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Diversity and Change in the Commercial Use of Genetic Resources: Implications for Access and Benefit Sharing Policy

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ABSTRACT

A wide range of sectors are engaged in the research and development of 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. Despite a surge of interest in bioprospecting arrangements in the 1990s, there have been surprisingly few such studies in the last decade, and understanding of these activities remains limited at the very time an international agreement on access to genetic resources and benefit sharing (the so-called Nagoya Protocol) has been finally adopted by the United Nations.

This paper results from a study undertaken to fill gaps in current understanding of ABS partnerships, collaborations and contractual agreements in the range of sectors using genetic resources. Through multiple stakeholder interviews, detailed case study analyses, and review of contracts and agreements, the study examined the nature of these relationships, and whether and how they achieve the objectives of sustainable use and equitable benefit sharing. A central finding, discussed in this paper, is that the activities that fall under 'bioprospecting' and 'ABS' are extremely diverse; there are large differences both within and across sectors in the ways genetic resources are used and benefits are shared. At the same time, the constant and rapid pace of scientific and technological advances, and less dramatic but still significant market and legal changes, mean that any ABS policy framework must be carefully developed to reflect and adapt to changing realities. Sustainable use, conservation and equity are complex goals in any scenario, but in the ABS policy arena achieving these goals is far more challenging given the diverse and changing nature of the activities to be regulated.

Keywords: Bioprospecting, access, benefit sharing, industry sectors, Convention on Biological Diversity.

JEL Classification: Q27, Q56 , Q57

1. INTRODUCTION

With the 2010 adoption of the legally binding Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, attention is increasingly turning to the practical implications of implementation. Policy-makers are also giving greater consideration to the ways in which genetic and biological resources are used commercially[1]. Despite increased interest in the policy framework for genetic resources, understanding of the research and commercial activities that policy-makers seek to regulate remains poor. Following the entry into force of the Convention on Biological Diversity (CBD) in 1993, a number of studies were undertaken on the commercial use of genetic resources and ABS arrangements (e.g. Mugabe et al. 1997; Secretariat of the Convention on Biological Diversity, 1997; ten Kate and Laird, 1999). However, in the last decade there have been far fewer such studies, even though commercial use has continued and changed, and the science and technology underlying bioprospecting has transformed the way genetic resources are used.

Addressing this gap is essential to ensure that the development of international and national ABS laws and procedures is informed by scientific, technological, and commercial realities. This paper thus aims to improve knowledge of the commercial use of genetic resources by presenting findings of research conducted over the past three years. We investigated the main industry sectors using genetic resources commercially; examined associated market, research and development trends; reviewed the ways in which these sectors access and use genetic resources and traditional knowledge and share benefits; and explored the institutional arrangements established between users and providers of resources and knowledge in a number of cases. The paper discusses these findings and concludes with an analysis about the impact of the CBD and national ABS policies, pointing towards some of the key issues that remain unresolved at international level.

2. METHODS

The study was conducted as part of research commissioned by the Secretariat of the Convention on Biological Diversity, undertaken between 2005-2008. Data collection methods involved a review of published and 'grey' literature; the collection and analysis of ABS contracts and agreements, including those associated with case studies and publicly available agreements such as those obtained from the WIPO database;[2] and interviews with 70 individuals from industry, government, non-government organizations (NGOs), international agencies, and research institutions. Additionally, seven case studies were selected for detailed analysis (see Laird and Wynberg 2008 for a detailed review of these studies).[3] Key informants were selected for interviews to represent viewpoints from the diversity of sectors engaged in ABS, specific expertise, as well as their involvement in identified case studies. Sectors investigated included the pharmaceutical, biotechnology, seed, crop protection, horticulture, cosmetic and personal care, fragrance and flavor, botanicals, and food and beverage industries. Semi-structured questionnaires were used as the primary method of data collection, and formed the basis for focused one-on-one interviews with key informants and for analysis of the contracts and agreements obtained.

Primary questions we asked of participants in each sector were: market, research and development trends; ways in which they accessed and used genetic resources and traditional knowledge and shared benefits; the types of arrangements set up between users and providers of resources and knowledge; and the impacts of the CBD and national ABS policies.

