Deal Making in Bioprospecting

CHARLES COSTANZA, *Consultant, Atlanta, Georgia, U.S.A.*
LEIF CHRISTOFFERSEN, *Associate, E. O. Wilson Biodiversity Foundation, U.S.A.*
CAROLYN ANDERSON, *President, Capia IP, U.S.A.*
JAY M. SHORT, *Founder, President, and Chairman, E. O. Wilson Biodiversity Foundation, U.S.A.*

ABSTRACT

There is an upward trend in demand for intellectual property protection in agriculture. While international agreements exist to protect agricultural biodiversity, the specific rights, benefits, and responsibilities of parties entering into commercial agreements that involve the use of genetic resources still must be clarified. This chapter provides practical guidance for creating agreements around the use of biodiversity resources, as well as guidance that may provide valuable insights for creating similar agreements on the use of unique agricultural resources.

1. INTRODUCTION

Intellectual property (IP) rights protection is increasingly available for many aspects of agriculture, particularly through utility patents and plant variety protection (PVP), known also as plant breeders' rights. Globally, however, the kinds of intellectual property rights that can be exercised over living things vary greatly. This is especially true for the living things that make up the *biodiversity* of the planet—the millions of naturally existing species and their attendant gene pools—as well as for *agricultural biodiversity*—that subset of biodiversity involving cultivated crops used for food, materials, fertilizers, energy, and so on. It is useful to recall that the United Nations (UN) Convention on Biological Diversity defines biodiversity as "*the variability among living organisms from all sources, including,* inter alia*, terrestrial, marine, and other aquatic ecosystems, and the ecological complexes of which they are part: this includes diversity within species, between species and of ecosystems*." With respect to IP rights, naturally occurring living organisms *cannot* be protected; nonhuman living things that have been modified by man *can* be protected. *Bioprospecting* is the exploration or screening of natural biodiversity or agricultural biodiversity in order to identify potential commercial applications from those genetic resources. Bioprospecting should not be confused with *biopiracy*, which is the unauthorized and uncompensated taking of biological or genetic resources.[1]

This chapter seeks to aid parties in creating biodiversity access agreements (BAA) for the use of unique genetic resources that require additional development to commercialize. There is considerable—although not widespread—experience to date in creating BAAs involving microbial genetic resources. This general discussion of biodiversity access agreements will not encompass all of the factors necessary to create every kind of commercial agreement, but it may prove useful for the following:

- **a reference model**. For creating a relationship for the use of a resource for which there are international guidelines, but for which, in most cases, clear procedures for structuring specific agreements do not exist. This lack of guidance has forced the public

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and private sectors to cooperate to achieve a mutually beneficial and sustainable relationship based on the commercial use of a unique genetic resource.
- **resource valuation**. For valuing resources that may hold significant commercial potential and may also require significant investment for developing a marketable product (capital, technology, and management).
- **stakeholder identification and value contribution**. For valuing resources in which many stakeholders have overlapping interests. (Proper valuation of these resources requires the consideration of traditional knowledge, farmers' rights, and other historic rights. The present condition and composition of a resource, such as an isolated natural compound or unique variety of plant, may be the result of multigenerational trials and errors. These and other factors need to be considered when determining the appropriate value of the resource so that benefits from commercial development can be fairly distributed.)
- **benefit sharing**. For the sharing of benefits between parties to an agreement.

2. BIODIVERSITY AND IP

2.1 *The international agreements*

Biodiversity is addressed by the UN Convention on Biological Diversity (CBD). The objectives of the CBD are:
- conservation of biodiversity
- sustainable use of the components of biodiversity
- fair and equitable sharing of the benefits from the use of genetic resources

By recognizing a national government's sovereignty over all genetic resources within its borders (Article 15) and facilitating access to these resources based on *"mutually agreeable terms"* subject to the *"prior informed consent"* of the country of origin, the CBD provides firm conceptual grounding which can be adapted to guide commercial agreements.

