



Bioscience at a Crossroads:

Implementing the Nagoya Protocol on
Access and Benefit Sharing in a Time of
Scientific, Technological and Industry Change

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Right – Production of Argan oil in Morocco, long used traditionally for personal care and now incorporated into many cosmetic products.
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INTRODUCTION

In 1993, the Convention on Biological Diversity (CBD) entered into force to promote the conservation of biodiversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising out of the utilization of genetic resources. At that time it was thought that a 'grand bargain' between the biologically rich South and the technologically and economically rich North would help to achieve the CBD's objectives. This was based on an estimate of the value of genetic resources to industries like pharmaceuticals, agriculture, cosmetics, botanicals, horticulture and biotechnology. It was believed that demand for access to these resources and the odds of developing a commercial product were significant enough to produce large financial revenues to fund conservation initiatives and create incentives for biodiversity conservation. For the first time, users of genetic resources and associated traditional knowledge were required to ensure that those providing these resources would benefit equitably.

In the early 1990s, pharmaceutical companies were collecting large numbers of plant and other samples for mass screening, and sometimes also examined traditional medicinal plant knowledge. Similarly, agricultural breeding and crop protection researchers were screening genetic resources for clearly defined characteristics, recognizable in the phenotype (observable physical traits). Horticultural companies, while largely interested in well-established cultivars, were increasingly investigating new introductions from the wild. Cosmetic companies were using natural ingredients, but mostly for the purposes of marketing rather than as the active ingredients in a product. There was increased interest in commercial botanical medicines, but again fuelled more by marketing and demand for 'natural' products from consumers than by research.

In these early years, bioprospecting and the application of access and benefit sharing (ABS) focused largely on the pharmaceutical and agricultural industries. Sectors that relied on the bulk supply of biological materials, such as cosmetics, botanicals and food and beverages,



Harvesting *Prunus africana* in Cameroon, a plant long traded to treat prostate problems. Photograph: Rachel Wynberg



Genetically modified vegetable in a flask. Copyright: Andrea Danti

were considered to fall outside the ABS realm. This changed in subsequent years as these industries became more research-intensive and it became apparent that companies did, in fact, 'prospect' for new compounds and traditional knowledge, if in ways different from higher-technology industries.

Significant shifts took place in the decades following the entry into force of the CBD. It became clear that industry demand for access and the odds of developing a commercial product were not as significant as had been hoped. Benefits to providers were not as substantial as anticipated. At the same time, dramatic advances in science and technology, and shifts in business environments and models, changed the nature of the demand for genetic resources and the ways in which they were used. The adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) under the World Trade Organization in the mid 1990s also fundamentally transformed the way in which industry operated and, alongside the surge of scientific and technological innovations, facilitated a rapid increase in the patenting of biologically based products and processes. The proliferation of mergers and acquisitions in the life-science industry in the 1990s and 2000s were particularly significant, shrinking the number of companies working in this field and changing the way in which genetic technologies and germplasm were owned and accessed by the seed, agrichemical and pharmaceutical industries.¹ Moreover, the world

was on the verge of a genetic revolution, reflected in the first commercial plantings of genetically modified crops in 1996 and a move towards evaluating biological material directly for the presence of useful genes.²

New scientific developments over the past two decades, along with changed markets and different business and intellectual property models, mean that the 2010 *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* will be implemented in a very different environment to that encountered by negotiators to the CBD in 1992. Not only has our understanding of the natural world changed dramatically, but the ways in which we study and use genetic resources do not resemble those of 20 years ago, and the pace of change is rapid and accelerating. Moreover, biodiversity loss has increased at a rate that is unprecedented in recent records, with many believing that we stand at a critical tipping point in the history of humankind. Unless we put more resources towards biodiversity conservation, we run the risk of losing much more and reaching a point of no return.

Understanding these changed realities is critical for the effective implementation of the Nagoya Protocol, and the resolution of basic ABS policy issues. It is important for governments to ensure that they are not regulating for activities and scenarios that no longer exist or have substantially transformed. It is also essential that new regulations do not do more harm than good, for example by limiting research that deepens our understanding of biodiversity, or by negatively impacting indigenous and local communities rather than enhancing benefits.

This policy brief reviews recent changes in scientific, technological and business realities and makes recommendations for governments seeking to regulate bioprospecting or biodiversity and implement the Nagoya Protocol. A focus is placed on the pharmaceutical and agricultural industries, which are at the cutting edge of scientific and technological developments and spend far more than other sectors on research and development, and whose activities have been the focus of international and national ABS deliberations for the past few decades. Policy briefs and fact sheets are also available for the pharmaceutical, agriculture, cosmetic and personal care, botanical, industrial biotechnology, and food and beverage industries.³

RECENT SCIENTIFIC AND TECHNOLOGICAL ADVANCES WITH IMPLICATIONS FOR ABS AND THE NAGOYA PROTOCOL

RECENT SCIENTIFIC AND TECHNOLOGICAL ADVANCES

In the past five years alone, our understanding of the natural world and our ability to study it have transformed. Genomics, which refers to the study of the totality of an individual's genetic makeup (genome), and the related fields of proteomics (the study of proteins), metabolomics (the study of metabolites – the substances produced by chemical reactions in the cells of organisms), transcriptomics (the study of the process of transferring genetic information from DNA to RNA) and phenomics (the study of phenotypes in relation to genomics) have emerged from the convergence of new molecular techniques, bioinformatics and automated laboratory tools for generating molecular data. These and other technologies have fundamentally changed approaches towards drug discovery, plant breeding, crop improvement and the development of new cosmetics and foods. Examples of a few developments with implications for the ABS policy process include the following:

Relationships between species and kingdoms. It is increasingly recognized that distinctions between organisms – plant, marine, invertebrate, microbial – are not always clear-cut. Promising compounds may in fact be produced by a few different organisms working together. For example, compounds once considered to be products of a plant or marine organism have been shown to be produced in conjunction with symbiotic microbial species, or solely by microorganisms.⁴

The rise of microorganisms. Over the past 15 to 20 years there has been a dramatic shift in research attention towards microorganisms in a range of different



There has been a dramatic research shift to microorganisms over the past twenty years. Photograph: Shutterstock

industries such as pharmaceuticals, agriculture, biotechnology and food. Marine organisms are also of increasing significance, but largely due to the microbes they contain. The genomes of microorganisms can be more easily sequenced than those of plants or insects, and can be grown in culture, which makes them easier to resupply as research progresses. Better isolation techniques and extraction of DNA directly from samples also means that the 99% of microbial diversity previously unavailable to researchers can now be studied.⁵ It has also become clear that microorganisms share a great deal of genetic material, and that an interesting compound found in a collection from South Africa might also be found in Morocco or Spain or the United States.

Genome mining. A diverse range of chemical and biological material has become available from sources already examined and thought exhausted. This has

been possible through genome mining, which switches on biosynthetic⁶ pathways to produce a far greater number of interesting compounds, or secondary metabolites, than were known before. For example, microorganisms in the genus *Streptomyces* that produce invaluable antibiotics have been found to have biosynthetic pathways for between ten and more than thirty compounds that under the right conditions might be switched on to produce new antibiotics.⁷

Greater speed, scale and efficiency. Across all sectors, the speed and capacity of research activities has increased dramatically. This includes a massive increase in the numbers of samples that can be screened and the number of molecular markers⁸ that can be used to analyse individual DNA samples simultaneously. Research now involves a much wider base of information, and a much bigger sample size. A researcher from one multinational company, for example, noted a tenfold increase over the past ten years in genetic pre-screening for interesting biotechnology traits or chemical structures for crop protection – from 20,000 to 200,000 samples. Such developments, along with huge increases in computing power and the development of bioinformatics to manage and organize large, complex datasets, mean that a broader base of germplasm and compounds can now be mined and tested for efficacy.

At the same time, the amount of genetic material needed for research has shrunk. As one academic researcher working on marine natural products put it: ‘With a miniscule amount of any material, we can get the genetic material out, sequence it, and learn how those chemicals might be programmed genetically to see if we can engineer it easily in the laboratory. Genetic information is now loaded onto public websites and even if the organism was collected from a remote location, once released publicly it is out there for anyone to see and use.’

In the agriculture sector, new technologies mean a likely increase in interest in wild crop relatives and farmer varieties. Several studies on the molecular diversity of crop plants and their wild relatives are shedding new light on the domestication process, and ways in which the diversity in ex-situ collections can be accessed in a much more targeted manner. New DNA sequencing technologies provide the power to investigate millions of polymorphisms (different

forms within the same species) and dramatically increase our capacity to understand genetic structure and select desirable attributes.⁹ These developments have significant implications for the improvement of crops and breeds, more especially in the context of climate change, population growth, shrinking areas of arable land and the rapid erosion of agrobiodiversity.

Greater precision. Across sectors, new molecular tools and the so-called ‘omic’ approaches are leading to better understanding of metabolic processes, allowing researchers to achieve greater precision in the identification of genes. Molecular marker tools, for example, are now commonly used to trace genetic inheritance in plant breeding programs or to look for useful gene patterns. These tools can also help to determine the function of genes and their interactions with other genes. Whole genome sequencing is revolutionizing analysis of crop germplasm, and is fast becoming a quick and cheap way to find traits for a breeding programme. In the pharmaceutical industry, sequencing of whole genomes has become ‘commonplace, rapid and relatively inexpensive’ with the number of bacterial genomes entering the public literature doubling every 20 months.¹⁰ There is much greater precision now across all industries. For example, in the food industry targets can be identified for particular receptors on the taste buds, with compounds modelled using microbes to attach to a particular receptor site. Many of these developments were unheard of 20 years ago.

Solving supply issues. Supply issues are a classic bottleneck in natural products drug discovery and development. In the past, problems associated with getting enough raw material, including cultivating a plant, culturing microorganisms, or re-collecting marine organisms, were common. Today, however, many supply issues are falling away. For example, Taxol (paclitaxel), the blockbuster cancer drug found originally in the Pacific yew tree (*Taxus brevifolia*), can now be produced on a large scale semi-synthetically from a more abundant natural precursor, as well as from isolated plant tissue cell cultures. Resupply of raw material for research, clinical trials and, in some cases, manufacturing remains a challenge for industry, but advances in addressing this problem have been dramatic in recent years.

IMPLICATIONS FOR ABS AND THE NAGOYA PROTOCOL

These and other advances such as the emergence of synthetic biology, genome engineering, next generation sequencing and metabolic engineering¹¹ have many implications for the Nagoya Protocol, including the fact that, because it is now possible to look deeper within organisms – at the genes – pharmaceutical, biotechnology and agriculture researchers are increasingly kept busy digging deeper into the species found in their backyards and in existing collections. Researchers can now investigate microorganisms that were previously inaccessible by looking within each organism’s genome to detect biosynthetic pathways that produce a wider range and larger number of interesting compounds. Genes producing an interesting compound in an organism collected in one country can also often be found in many other countries, including the researchers’ own. As one head of natural products at a large pharmaceutical company put it: ‘The days of going out and collecting things on a mass scale ... are behind us. There is still value there, but we need to be smarter about how we do this. The real value in organisms is the genes that enable organisms to make the compounds that they do. We need to incorporate this into our models for benefit-sharing.’