3. RESULTS AND DISCUSSION

3.1. Scientific, technological and market change: an overview of sectors

A wide range of sectors engage in the research and development of commercial products from genetic resources, and the different and distinct ways in which they undertake research and development, use genetic resources, and demand access to these resources was highlighted by the research undertaken for this project. Commercial sectors also enter into extremely varied ABS arrangements, collaborations and contractual agreements and are profoundly different in their profitability, size and research and development investments.

For example, drug discovery and development typically take more than ten years in the $837 billion pharmaceutical industry (IMS, 2010). Only rarely will an individual compound result in a commercial product, and the cost may exceed US$1 billion (PhRMA, 2009). However, blockbuster drugs emerging from the annual $65 billion investment in research and development (R&D) in this sector (PhRMA, 2009) can generate over a billion dollars in sales a year for large multinational companies (Angell, 2004; IMS, 2007). The scale of investment in R&D and profits in the pharmaceutical industry dwarf other sectors such as botanical medicine, horticulture, and industrial process biotechnology, but the number of products that result from pharmaceutical pipelines is small in comparison. Also relatively small is the role of natural products, which not only receives inconsistent support but is also only one of many segments of pharmaceutical R&D.

Over the last few decades, natural products as a source of molecular diversity for drug discovery and development have been overshadowed by approaches using combinatorial chemistry and biology (Cragg et al., 2005; Koehn and Carter, 2005; Newman and Cragg, 2007). Natural products were considered too slow, too costly, and too problematic from both a scientific perspective, and because of the legal and public relations uncertainties associated with gaining access to genetic resources as a result of the CBD (Koehn and Carter, 2005; Laird and Wynberg, 2005). However, combinatorial chemistry did not live up to its early promise, and breakthroughs in technologies (e.g. separation and structure-determination), and the ability to 'mine' the genomes of natural products, have once again made them interesting sources of chemical diversity and lead generation (Koehn and Carter, 2005; McAlpine et al., 2005).

This new wave of natural products research is largely the focus of small companies and academic and government research groups, however. During the last few decades, most large pharmaceutical companies moved out of natural products and, as an industry natural products researcher explained, it 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…"*. The R&D model of today, therefore, is one in which smaller groups develop hits and leads, and then form alliances with large companies to develop products. In a number of cases, the relationships between large companies and smaller natural products discovery units are highly collaborative. For example, in a partnership between Astra Zeneca and Griffith University in Australia, discovery was undertaken through close communication between the partners, with the smaller company or research institute serving in effect as an extension of the larger companies' R&D program (Laird et al., 2008). Diverse and changing approaches to R&D and the institutional make-up of the pharmaceutical industry are further heightened by the dramatic scientific and technological changes which characterize this sector.

The US$85 billion (Ernst & Young, 2011) research-intensive biotechnology industry is also a study in diversity, made up as it is of agricultural, pharmaceutical and industrial process biotechnology companies. These companies range in size and scope from those that are small, dedicated and research-intensive to large, diversified companies with significant in-house resources. The ways in which biotechnology companies use genetic resources and the products they develop also varies significantly. For example, some 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 to crops.

Substantial scientific and technological change within the agricultural biotechnology industry and its associated seed and crop protection industries has been the focus of a great deal of attention in recent years. Two trends in particular warrant mention, both fueled by increased R&D investment in this sector. First, the increasing dominance of modern biotechnology, or genetic engineering; and second, the rate at which commercial varieties can be bred and commercialized. Traits that improve performance and farming efficiency for major crops have comprised 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 compounds subject to biological screening.

As with the pharmaceutical industry, these major scientific and technological developments have transformed the seed and crop protection sectors. Increased investment requirements for research have also made market entry using these technologies more difficult for smaller companies, with an estimated 10-15% of turnover used for R&D in the seed industry alone (van den Hurk, Plantum NL, the Dutch Seed Association, pers. comm. 2008). The sector has thus increasingly become more research intensive, in common with trends in pharmaceutical and biotechnology industries. At the same time, market trends have led to increasing convergence and consolidation within the industry: in 2007 just ten companies accounted for 55% of the US$26,7 billion commercial seed market, and for 67% of the global proprietary seed market (ETC, 2008).