Agricultural biodiversity in particular is governed also by the International Treaty on Plant Genetic Resources for Food and Agriculture (the Treaty). This agreement encourages open access to plant genetic resources and requires sharing the benefits of these resources through the exchange of information, access to technology transfer, capacity building, and the sharing of financial and other benefits of commercialization.[2]

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement of the World Trade Organization (WTO) provides minimal guidance on the issue of agricultural biodiversity, exempting both plants and animals that are not classified as modified microorganisms. Article 7 of TRIPS states that the protection and enforcement of IP rights should contribute to:
- the promotion of technological innovation and the transfer and dissemination of technology
- the mutual advantage of producers and users of technological knowledge that is conducive to social and economic welfare
- a balance of rights and obligations

The TRIPS agreement requires that signatories either provide patent protection of plant varieties or devise an effective sui generis (a specifically dedicated and unique) system for plant variety protection.

Currently, there is an effort to standardize countries' sui generis plant variety protection systems through the International Union for the Protection of New Varieties of Plants (UPOV) Convention, the purpose of which is to "*ensure that the members of [UPOV] acknowledge the achievements of breeders of new varieties of plants, by granting them an intellectual property right, on the basis of a set of clearly defined principles*." [3,4,5]

The CBD, the Treaty, TRIPS Agreement, and UPOV Convention provide general guidance for parties engaged in developing their own agreements for access to genetic resources. It is important to realize, however, that the existing (international) agreements are based on broad standards of conduct. The agreements provide overarching principals but not instructions on how to meet the requirements of every unique situation. The

Bonn Guidelines, adopted by the COP in 2001, serve as a first step in bridging the gap between international agreements and the requirements of parties negotiating access to biodiversity resources. In 2005 the Biotechnology Industry Organization (BIO) developed and published its own guidelines for members engaged in the discovery of natural products such as enzymes, chemicals, and small molecules.[6]

From the perspective of two parties attempting to come to an agreement on providing or obtaining access to a unique genetic resource, which may or may not become a successful commercial product, the international agreements leave many questions unanswered. Parties must use common sense to strike a balance between protecting rights and providing fair compensation, on the one hand, and working within limits imposed by markets and legal frameworks on the other.[7] In the case of commercializing biodiversity, the parties must agree upon ownership of the resource and the subsequent product, the amount of investment required to bring the product to market, and the distribution of benefits resulting from the sale of the product.

One commentator[8] has noted a difference in negotiating access to agricultural genetic resources and nonagricultural (particularly microbial) genetic resources: whereas microbial biodiversity governed under the CBD has been seen as bilateral bargaining, the Treaty puts a premium on open access, seeking to keep access costs low and bolster global food security by encouraging breeding and research. The model provided in this chapter does emphasize sharing in a manner consistent with the Bonn Guidelines of the CBD and many of the financial and nonfinancial benefits outlined in the Treaty.

2.2 *Beyond international agreements*

Given the limited guidance on terms for biodiversity agreements, the private and public sectors have had to collaborate to create biodiversity access agreements (BAA) on a case-by-case basis. Over time, some companies have developed frameworks based on internationally accepted principles for creating BAAs. For example, Diversa, a publicly traded U.S. biotechnology firm (NASDAQ: DVSA), has entered into many BAAs with partners including Alaska, Antarctica, Australia, Bermuda, Costa Rica, Ghana, Hawaii, Iceland, Indonesia, Kenya, Mexico, Puerto Rico, Russia, the San Diego Zoo, South Africa, and Yellowstone National Park. The company, which is involved in the discovery and evolution of novel genes and genetic pathways from unique environmental sources, sees access to microbial biodiversity as critical to ensuring a greater diversity of genetic material; this access increases the chances of discovering a novel and unique gene for a new product or application. During a time when few or no models, guidelines, or requirements existed, Dr. Jay M. Short, then chief executive officer and chief technology officer of Diversa, and his team of intellectual property, commercial, and scientific specialists developed and refined a set of principles for selecting areas of the world in which to work, selecting partners, and creating agreements with governments, academic institutions, and private companies to help ensure long-term relationships based on the sustainable use of biodiversity.