The quantity of material needed to discover new molecules is also a fraction of that needed even ten years ago, with only a few micrograms sufficient in many cases. Return to provider countries to obtain larger quantities of raw material for expanded research on species showing promise has long been an important component of monitoring in bioprospecting agreements, but this too is becoming less and less necessary. Additionally, genetic information is now published and made available in the public domain, creating further complications for monitoring in the absence of effective ABS measures. These developments are very important to consider in the context of ongoing discussions regarding the internationally recognized certificate of compliance and the establishment of checkpoints to monitor the utilization of genetic resources as outlined in Article 17 of the Nagoya Protocol.

RECENT BUSINESS TRENDS WITH IMPLICATIONS FOR ABS AND THE NAGOYA PROTOCOL

RECENT BUSINESS TRENDS

Changes in business practice are equally significant for ABS. Demand for genetic resources is often affected by consumer demand for natural ingredients, business trends and regulatory developments. There is enormous variation by sector, and the business and legal context of each is an important area for policy-makers to monitor.

The global pharmaceutical industry, for example, is in a time of dramatic transition. This affects the demand for access to genetic resources. Although revenues are greater than ever before, new drug launches on the market are in decline. Patent expirations are leading to projected revenue declines,¹² and there is downward pressure on prices in Europe and Japan. Yet markets for pharmaceuticals are also increasing in emerging markets, particularly from Asia (most notably China and India) and South America (Brazil). The aggregate projected growth up to 2014 from emerging markets is similar in size to the slowed growth from developed country markets, but it is not clear if this will last.¹³

US and European companies continue to dominate the pharmaceutical industry, with the majority of big companies based in this region, but many believe that consolidation through mergers and acquisitions has hurt the industry's competitiveness and ability to innovate. Over the past 30 years, 34 companies have consolidated into seven very large companies.¹⁴ However, there has not been an increase in the number of new drugs coming onto the market. Many observers are concerned with prospects for the pharmaceutical industry.¹⁵ The impact of these business developments on pharmaceutical research and development is significant. Although it is still the sector with the most intensive research and

development,¹⁶ biopharmaceutical budgets for R&D are in decline. In 2010, research and development spending was at a three-year low of US\$68 billion, and additional cuts are likely with patent expirations in 2012.

Many of the large companies with active natural products programmes and associated bioprospecting efforts overseas have closed their programmes, including Merck, Bristol Myers-Squibb, AstraZeneca, GlaxoSmithKline and Monsanto. Today natural product discovery is found largely in smaller discovery companies, semi-governmental or governmental entities and universities around the world. Elements of large pharmaceutical natural products programmes have been spun off into non-profits or semi-governmental entities, and compound libraries have been given away or sold off cheaply.¹⁷

A similar set of trends is visible in the agriculture sector, which has seen massive transformation over the past 40 years, beginning with the purchase by pharmaceutical and petrochemical companies of small, family-owned seed firms in the 1970s, the emergence of a 'life industry' in the 1980s, incorporating seeds, agrichemicals and pharmaceuticals, and a proliferation of mergers and acquisitions in the 1990s and 2000s. While these trends have been due in part to the desire to control markets and eliminate competition, they have also been underpinned by strategies to take ownership of new genetic technologies through the purchase of biotechnology companies, the acquisition of patents for key technologies and products and, importantly, through ownership or partnerships, to increase access to germplasm. As noted by market analysts Context Network, the seed sector has evolved from a 'production/niche marketplace to a technology distribution marketplace'.¹⁸

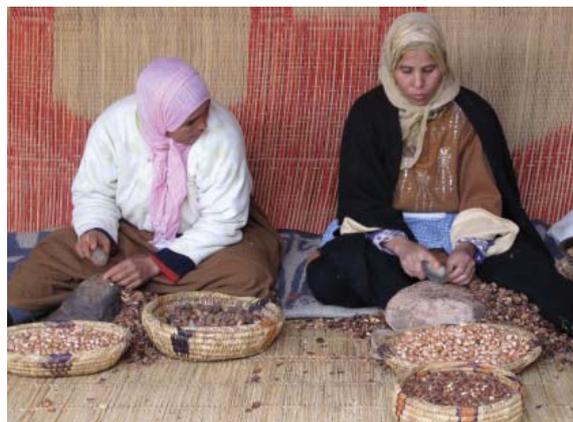
These trends are very striking in the crop protection industry where ten companies control 82% of the global pesticide market. Crop protection sales have climbed steadily over the past two decades, from US\$25 billion in 1990 to almost US\$40 billion in 2010. Increasingly, seed and agrichemical interests are converging, allowing companies to position themselves as major suppliers of both seed and agrichemicals. Genetically engineered seed, for example, is now sold as a proprietary 'package' with the herbicide to which it is resistant.

One of the greatest demands in the crop protection industry is to develop new insect control traits, particularly to manage resistance. Here, chemical discovery has been aided significantly by genomics, to identify suitable product candidates, and combinatorial chemistry,¹⁹ which has increased the number of products subject to biological screening. Over the past 15 years there has been an almost threefold increase in the average number of new molecules synthesized and subjected to biological research for new leads. A key trend has been a shift in expenditure from conventional agrichemical research to an expansion of in-house research and development efforts on transgenic crops.