Although making use of genetic resources in appreciably different ways from the industries discussed, the US$14.4 million ornamental horticulture industry has also been significantly impacted by scientific and technological advances in recent years (Hall, 2004; UN Comtrade, 2009). The industry comprises fresh cut flowers, live plants, bulbs, tubers and corms and fresh cut foliage and involves a variety of different sized companies, many engaged in breeding ornamental plant varieties. Scientific and technological advances include tissue culture biotechnology and plug production, providing growers with uniform, consistent plantlets or cuttings that may offer disease resistance; slow-release and soluble fertilisation and irrigation technology to improve production; and automation technology and climate control systems that increase the efficiency of many commercial nurseries and greenhouses (Hall, 2004). The adoption of information technology has also led to fundamental changes in business practices. Some examples include the capability to improve supply chain management through ‘just-in-time’ delivery; the ability to develop targeted relationships with customers through practices such as Efficient Consumer Response; improved business-to-business (‘B2B’) collaborations through the Internet; and increased on-line transactions (Hall, 2004).

A final cluster of industries considered in this paper comprise those involved in personal care and cosmetics, botanicals (including phytomedicines), flavour and fragrance, and food and beverage. These sectors 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 nature, and in many cases traditional knowledge, as the starting point for new product development; bulk sourcing of raw plant materials; and broadly similar financial profiles (much smaller than the pharmaceutical industry, for example). These sectors also directly respond to consumer interest in the environmental footprint of products and the social responsibility of companies; certification and labeling of products as 'organic', 'Fairtrade' or with information about their origin and 'food miles' is thus common. Research and development of new products varies considerably, including cost, time and the level of science and technology involved. Some companies sell bulk unprocessed herbs, others may process plants into extracts, and a few might run screens, identify active compounds, and undertake clinical trials, much as pharmaceutical companies do. Demand for proven, effective and safe products has led to increased investments in R&D in recent years, although these remain much less than the pharmaceutical or biotechnology industries. The emphasis remains on generating new and many commercial products, rather than a smaller number of extremely high-value products as occurs with pharmaceuticals.

3.2. The demand for and use of genetic resources

Advances in science and technology, combined with changes in markets, laws and consumer preferences mean that the nature of demand for access to genetic resources is constantly changing. This has a profound impact on the way in which ABS arrangements are pursued and developed, and in turn how national ABS laws will work in practice.

In most sectors today, demand for access to 'wild' genetic resources from biologically diverse sources has declined, even as interest in genetic resources overall has increased. In the case of the seed industry, for example, demand for wild genetic resources has been replaced in recent years by *ex-situ* and private collections. However, because of the need to decrease crop vulnerability to pests and diseases, and concomitant consumer pressure to reduce the use of pesticides, a smaller demand continues to exist for genetic resources in wild material that may have insect- and disease-resistant properties (Rubenstein et al., 2005; Laird and Wynberg, 2008). The ornamental horticulture industry also has a low dependence on wild genetic resources today, but some companies continue to hunt for wild material with a view to introducing novel ornamental species or providing new variations of colour and other character traits (Laird and Wynberg, 2008).

In contrast, the botanical medicine, cosmetic and personal care, and food and beverage industries draw significantly upon wild resources as part of their product development and marketing strategies and in recent years have shown increased interest in novel species, and associated traditional knowledge. Flavors and fragrances derived from nature may eventually be synthesized, but other natural ingredients, and whole products like teas and botanical medicines, depend upon nature as the basis for product development. Demand for access to biological resources used in these sectors, including for ingredients and products 'new' to the market, is likely to continue because these help companies to differentiate themselves in competitive markets.

Biotechnology companies maintain an active interest in the biochemical diversity found in genetic resources from diverse and extreme environments and ecological niches (eg salt lakes, deserts,

caves, hydrothermal vents and cold seeps in the deep seabed) as well as areas with microbial diversity associated with endemic flora and fauna (Arico and Salpin, 2005). As the most abundant, diverse and least understood organisms on the planet (Mathur et al. 2004; Friedman, 2007), microorganisms are of increasing importance. 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). Because of rapid advances in genomic science, however, biotechnology companies are also able to do more research on existing collections, and on species found locally. In addition, large numbers of microbial genomes are being published and placed in the public domain, and through advances in science and technology 'artifical' diversity can now be generated in the laboratory (Ole Kirk, Novozymes, pers. comm., 2007).