Through its decade of experience with BAAs, the Diversa biodiversity team determined that there are three main factors that lead to a successful biodiversity collaboration:

1. Efficient and reasonable benefit-sharing negotiations
2. Efficient and reasonable permit systems (requiring three months or fewer to secure a permit and oblige the permit holder to reasonable reporting criteria). It should be understood that all national, regional, or local regulation that affects an agreement should be sufficient to provide reasonable regulatory oversight without creating an unnecessary burden on the parties
3. Capacity building

Based on the experience of Diversa, the following characteristics have been useful for evaluating the best locations to establish biodoversity collaborations:

- **legal framework and political will**. As is the case with access to agricultural biodiversity, many countries have not yet fully addressed

the legislative and regulatory issues required for BAAs. Other countries may have significant legislation on biodiversity that is so comprehensive and complicated that it becomes too cumbersome for BAAs. In other cases, problems may lie with IP protection. Countries that have not previously concluded BAAs often lack the basic administrative procedures, such as approvals for the export of DNA samples, required to fulfill such agreements. In these cases, the government's political will to help orient and train their officials about bioprospecting is critical to the success of any international bioprospecting initiative.

- **equal treatment for all companies**. Although no national laws regulating access to biodiversity may exist in a particular country, it should view all potential commercial collaborators equally (these frequently include academics who are conducting research funded by a private commercial research interest), such that all commercially oriented researchers collecting samples should be required to enter into a government-sanctioned BAA that follows the guidelines and supports the objectives of the CBD.
- **strong scientific and conservation partners**. Appropriate scientific capabilities speed the process of narrowing the search for target organisms. As these collaboration partners receive training, they are able to provide more value-added services.
- **unique and protected habitats**. A greater diversity of habitats translates to a greater diversity of genetic material, and, consequently, increases the chances of discovering novel and unique genetic material for a new product or application. Protected habitats are important because they indicate that there are sufficient genetic resources to support a long-term biodiversity (or bioprospecting) collaboration.

Once a collaboration partner has been identified, the terms of the BAA must be decided. Highlighted below are key issues that influence the success of BAAs. This list has evolved significantly both through the implementation of BAAs (based on assessments and guidance from companies and biodiversity collaborators[9]) and through monitoring and adapting to changes within international conventions. The main issues include:

- **legal rights to genetic resources**. Countries that are able to efficiently assign and clearly define a company's legal rights with respect to the use of environmental samples and associated genetic material make attractive potential collaboration partners. Assigning and defining these rights reduces the risk of future claims being made against any commercial discoveries.
- **prior informed consent**. Recognizing that land owners and managers have a stake in bioprospecting activities, companies should require that biodiversity collaborators secure informed consent from landowners and managers prior to collecting samples.
- **rights to patent and commercialize**. The rights to patent and commercialize are critical to the creation of benefits that can be shared among the parties to a BAA. The way benefits are to be distributed will be outlined in the agreement. Diversa, in its BAAs, maintains the rights to patent and commercialize its inventions, including genes and gene products derived from samples.
- **competition between biodiversity collaborators**. Many companies have proprietary technologies that are necessary to commercialize their biodiversity-derived products. Companies do not want their biodiversity collaborators to use the proprietary technology transferred as part of the BAA to compete against them (the companies). Accordingly, strict and conservative interpretations of confidentiality are critical ingredients for developing a productive relationship.
- **transfers to third parties**. For some companies, their greatest competitive advantage is proprietary technology, and it is critical that it not be shared with third parties. Technology transfer to a collaborator is for the benefit of the collaborator in the context

of its own capacity building. Companies should respect and protect the confidentiality of their biodiversity collaborators' proprietary knowledge and information. Further, terms should be included in their agreements that prevent companies from transferring samples to third parties without the written permission of the biodiversity collaborators.