A striking and continuing trend has been the escalation of private sector interest in agricultural research and an associated decline in public sector research.²⁰ In developed countries, public funding has tended to move further upstream into research and germplasm development, and the private sector has been encouraged to produce seeds. Although public seed production in developing countries was supported in the 1980s and 1990s, donors have increasingly reduced this support, leading to rising private sector involvement in seed supply in developing countries.

IMPLICATIONS FOR ABS AND THE NAGOYA PROTOCOL

Implications of these trends for ABS policy are multifaceted. In the pharmaceutical sector, large companies are no longer demanding access to genetic resources on any scale, and it is smaller discovery companies and academic research laboratories that undertake most natural products research, although largely from existing collections and their own



Production of Argan oil in Morocco, long used traditionally for personal care and now incorporated into many cosmetic products.
Photograph: Rachel Wynberg

backyards. These groups are more inconsistently informed about the CBD, and are more numerous and dispersed, and therefore difficult to monitor. In the industrial biotechnology industry as well, there is very limited opportunity for outsiders to monitor the research activities of often privately owned or smaller companies. In the agricultural sector, reliance on genetic diversity remains strong, as it is essential to improving varieties and constitutes the basis of agriculture. However, this varies across companies, with many large companies often focusing on their own collections and proprietary technologies, and smaller companies more dependent on access to public sector collections and thus perhaps more directly affected by ABS. Access to genetic resources in the agriculture sector is also determined both by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) for Annex 1 crops, and by the Nagoya Protocol for crops outside of Annex 1, or for the use of Annex 1 crops not used for the specific purposes of the ITPGRFA.

Governments could undertake significant outreach programmes to educate and build capacity in academia and smaller companies; could raise awareness in all user groups about the obligations under the Nagoya Protocol; and could draw a larger pool of these individuals into national and international policy processes. Larger companies working in collaboration with smaller companies and universities could also play an important role in raising awareness about ABS requirements.

INDUSTRY AND THE CBD

The rapidity of scientific and technological developments means that there is a critical need to build understanding about these trends among policy-makers in order to ensure that ABS regulations are effective, meaningful and appropriate. Improving knowledge about the market, as well as industry and societal trends that drive demand for access to genetic resources and shape benefit sharing, is equally important. ABS strategies, policies and laws need to be responsive to dynamic changes in the biosciences and bio-economy, and industry in turn needs to respond to the fundamental principles of ABS, raise awareness of its obligations under the CBD and Nagoya Protocol, ensure more equitable benefit sharing with providers of genetic resources and knowledge, and build these values into business practices.

There is a great need to build better linkages between the private sector and governments implementing the CBD in order to enable these mutual understandings. Industry engagement with ABS and the CBD has varied considerably over the past 20 years. In the early years of the CBD, discussions largely focused on pharmaceuticals and agriculture. Yet the scientific and technological trends described above, the increased market demand for natural ingredients and the Nagoya Protocol's focus on the utilization of genetic resources means that today almost every sector involved in conducting research and development on the genetic and/or biochemical composition of genetic resources is affected to some degree by ABS requirements.

Industry engagement with ABS and the CBD, however, still varies both across and within sectors. The differential involvement of sectors is largely determined by the extent of their reliance on genetic material and traditional knowledge, their size, perceived risks and values associated with the use of genetic resources and traditional knowledge, and the relevance of the CBD to their work. In the agricultural sector, for example, reliance on genetic diversity remains strong, but for many involved in this sector, ABS engagement has primarily been through the

ITPGRFA, which is the primary international instrument regulating the exchange of key crops through Annex 1 of the Treaty and the Standard Material Transfer Agreement (SMTA).²¹ However, many genetic resources are not listed in Annex 1, and access to these resources, as well as to Annex 1 crops used outside of the scope of the ITPGRFA, is governed by the CBD – as well as the Nagoya Protocol, once it enters into force. There is a need to ensure that all instruments are implemented in a mutually supportive manner.

In the pharmaceutical industry there has been consistent, if moderate, engagement with the ABS policy process, but in large companies the basic elements of ABS are now accepted as standard practice. Collection by company staff while on holiday (a source of new leads in previous decades) is now a thing of the past, with companies recognizing that without an ABS agreement, a sample would be useless, and a very expensive final product contested. In smaller companies and academic institutions, awareness of CBD obligations is more inconsistent but still fairly widespread. Many small companies complain that they do not have the 'bandwidth' (ie internal staffing, including legal experts) to undertake ABS agreements, and so many stay away from collecting genetic resources that require these agreements.

Increasing consumer interest in natural ingredients has led to much greater use of genetic resources and traditional knowledge by the cosmetic industry, and this sector is increasingly adopting ABS as best practice and engaging with CBD discussions. Other sectors, however, such as food and beverage and botanicals, which use a vast range of ingredients from many different suppliers in their formulations, have not fully grasped the legal and ethical obligations that arise from the CBD and rarely see these requirements as relevant to their business model. This is slowly changing in a few countries, as governments introduce laws that require ABS compliance before access to genetic resources is permitted.

Awareness about ABS has undoubtedly grown within and across different sectors. The positive role that the CBD can play in promoting equitable relationships, conservation and best practice is now well recognized, and the political will to comply with ABS principles has evolved significantly. The Nagoya Protocol has given added impetus to this trend. While there has been



Indigenous Himba women in Namibia selling plants for research and development in the global perfumes industry. Photograph: Rachel Wynberg

growing unease about ABS in the past from both users and providers, the Nagoya Protocol has taken many of these concerns on board.