In the pharmaceutical industry, these new research tools also mean that diversity found in existing collections and one's own 'backyard' (most companies are based in the US, Europe and Japan), particularly that found in the previously inaccessible genomes of microorganisms, can provide sufficient research material. Demand for access to novel collections, and 'prospecting' overseas, has declined in recent decades, as researchers look more deeply and effectively at material that can be easily sourced, and around which there is legal certainty regarding ownership.

However, many researchers believe that there is a great deal still to be learned from nature, and that the same scientific and technological advances that currently lead research programs to focus on existing collections of material available at home may very well lead to expanded interest once again in a broader range of biological diversity (Laird and Wynberg, 2008). It is also the case that pharmaceutical, biotechnology, and other companies continue to source 'new' material via partnerships and intermediaries, and although they are not receiving bulk supplies of samples for screening as in the past, they are developing promising leads coming out of collaborator's discovery programs. Remarked a pharmaceutical 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… 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 these partnerships provide us with a clear intellectual property position with regards to the material."*

Indeed, a key finding of this research is that across sectors demand for access is tied increasingly to more extensive partnerships than in the past. These collaborations and partnerships vary significantly, and exist along a gradient from the supply of samples/raw material to full partnerships involving joint research and significant technology transfer and capacity building. In the past, most such arrangements were based on the supply of samples, and a loosely defined set of 'benefits' for providers. Today, more involved, mutually-beneficial, research collaborations linked to these materials are common. The US National Cancer Institute (NCI), for example, has 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).

In the case of the partnership between Astra Zeneca and Griffith University in Australia, a significant part of the discovery process was done in the provider country. AstraZeneca invested more than $100 million over the 14 year lifetime of the partnership, transferring technology and building capacity in high throughput screening, 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 the development of the Queensland Compound Library, which contains 45,000 specimens representing unique biological diversity collected during the course of the project, intended to help researchers in the region translate innovative discoveries into commercial products. Now that their exclusive arrangement with Astra Zeneca has ended, Griffith University is well-positioned to take advantage of the growing demand within industry for natural product discovery partnerships (Laird et al., 2008).

3.3 Compliance and tracking in a changing world

Compliance and tracking are significant issues on the ABS policy-making agenda. However, there is enormous variation in the way genetic material is used and therefore can be tracked. Industry has an interest in tracking and compliance to help bolster the legal certainty associated with material supplied. Legal certainty and clarity over rights to material protect industry's investment in R&D and commercialization, and shelter industry from biopiracy accusations and negative publicity. On the other hand, providers of genetic material and knowledge want to ensure that access is given with their full and informed consent, that they benefit fairly from the use of material supplied, and that monitoring mechanisms are in place to ensure compliance (IUCN-Canada, 2006; Rosenberg, 2006; Laird and Wynberg, 2008).

Most companies have internal databases to track the movement of genetic material, along with restrictions on the ways in which material can be used, and to whom it can be sent. However, problems with tracking can still emerge. For example, the development of new seed or ornamental varieties changes the genetic identity of material, which then becomes increasingly difficult to track. Changes in science and technology mean that increasingly it will be the case that physical material is not what is shared. For example, the DNA sequence of many organisms is available to the scientific community in the form of electronic data that can be used in the laboratory to reconstruct pieces of DNA. Much research on these sequences is done today by computers, as part of bioinformatics programs (Endy, 2005; Bio Fab Group, 2006).

It is also increasingly clear that the subject of agreements – e.g. plant collections – may not actually be the source of active compounds. Many active compounds, including those used to develop a number of pharmaceuticals (e.g. taxol, camptothecin, vincristine, and podophyllotoxin), have recently been found to be products of symbiotic microbial species (Cragg et al., 2005; Newman and Cragg, 2007). 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).