- **exclusivity requirements**. The terms of the BAA should not restrict biodiversity collaborators from cooperating with other companies. The more biodiversity collaboration agreements that exist, the more viable is the biodiversity collaborator and the more resources it has to preserve biodiversity in its country because of the added benefits and experience it receives from other industrial or commercial collaboration. However, many companies may resist collaborator involvement with competitors with regard to specific projects, due to their own confidentiality requirements or their need to secure a competitive advantage through access to a unique source of genetic material.

Countries also must evaluate the potentially collaborating corporations, nongovernmental organizations (NGOs), or academic institutions to judge their suitability as partners. Criteria for evaluation include

- **low-impact sample collection**. Biodiversity collaborators should understand that while biodiversity can be the raw material for commercial products and the potential source of untold scientific discovery, biodiversity is also a precious, limited resource. Therefore all sample-collecting regimes should be adapted to minimize the impact on the environment in order to preserve biodiversity (for example, sample sizes and collection frequency should be kept to a minimum).
- **adherence to international conventions and best practices**. Partners must demonstrate an understanding of and adherence to the principles of the CBD and the TRIPS Agreement. Partners with experience in BAAs may also have their own criteria based on international convention and practical experience.
- **track record**. Countries and collaborators should understand their commercial partner's experience with BAAs. BAAs have been and continue to be closely watched by the international community, and many companies have an established track record. If they do not, countries and collaborators should scrutinize, and if possible, compare to other agreements the proposed terms of benefit-sharing arrangements, protocols for sample collection, and conditions related to transfers to third parties. If partners have been criticized for past BAAs, countries should determine how they have changed their policies or their approach. What assurances are they willing to provide to ensure that those mistakes are not repeated?

3. BIODIVERSITY ACCESS AGREEMENTS

Once the parties have determined that they want to create a BAA, the challenge is to formulate a relationship that will provide access to a necessary stream of processed raw material (for example, novel genetic material) while ensuring the sustainability of that resource and compensating the party granting access by sharing benefits. BAAs contain basic elements that are common to all standard contracts, but they also contain very specific information that changes from agreement to agreement. This section discusses the necessary elements for a BAA.

3.1 *Parties to an agreement*

The most basic element of the BAA is to determine the appropriate parties to the agreement. It is critical to identify who has the proper authority to grant access to the particular biodiversity resource. In addition, it is important to identify all parties affected by access to the biodiversity resource, such as those people who live and work in proximity to it. Specifically, the parties need to identify the following:

- individuals or groups who legally control access to the resource in question (Ownership rights and authority can be documented

through permits, and that documentation should be included as an appendix to a BAA.)
- authorities who are authorized to grant access (the so-called competent authorities)
- individuals or groups who have been the "stewards" of the resource
- individuals who have been tenants of the land on which the resource is located
- individuals or groups who are currently using the resource
- individuals or groups who want access to the resource for commercial development
- universities, NGOs, researchers, conservationists, and so on, who will use access for nontraditional purposes

The National Focal Point for Access and Benefit Sharing (ABS) is frequently a good starting point for clarifying issues of authority, jurisdiction, stewardship, and tenancy.[10] As a practical matter, the company should request that the prospective biodiversity collaborator[11] provide evidence that it has authority to enter into a BAA, collect samples from designated areas, and share in the benefits that may arise from such collaborative work.[12]

3.2 *Duration of the agreement*

The period of time that the BAA is in effect should be indicated in the initial agreement. It is important for this time horizon to be referenced in later sections regarding the future ownership and disposal of genetic or other material obtained under the agreement, as well as the future benefits that may be derived from the commercialization of a biodiversity-based product. It is advisable for the parties to:
- determine how long the access agreement will be in place
- indicate how parties may terminate the agreement
- determine whether the agreement can be renewed or negotiated and what the terms are for a possible renewal or renegotiation