Common concerns have focused on the multiple policies governing genetic resources at the national level, the variety of government departments involved, the perception that procedures may be very cumbersome or unclear, and the lack of clarity about which ministry carries the authority for negotiating ABS agreements. There has therefore been little legal certainty, a concern recognized by the Nagoya Protocol. Without certainty, it has been difficult for partnerships to develop between users and providers, despite widespread recognition of the importance of these approaches. There have also often been misunderstandings about the value of genetic resources for research and development, and for commercialization.

There has also been frustration with the perceived obstacles ABS has created in some countries to basic academic research, commercial research that might yield benefits and, despite policy intentions to the contrary, the lack of incentives for conservation. 'For me,' remarked one company representative, 'it is a real pity to see that it is easier to cut down a forest for timber than to get a few hundred grams of renewable plant samples for cancer research.' Cumbersome laws

have also created problems for providers, making it difficult for communities to understand their rights, and to negotiate on equal footing with commercial representatives.²²

Acquiring prior informed consent (PIC) poses particular difficulties for users and providers alike. The CBD and the Nagoya Protocol give legal authority for providing PIC to national governments, and Parties need to take measures to ensure that the PIC of indigenous and local communities is obtained for access to their traditional knowledge as well as to their genetic resources where they have established rights to grant access to such resources. Most companies, however, consider it beyond their expertise to navigate the complex political and social terrain of seeking PIC from both governments and indigenous and local communities, and rely on intermediaries to provide this service, along with collecting samples and ensuring research collaboration. Governments may also struggle to give guidance, particularly in cases where resources are widely distributed, or communities very remote.

By its nature the PIC process is slow and iterative, but the science is often fast-moving and the business environment competitive, including between research departments within a single company. As one pharmaceutical company representative put it: 'Expediency is very important for our current model of discovery. Even if people have good intentions to get permits and support benefit sharing, if it takes many years to get a permit the company is likely to lose interest and the research program will lose its funding.' It is important to overcome this mismatch without compromising ABS principles, human rights, scientific advancement and economic opportunities.

Concerns about legal certainty, clarity and ease of permitting procedures, and lack of understanding of current science and industry are not directed at a certain type of provider government or country, but at governments in general. Many countries are both providers and users of genetic resources and associated traditional knowledge, and the distinction between them is likely to blur further as companies increasingly look in their own backyards for genetic resources. Industry representatives regularly express the same concerns about ABS policy in their own countries as they do about ABS in others, and about the broader ABS policy process.

RECOMMENDATIONS

The Nagoya Protocol was adopted to further operationalize the ABS provisions of the CBD, thus addressing many of the difficulties outlined above. Implemented effectively, the Protocol provides an opportunity for users and providers of genetic resources and associated traditional knowledge, fulfilling their respective obligations, to work together to achieve the objectives of the CBD. The Protocol addresses the primary industry concerns of legal certainty, and ease and clarity in regulations, and providers' concern that user governments should ensure companies under their jurisdiction follow ABS laws and comply with ABS agreements. The Protocol was established to create a new enabling environment in which all can learn from the lessons acquired since the adoption of the CBD. Following are recommendations to assist policy-makers seeking to accommodate advances in science and technology, and changes in business environments and models, as they revisit ABS policies and work to implement the Nagoya Protocol.

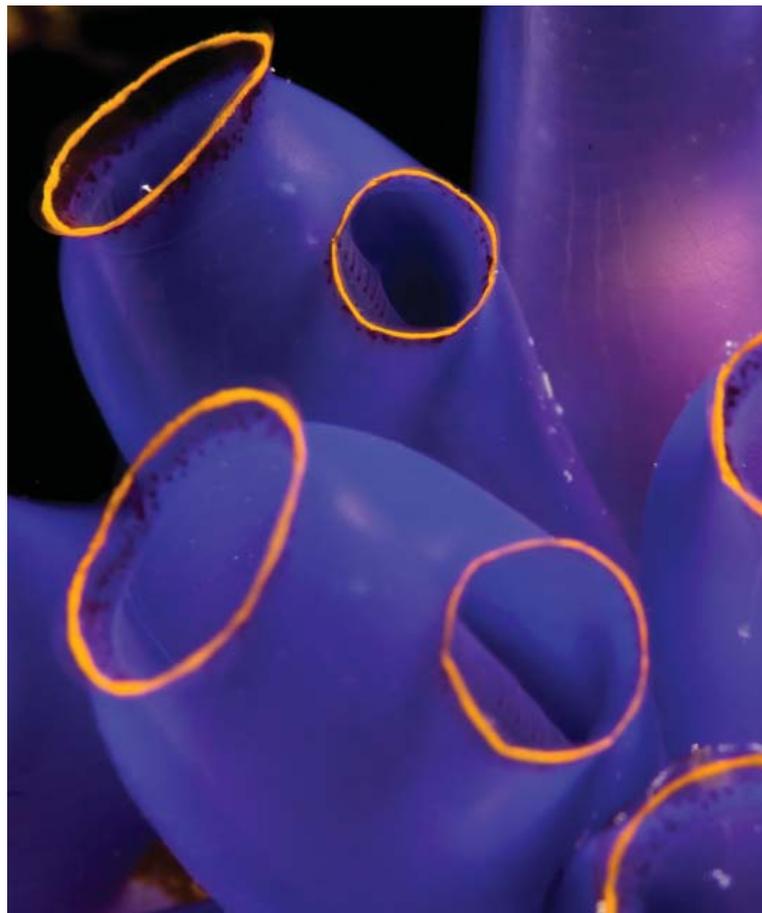
1. Determining the objectives which ABS measures are intended to serve and developing a strategy for achieving them

Countries have very different scientific and technological capacities, biological resources, traditional knowledge sets, levels of economic development and conservation goals. They may also be both providers and users of genetic resources and associated traditional knowledge. Different priorities will be placed on ABS depending on these and related factors. Threats to biodiversity through logging, mining or agriculture, for example, may be more pressing for some environment ministries, while for others biosciences may form a cornerstone of economic development and require the very careful positioning of ABS to facilitate a supportive environment for these industries to thrive. Other countries may regard ABS as a central pillar for their conservation and sustainable use strategies, for developing their endogenous research capabilities or for generating benefits for indigenous and local communities.