Constant scientific and technological developments that change the way genetic resources are understood, accessed and used mean that traditional forms of human collaboration based on trust and mutual respect – by-products of partnerships to a far greater extent than agreements solely for

the supply of samples – are necessary to make these agreements work in practice. Indeed, no agreement today can likely anticipate the state of science and technology in even five years' time.

3.4 Use of traditional knowledge

Demand for access to genetic resources is closely linked to that for traditional knowledge associated with those resources. However, the role of traditional knowledge varies significantly by sector. Within the pharmaceutical industry it has been relatively small in recent decades, and appears to be growing smaller. In part this is due to the emphasis of pharmaceutical drug development on disease categories that do not feature prominently in traditional medicine, but it is also due to the increasing role of microorganisms, and the diminished role of plants, in discovery. It is also the case that new research approaches do not easily integrate the type of information available through traditional knowledge, although companies still consult the literature and databases, once a promising lead is identified (Laird and Wynberg, 2008).

Companies within the seed, crop protection and plant biotechnology sectors prefer to avoid collecting traditional/farmers' knowledge as far as possible because of the legal and ethical complications involved. Most 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 the legitimacy to negotiate with traditional knowledge holders. Questions of certainty and legal clarity are central to decisions relating to the use of traditional knowledge in all sectors. 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 national genebanks or those of the Consultative Group on International Agricultural Research (CGIAR), raising questions of another kind regarding the origin of these resources and associated farmers' rights.

The main exceptions to avoidance of traditional knowledge are found in the botanical, personal care and cosmetic, and food and beverage industries, which actively seek out innovative new ingredients in nature, often led by traditional knowledge. Traditional knowledge is used in marketing, and in some countries as part of proof of product efficacy and safety. While relying more heavily on traditional knowledge, these sectors tend to also be the least informed about the CBD, and the need to acquire prior informed consent and share benefits with traditional knowledge holders when seeking access to resources and knowledge.

On average, however, awareness of industry's obligations to traditional knowledge holders has increased significantly in recent decades. For example, traditional knowledge of the indigenous San was used to inform research by the South African-based Council for Scientific and Industrial Research (CSIR) on the succulent plant *Hoodia*. A 1997 patent was filed by the CSIR for use of active constituents of the plant responsible for suppressing appetite but without acknowledgement of the contribution of the San, nor their prior informed consent (Wynberg, 2004; Wynberg and Chennells, 2009). In 2003, however, following considerable media attention and intense negotiations, a benefit-sharing agreement was reached between the CSIR and the San, to give the San a share of royalties from product sales.

Despite such advances across industries, there remains a continued need for education and awareness-raising and, importantly, resolution about policy and legal mechanisms to incorporate traditional knowledge in ABS agreements and partnerships. Moreover, basic questions remain unanswered: How are the owners of traditional knowledge identified? What are the most appropriate ways to seek prior informed consent and share benefits? And what if knowledge is shared by a number of communities?

3.5 Variations in benefit sharing across sectors

The benefits that result from ABS partnerships for providers of genetic resources also reflect diversity within and between commercial sectors. 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 have 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 $1.318 billion to develop a new drug, including the cost of failures (PhRMA, 2009). 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, the development cycle for an industrial biotechnology product – such as enzymes for biofuels or detergents – may take no more than one to two years from when a lead enzyme is identified. Food and feed products take longer, due to more involved approval procedures and requirements for toxicology, but their development is still unlikely to take more than three years (Laird and Wynberg, 2008).

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, the industrial process biotechnology company 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, Laird and Wynberg 2008) 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 five to eight new products a year (Ole Kirk, Novozymes, pers. comm., 2007).

The scale of potential benefit sharing varies as a result of differences in the time and cost to develop products, and their eventual earnings, but it also reflects differences in industry business practices and approaches. For example, in the pharmaceutical industry, the last two decades have witnessed the evolution of a standard package of monetary and non-monetary benefits associated with bioprospecting that includes a strong focus on royalties, and is unique to this sector (e.g. Secretariat of the CBD 1997; ten Kate and Laird, 1999; Laird and Wynberg, 2005). In the seed sector, benefit sharing has long been considered a standard part of business that takes place at different levels of the seed value chain and manifests as a mix of technology transfer, knowledge transfer, royalties in the case of commercialization, license fees, and laboratory improvements. However, benefit sharing in the seed industry is diverse 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.

