chemistry is complicated and combinatorial chemistry produces such easy chemicals. Natural products are under pressure from inside companies, and now with the CBD externally as well. Jobs are disappearing in the natural product drug discovery sector in many countries; in the last seven years the whole US-based industrial natural product discovery got squeezed out".

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).

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).

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 Latin America, 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 (http://collections.plos.org/plosbiology/gos-2007.php). 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).

4.3 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. For example, in Nigeria an 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).

Traditional knowledge is widely used in the botanicals, personal care and cosmetic, and food and beverage industries. 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. 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).

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).

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, are human genetic resources included in ABS measures (they are explicitly excluded from the CBD), or non-human genetic resources found in humans (eg HIV, H5N1 virus, malaria parasite)? (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 to these agreements 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 - 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 the clarification of 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

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[1]. 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 a European natural products program manager (pers. comm., 2007) notes: "Capacity-building is much more valuable than royalties. 99.9% of cases will never produce royalties. We provide training, know-how, equipment, scientists come to work with us in Basel… but too often the only benefit of interest to

[1] 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.

governments is royalties." In the Astra Zeneca-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 Bioqlicar 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 Teff (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 Teff 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 Teff 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 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).

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, and its extent and interpretation has often been contested. 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. Astra Zeneca 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.

4.7 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 retain 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, while under a plant patent system 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 Teff case study, however, new Teff 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 Teff 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; the requirement to pay 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.

5. 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.

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.

6. 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 of 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 research institutions 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. 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 **inter-locking 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.

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. 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. Increasingly, it appears unlikely that countries can effectively and comprehensively regulate, or groups can adequately track and monitor, the use of resources they provide to users. This points to 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 its extent and interpretation has often been contested. 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. 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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