Research and development of genetic resources is becoming increasingly important in the food industry. Photograph: Rachel Wynberg

Soft coral, Sulawesi, Indonesia. Photograph: Shutterstock.



It is vital that countries take stock of their priorities, identify the objectives ABS measures are intended to serve and develop a strategy for achieving them. In addition to addressing biodiversity concerns, this strategy could take particular cognizance of changes in the demand for genetic resources, the value of genetic resources, evolving technologies for their development, market conditions and consumer trends. It could also include identifying checkpoints to monitor compliance on the basis of a good understanding of the range of users operating in their country, and how these users access genetic resources and utilize them.

2. Cutting the cloth to fit: crafting laws and policies to accommodate different types of use

The utilization of genetic resources requires specific regulation, but knowing which activities and resources should be regulated can be confusing for both user and provider governments. The process of developing ABS laws and policies will therefore be most effective if it begins with an analysis of the different ways genetic resources are used, including subsistence, informal trade between communities, regional trade, discovery research, research tools, and biological material traded as bulk commodities, or biotrade. Many of these uses do not fall within ABS policies, and seeking to regulate them as such could backfire and produce unintended consequences. A 'one size fits all' approach may therefore be difficult to implement and may have negative consequences for providers and users alike, particularly if biological and genetic resources are folded into a single regulatory framework.

According to the CBD and the Nagoya Protocol, ABS policies are intended to address research and development on genetic resources and associated traditional knowledge, and biodiscovery, rather than the commodity trade of raw materials that may result from research and development, or local trade and subsistence use. While it is important to ensure that regulatory frameworks address the differences between biotrade and biodiscovery, it also needs to be acknowledged that these distinctions are becoming less clear with the increasing research and development focus of commodity-based industries such as food.

Genetic resources often enter very complex value chains that pass through multiple countries and are

incorporated into thousands of different types of products for different markets. It is important for governments to understand these chains and then determine at which point regulation, including checkpoints, may be most effective to achieve benefit-sharing and conservation objectives.

ABS measures are most effective when they also take into account the diversity in user industries, including differences in research and development and the role of genetic resources, the value of genetic resources to companies, the types of commercial products that result, the profitability of products and the scale of industry revenues. The types of benefits that result from different types of uses will vary significantly. Building scientific capacity in the laboratory, research collaborations and royalties are common to higher-technology sectors like pharmaceuticals and agriculture. The capacity-building associated with raw material supply is more common for those, such as the botanical, cosmetic and food industries, that continue to rely on biological resources as part of manufacturing processes.

The introduction of ABS measures also needs to consider the fact that different ministries, such as agriculture, health, environment, science, technology, trade and industry, may have different policy approaches they wish to pursue, and different genetic resources falling under their respective mandates. Coordination and communication between these ministries is important, not only to ensure that there is coherence in policy and implementation, but also to develop common understandings about the ways in which genetic resources are used within and across different industries.

3. Creating a legal and scientific environment receptive to research and commercial partnerships

The absence of legal certainty in many countries is commonly regarded as one of the most serious stumbling blocks in the way of biodiscovery, with many companies citing the importance of legal security, clear and workable ABS procedures, and a responsive and capacitated government as key factors influencing their choice of where to work. Legal certainty is also essential to providers of genetic resources and associated traditional knowledge to ensure that

users are complying with mutually agreed terms (MAT) and domestic ABS legislation when accessing and utilizing their genetic resources and associated traditional knowledge.

The Nagoya Protocol recognizes these concerns. On one hand, it emphasizes the importance of legal certainty, clarity and transparency in domestic ABS laws, and on the other it imposes obligations on parties to take measures so that users under their jurisdiction comply with ABS legislation and mutually agreed terms. Parties are also required to designate one or more competent national authorities, an ABS national focal point and one or more checkpoints. National focal points are responsible for making information available on procedures for obtaining PIC and establishing mutually agreed terms, as well as information on competent national authorities, indigenous and local communities and relevant stakeholders (Article 13). Through these measures, the Protocol aims to create an environment of legal certainty and mutual trust for both providers and users of genetic resources and associated traditional knowledge. It is important for countries to ratify and implement the Nagoya Protocol as soon as possible to ensure that it becomes fully operational in order to give effect to these provisions.

Lessons should be learned from countries that have already made headway in regulating for ABS and establishing administrative arrangements. A 'stepwise' approach to ABS laws and development is advised, along with provisions that allow for flexibility and review. This iterative process could mean that countries start off by developing a simple ABS legal framework that is easy to implement and fits into existing administrative systems and institutions. With time and experience, laws can adapt to the rapid scientific and technological changes that characterize industries using genetic resources. Complex and rigid regulatory frameworks often require time-consuming processes to develop understandings and agreements between partners, seldom meet conservation and development objectives, and often result in halting research altogether. Consideration should be given to simple and streamlined procedures. Such iterative and flexible processes could also be employed in the establishment of checkpoints and compliance measures in countries, to allow for lessons to be learned as these new structures are employed,

and for monitoring to adapt to rapidly changing scientific and business realities.