3.3 *Jurisdiction*

Parties must agree on the legal framework within which the agreement will function. Doing so requires that the companies determine:
- which country's laws will take precedence in the contract
- to what degree international conventions will be incorporated into the contract
- what method of dispute resolution will be required in the event of disagreements (arbitration versus litigation)

3.4 *Contribution of each party*

The parties must agree not only on what they propose to contribute to the deal but also on how to value the contribution. For the creation of BAAs, firms will see biodiversity as raw material for a biodiversity-derived product, the realization of which will require their processing, manufacturing, and marketing to make the collaboration commercially viable. Countries contributing the biodiversity resource must consider the many values of the genetic resource when creating the BAA. A variety of benefit-sharing mechanisms, both financial and nonfinancial, can be used to compensate parties for their contributions to the venture. Valuation of the biological or genetic resource and equitable benefit sharing are ultimately the responsibility of the parties to the BAA and must be detailed in the BAA.

As companies, research institutes, academic institutions, and government agencies cooperate on exploring biodiversity for commercial applications and products, they enter into agreements that govern access and also define a regime for sharing benefits. This requires the valuation of a genetic resource as an input into the development of the product. Significant effort in the form of, for example, processing, manufacturing, or marketing required to transform the microbial biodiversity into a marketable product must also be considered. The market will determine the value of a biodiversity-derived product. Companies will know the commercialization costs and their target profit margin. For the company to see the project as economically viable, biodiversity access royalties, collection fees, and other benefits to collaboration partners would have to be covered by market value of the product *less* commercialization costs *less* target profit. The uniqueness of the biodiversity (that is, the fact that it has not previously been commoditized) will influence

the value placed on it by a company, with a higher degree of "uniqueness"[13] being more highly valued.

In practice, as this is a relatively new market in terms of the formation of such collaborations and formal agreements, it may be difficult to convince companies to recognize the full value of the biodiversity resource and the contribution of the biodiversity collaborator to the satisfaction of the international environmental community. Companies and biodiversity collaborators must find a middle ground where the negotiated benefits to the collaborator are not economically prohibitive to product development but do provide incentives to the collaborator to participate in the BAA. As the market matures, biodiversity collaborators should be able to increase the value of their contribution as they increase their capacities through training and the transfer of technology that they receive from companies. Moreover, as companies become more accustomed to these collaborations, the companies are likely to be more open to increasing benefits to their collaborators. Many BAAs have been abandoned due to ambitious demands for benefit-sharing terms that are economically unfeasible. Parties to the BAA, therefore, must carefully and collaboratively determine the value of their contributions to the overall development and marketing of the product as a percentage of the entire contribution.

Finally, financial benefits are finite and may not be realized immediately. They also may require significant, long-term investment to be realized. Fortunately, there are a number of nonfinancial benefits potentially available that could encourage participation in a deal, as described below in the section on benefit sharing.

3.5 *Rights and responsibilities of each party*

In addition to each party's contribution, the BAA should provide specific information about the expectations of action and conduct that the parties have for themselves and one another.

3.5.1 *Rights*

The BAA will generate many questions about IP rights. Typically, the collaborator will provide access to the resource, and depending upon its scientific capacity, collection samples and isolated strains. These samples or isolates are then further developed by the company. Between the stages of granting access and the commercial sale of a product resulting from a BAA, there are intermediate stages, many of which create IP rights issues.