In contrast, the botanical medicine, personal care and cosmetic, fragrance and flavor, and food and beverage sectors tend to provide little or no financial returns through royalties and milestone payments to providers, and when they do share benefits focus instead upon those linked to the supply of raw materials, including equipment, premium prices paid for material, training, job creation, and building of local capacity and industries. These benefits can be significant, and can build capacity that allows communities to participate in the trade of local biological resources at higher levels, particularly in cases when local groups – such as the trade association PhytoTrade Africa in southern Africa – or companies such as Aveda or the Brazilian company Natura, support this process (Laird and Wynberg, 2008).[4]

3.6 Engagement with the CBD

A final and perhaps most significant distinction between sectors concerns the relationship of industry to the CBD and the ABS policy process. Despite a history of sporadic and largely limited involvement in ABS policy discussions, there appears to be increasing engagement by users of genetic resources in CBD forums. In the early and mid-1990s, a number of academic and commercial researchers from industry 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, partly in response to negotiations for an International ABS Protocol, and proposals for 'disclosure of origin' on patent applications, as well as wider concerns about the impact such proposals may have on industry R&D well-beyond bioprospecting activities (e.g. EFPIA, 2004; DuPont, 2007; Smith and Grace, 2007). At the last meeting of the governing body of the CBD, COP 10, which also led to the adoption of the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing, unprecedented numbers of industry representatives participated and numerous satellite events were organized by industry. Seed and plant biotechnology companies have been particularly concerned that the Nagoya Protocol could restrict access to ornamental and vegetable species not covered by the International Treaty on Plant Genetic Resources for Food and Agriculture, which sets up a multilateral ABS system for 35 food crops and 29 forage plants considered important for food security (Andersen, 2008).

Industry engagement with ABS policy processes was also recently fuelled 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 (Rosenthal, 2006; Wynberg and Laird, 2007).

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. This, despite the fact that companies in these sectors actively seek out innovative new ingredients in nature, and some have been charged with biopiracy due to their ignorance of the CBD (Brinckmann, 2007). Exceptions exist, of course (see for example Laird and Wynberg, 2008), and 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; wwwphytotradeafrica.org) and The Union for Ethical Biotrade (www.uebt.ch).

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 industries, 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.

4. CONCLUSIONS

The previous discussion provides only a snapshot of the diversity and change between and within sectors that use genetic resources, in order to illustrate a seemingly obvious but often-overlooked point: the dramatic differences in the ways genetic and biological resources are accessed and used by industry must be incorporated into ABS policy deliberations. At the same time, the rapid pace of scientific and technological change means that ABS policies must also be flexible and open to regular review. A broad framework that ensures uniformity of principles and consistency in approach such as the Nagoya Protocol could be elaborated in different ways and at different scales at the national level in order to accommodate variation and change in research and activities (e.g. academic vs commercial, discovery vs development and commercialization).

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. To some extent it has also been due to industry 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. Greater engagement by industry in the CBD and national ABS policy processes would significantly improve understanding of the diverse and evolving nature of genetic resource use, and the effectiveness of resulting laws and policies.

5. NOTES

[1]The scope of this paper is primarily focused on genetic resources – genetic material of actual or potential value - as part of the access and benefit sharing component of the Convention on Biological Diversity (CBD). However, a number of the sectors that make use of genetic resources may also use biological resources – a broader category that includes genetic resources, but also organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity (CBD, 2002). Some of the experiences of these sectors are thus examined as part of the analysis.

[2] http://www.wipo.int/tk/en/databases/contracts/

[3] These (i) included a natural product drug discovery partnership between the pharmaceutical company AstraZeneca and Griffith University in Queensland, Australia; (ii) agreements to collect micro-organisms between the industrial process biotechnology companies Novozymes (Denmark).

[4] Partnerships based on sourcing raw materials are also a potential benefit in the pharmaceutical industry. 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 (Petersen and Kuhn, 2007). However, this is not a common form of benefit sharing in this sector, which prefers to synthesize products.

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