In addition to creating a favourable legal environment, efforts also need to be made to build domestic capacity and infrastructure to support higher levels of scientific collaboration, and to maximize the gains from ABS partnerships. Technology transfer to provider countries is an important component of benefit-sharing agreements, enabling countries to develop their endogenous research capacities and add value to their genetic resources.

4. Improving the capacity of governments, including understanding of how genetic resources are commercially used and developed

Many governments remain ill-informed about the scientific, technological and commercial realities of biodiscovery, and the factors that influence corporate behaviour. As a result, there are often challenges in bridging the expectations, experiences and practices of users, providers and regulators, including common misunderstandings about the value of genetic resources and the research and risk required to successfully develop a commercial product. This may lead to inappropriate regulation and implementation difficulties.

In implementing Article 22 of the Nagoya Protocol, which deals with capacity, efforts could be made to improve government capacity and understanding of the scientific, technological, market and legal aspects of biodiscovery and the industries of which it is a part. Individuals with scientific, commercial and related expertise could be included in the staff of competent national authorities and in national ABS policy dialogues. Scientists with experience in these fields could inform decision-makers at the national level. Increased exchanges could be encouraged between government officials, scientists, market analysts and those involved in product research and development. Greater interactions could also be encouraged between ministries of environment and those with responsibility for science, technology, trade and industry.

Parties and other relevant stakeholders could make use of information-sharing mechanisms and tools, such as the ABS Clearing-House, as a means to build

greater understanding about the commercial use of biodiversity. This could include information on the range of sectors undertaking research on genetic resources, scientific and technological developments, demand for access, trends in benefit sharing and new ABS agreements. Through regular updates, parties might be better able to stay abreast of the commercial activities they seek to regulate.

5. Implementing an evolving approach to monitor the utilization of genetic resources.

Scientific and technological changes in molecular biology and bioinformatics have important implications for monitoring and compliance. Increasingly, what is shared is not physical material, so the tracking of physical material through the use of bar codes no longer offers adequate protection. For example, DNA sequences are now available in the form of electronic data which are manipulated by computers. Moreover, microbes can now often directly produce active compounds, obviating the need for the original plant or animal source. Because microorganisms share a great deal of genetic material around the globe, a promising gene from an organism collected in one country could, in some cases, then be found in another, including a given company's own.

Advances in science and technology mean that monitoring the activities of the pharmaceutical and agriculture sectors and companies doing advanced genetic research is especially challenging. ABS complexities of a different kind, however, emerge for those companies that both undertake research and purchase crude biological materials, such as the botanicals, cosmetics, and food and beverage industries. Traditional ABS agreements and monitoring mechanisms may be more straightforward for these sectors, but their tendency to use multiple natural ingredients from many different sources and countries and to draw upon traditional knowledge brings new challenges for regulators.

Monitoring is important for both users and providers. Providers need to be reassured that they must consent to and benefit from the use of material or knowledge supplied, while users want to be assured of legal certainty in using the materials provided as mutually agreed. Some countries have promoted disclosure of

origin or source of materials in patent applications as a tool for monitoring compliance, with several countries having adopted such provisions in their national laws. To address monitoring and compliance issues, Article 17 of the Nagoya Protocol articulates a number of measures to monitor and enhance transparency about the utilization of genetic resources, including the establishment of an internationally recognized certificate of compliance and checkpoints, while Article 18 sets out a framework for compliance with mutually agreed terms. As part of establishing compliance measures, governments could examine the range of users in their country, identify ways genetic resources are accessed and used, and develop a national analysis and strategy. This will help governments determine which checkpoints within their country are likely to be most effective in ensuring that users falling under their jurisdiction respect ABS requirements. In addition to these compliance measures, long-term partnerships and the development of trust between users and providers remain important components of any monitoring system.

6. Undertaking national consultations that explicitly include the inputs and expertise of scientists

A flexible and iterative consultation process can help policy-makers adjust to rapidly changing scientific, technological and business realities. A regular process of consultation with key stakeholders – business, academia, communities, and others – can help governments grappling with a complex and changing area of research and commercial activity. Different countries will have different levels of stakeholder involvement; some may have a more active scientific community and private sector, for example, while others may place a greater emphasis on inter-governmental consultation. Most countries, however, will have an academic and research community, as well as a local business community interested in these resources (although obviously the scale and nature of private sector use of genetic resources varies enormously from country to country). It is important for such interests to be brought into the ABS consultation process.