- **use of samples**. Parties should determine how samples collected under the BAA can be used by the parties. For instance, can the samples be distributed to third parties (such as research partners of either party)? If so, does doing so require written notification from the other party, and what is the required time for a response?
- **IP rights for inventions, samples, and derivatives**. Any IP rights resulting from the BAA must be fully explained and addressed within the BAA. Diversa, for example, maintains its right to own its inventions based on unique genetic material obtained under a BAA. It is important to note that this does not limit a biodiversity collaborator's right to benefits from the invention. This is negotiated under the benefit-sharing section of the agreement. Diversa also maintains the ownership rights of the derivatives that it makes from samples. The samples themselves remain the property of the biodiversity collaborator.
- **publication of knowledge**. Parties must determine who will have the rights to publish novel information resulting from the BAA.

3.5.2 *Responsibilities*

The parties must also determine their respective responsibilities. Examples of operational responsibility include sample collection and processing, regular reporting, communications, and administrative filings. Below is an excerpt from a BAA which outlines the responsibilities of the parties:

Collaborator will be responsible for the collection, processing and shipment to [the Company] of environmental samples from diverse habitats and/or DNA samples isolated from such environmental samples using the [the Company's] technology. Collaborator shall further be responsible for planning and execution of collection trips with and without the participation of [Company] personnel. Collaborator

will provide laboratory space for the collaboration activities. Environmental samples shall include, but not be limited to, soils, sediments, mire, earth, microbial mats and filaments, plants, ecto and endo symbiont microbial communities, endophytes, fungi, animal and/or insect excrement, marine and terrestrial invertebrates, air and water. Collaborator will provide to [the Company] a minimum of [number] environmental samples per year.[14]

3.6 *Benefit sharing*

Once the parties have agreed upon the value of their contributions to the deal, they must discuss the sharing of benefits that encourage the sustainable use of the genetic resource. There are many options for sharing benefits, both financial and nonfinancial.[15] Table 1 provides an extensive list of financial and nonfinancial benefit-sharing possibilities, and divides them into short-, medium-, and long-term categories. An appropriate, deal-specific mixture of financial and nonfinancial benefits will enable a company to provide incentives for biodiversity collaboration while working within international guidelines and remaining responsible to shareholders.

3.6.1 *Sharing financial benefits*

The short-term financial benefits listed in Table 1 deal with up-front access payments, sample collection fees, contribution to collaborator research budgets, and use-based contributions to funds set up to preserve biodiversity. In the medium term, financial benefits include milestone payments for the achievement of certain goals during collaboration and research funding. Longer-term benefits include a share in the profit from sales and increased opportunities to earn money for performing value-adding tasks in the production process.

Several observations can be made about the negotiation process for determining these benefits. For markets with relatively small potential payouts, biodiversity collaborators may favor receiving sure payments for performance up front versus some portion of unknown future royalties. Conversely, when there are many potential applications coupled with potentially large revenues, biodiversity collaborators may be interested in a larger share of royalties at the expense of up-front payments, hoping for a percentage of a larger payout. In this case, biodiversity collaborators would have to weigh the importance of receiving money sooner versus the potentially larger payout of up to 15 to 20 years or more later.[16]

In many cases, the market potential of the collaboration will be obvious at the outset; in other cases it will not. Where the potential is not obvious, graduated royalties could be used, which change the percentage of proceeds from product sales according to such variables as the sales volume or end-product market segment.

3.6.2 *Sharing nonfinancial benefits*

There are many nonfinancial benefits at the parties' disposal. Many have noted that for access and benefit-sharing agreements for both microbial biodiversity and plant genetic resources, nonfinancial benefits may be more valuable to developing countries than financial benefits.[17, 18] Nonfinancial benefits can be shared in the short-, medium-, and long-term as well. Over the life of the collaboration, these benefits will accrue to the biodiversity collaborator on all levels (national, regional, institutional, and individual). Professional development for individuals and capacity building and technology transfer at the country, regional, and institutional levels will enable the collaborator to perform more value-added work. As a result, the biodiversity collaborator can generate additional revenues and access more upside potential by contributing more to the development of products resulting from the BAA.