ENDNOTES

- Howard, P.H. 2009. Visualizing consolidation in the global seed industry: 1996–2008. Sustainability 1: 1266–1287; ETC Group 2011. Who will control the green economy? Communiqué no. 107, ETC Group, Ottawa, Canada.
- Tanksley, S.D. and McCouch, S.R. 1997. Seed banks and molecular maps: unlocking genetic potential from the wild. Science 277(5329): 1063–1066.
- www.cbd.int/abs
- Newman, D.J. and Cragg, G.M. 2007. Natural products as sources of new drugs over the last 25 years. Journal of Natural Products 70(3): 461; Yu, M.J., Kishi, Y. and Littlefield, B.A. 2012. Discovery of E7389, a fully synthetic macrocyclic ketone analog of halochondrin B. In: Cragg, G.M., Kingston, D.G.I. and Newman, D.J. (eds). 2012. Anticancer agents from natural products (second edition). CRC Press, Boca Raton, FL; Cragg, G.M. and Newman, D.J. 2009. Access issues related to the USA National Cancer Institute's (NCI) natural products drug discovery and development program. In: Bhatti, S., Carrizosa, S., McGuire, P. and Young, T. (eds). 2009. Contracting for ABS: the legal and scientific implications of bioprospecting contracts. ABS Series no. 4, IUCN Environmental Policy and Law Paper no. 67.4. IUCN Environmental Law Centre, Bonn, Germany; Newman, D.J. and Cragg, G.M. 2009. Microbial antitumor drugs: natural products of microbial origin as anticancer agents. Current Opinion in Investigational Drugs. 10(12): 1280–1296.
- Zhang, H., Wang, Y. and Pfeiffer, B.A. 2008. Bacterial hosts for natural product production. Molecular Pharmaceutics 5(2): 212–225, American Chemical Society; McAlpine, J.B. 2009. Advances in the understanding and use of the genomic base of microbial secondary metabolite biosynthesis for the discovery of new natural products. Journal of Natural Products 72(3): 566–572; Handelsman, J. 2005. How to find new antibiotics. The Scientist 19(19): 20, 10 October 2005.
- Biosynthesis is a process in the cells of living organisms which, through the use of enzymes, produces a complex chemical compound. Examples of products from biosynthesis include proteins, vitamins and antibiotics.
- McAlpine, J.B. 2009. Advances in the understanding and use of the genomic base of microbial secondary metabolite biosynthesis for the discovery of new natural products. Journal of Natural Products 72(3): 566–572; McAlpine, J.B., Bachmann, B.O., Pirae, M., Tremblay, S., Alarco, A.M., Zazopoulos, E. and Farnet, C.M. 2005. Microbial genomics as a guide to drug discovery and structural elucidation: ECO-02301, a novel antifungal agent, as an example. Journal of Natural Products 68: 493–496.
- Molecular markers are fragments of DNA associated with a certain location within the genome. Molecular markers are used in molecular biology and biotechnology to identify a particular sequence of DNA in a pool of unknown DNA.
- Glaszmann, J.C., Kilian, B., Upadhyaya, H.D. and Varshney, R.K. 2010. Accessing genetic diversity for crop improvement. Current Opinion in Plant Biology 13: 167–173.
- McAlpine, J.B. 2009. Advances in the understanding and use of the genomic base of microbial secondary metabolite biosynthesis for the discovery of new natural products. Journal of Natural Products 72(3): 566–572.
- Oldham P, Hall S, Burton G (2012) Synthetic Biology: Mapping the Scientific Landscape. PLoS ONE 7(4): e34368. doi:10.1371/journal.pone.0034368.
- In 2011, drugs worth US\$12 billion went off patent, and in 2012 the figure is projected to grow to US\$30 billion. Examples in the past year include a product representing 40% of Eisai's sales, Sanofi's second best-selling drug (\$8.8 billion in annual sales in 2010) and Merck's loss this year of Singulair, which earns more than \$5 billion a year for the company. (Krishnan, A. 2011. Drug patents expiration in 2011 and 2012 – a bumpy ride ahead for big pharma as big drugs lose patent protection. IHS Healthcare, pharma blog.)
- Gatya, G. and Savage, C. 2010. IMS forecasts global pharmaceutical market growth of 5–8% annually through 2014; maintains expectations of 4–6% growth in 2010. IMS Health, Norwalk, CT, 20 April. EFPIA, 2010. The Pharmaceutical Industry in Figures. EFPIA, Brussels.
- Kearney, P. 2011. What is the future for the big pharma model? AFG Venture Group Dispatches.
- Baum, R. 2011. Changing pharmaceutical paradigms. Chemical and Engineering News. Central Science: the Editor's Blog, 4 October 2011, cenblog.org.
- PhRMA, 2012. Pharmaceutical industry profile 2012. Pharmaceutical Research and Manufacturers of America, Washington DC. EFPIA, 2011. The Pharmaceutical Industry in Figures. EFPIA, Brussels.
- For example, in 2011, Merck gave its library of natural compounds to a non-profit, including 100,000 extracts representing 60% of all known plant genera. (Conniff, R. 2012. A bitter pill. Conservation. Spring 2012:18-23.)
- For example, in the 1980s the university and public sector accounted for 50% of US patents relating to genes from the bacterium *Bacillus thuringiensis*, now used widely in genetically modified crops to confer insect resistance. By 1994, 77% of patents in this area were held by small biotech start-up companies, and by 2004 consolidation and acquisitions had resulted in over 65% of patents relating to the insect-resistant trait incorporated into genetically modified crops being held by the top five biotechnology companies. Between 2003 and 2007 a single company accounted for 63% of granted patents. (Louwaars, N., Dons, H., Van Overwalle, G., Raven, H., Arundel, A., Eaton, D. and Nelis, A. 2009. Breeding business: the future of plant breeding in the light of developments in patent rights and plant breeder's rights. Centre for Genetic Resources, Wageningen, Netherlands. Rangnekar, D. 2005. The impact of patents and plant breeders rights on agricultural research. Unpublished policy brief.
- Combinatorial chemistry is the rapid synthesis and screening of large numbers of different but related chemical compounds from sets of building blocks to identify useful products such as drug candidates.
- FAQ, 2010. The second report on the state of the world's plant genetic resources for food and agriculture. FAQ, Rome, Italy.
- www.planttreaty.org
- Van Niekerk, J. and Wynberg, R. 2012. The trade in Pelargonium soidoides: rural livelihood relief or bounty for the 'bio-bucaneers'? Development Southern Africa 29(4): 530–547.



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