Short-term, nonfinancial benefits may include biodiversity collaborator access to facilities and proprietary databases that may otherwise be inaccessible. In the medium term, technical know-how, training in specific technologies, new equipment, and more reliable stocks of laboratory supplies can enhance the biodiversity collaborator's scientific capacity. In addition, including biodiversity collaborators in planning and decision making increases their administrative capacity for additional projects. Longer-term benefits, aside from the cascading effects of the above, may include ownership of IP rights and access to technologies and products that result from the

Table 1: Short-, Medium-, and Long-Term Benefits: Nonfinancial and Financial

Time frame	Benefit Type	Monetary	Nonmonetary
Short-term	access to corporate facilities and databases		X
	advance payments	X	
	bioprospecting fees (up-front fees)	X	
	payments per sample (sample fees)	X	
	share in research budget or equipment	X	
	fees to trust funds for conservation and sustainable use of biodiversity	X	
	research support for a project that is considered important or critical for the biodiversity collaborator	X	X
	publications that stem from the research activities of the biodiversity collaboration that is written by all parties to the agreement		X
	joint development and pursuit of grant opportunities to support and expand the biodiversity collaboration		X
Medium-term	acknowledgment in publications		X
	joint research and scientific capacity building		X
	administrative capacity building		X
	participation in planning and decision making		X
	protection of local existing applications of IP rights		X
	technology transfer (equipment, material donation, sharing of know-how)		X
	training in bioprospecting, collection, and preparation of samples; biodiversity monitoring, socioeconomic monitoring, and/or nursery and agronomic techniques (increased conservation capacity)		X

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Table 1 (continued)

Time frame	Benefit Type	Monetary	Nonmonetary
Medium-term	research support for a project that is considered important or critical for the biodiversity collaborator	X	X
	publications that stem from the research activities of the biodiversity collaboration that are written by all parties to the agreement		X
	joint development and pursuit of grant opportunities to support and expand the biodiversity collaboration		X
	commitment to resupply in source country		X
	research funding	X	
	milestone payments	X	
Long-term	co-ownership or sole ownership of IP rights		X
	development of alternative income generating schemes	X	
	free access to technology and products resulting from agreements		X
	research support for a project that is considered important or critical for the biodiversity collaborator	X	X
	publications that stem from the research activities of the biodiversity collaboration that are written or approved by all parties to the agreement		X
	joint development and pursuit of grant opportunities to support and expand the biodiversity collaboration		X
	percentage royalties on net sales	X	
	gross sales, license issue fees, and other revenues	X	
	participation in value added	X	

Source: Adapted from Liebig and from Tides Center/Biodiversity Action Network.[19]

collaboration. Across all three time frames, the parties could consider pursuing grant opportunities to expand their research activities, as well as working together to produce publications. The biodiversity collaborator might consider asking the company to provide research support for a project that is important to the biodiversity collaborator and is more easily implemented by incorporating the company's technology.

Box 1 contains an excerpt from a benefit-sharing section of a BAA and provides instances of both financial and nonfinancial benefits. While the actual percentages and dollar volumes have been removed (as they provide no useful insight without the details of the entire deal), this example illustrates a very specific royalty payment scenario in which sources of income have been separated and shared differentially. The agreement envisions revenue from both direct sales of the product by the company and from licensing to third parties. Proceeds from direct sales are shared on a graduated basis. The biodiversity collaborator receives a percentage of net direct sales up to a certain dollar limit. Should net direct sales exceed that amount the biodiversity collaborator will receive additional income. As an example, assume the net direct sales of US$150 million. If the agreement held that the biodiversity collaborator receives 0.5% of the first US$75 million in net direct sales, and 1.0% of net direct sales exceeding US$75 million, the biodiversity collaborator would receive US$1.125 million. For revenues derived from licensing, the agreement provides a similar graduated benefit-sharing mechanism.

The agreement presented in Box 1 has a royalty stacking provision. *Royalty stacking* occurs when there are multiple patents that affect the final product. It is often the case that a number of different patented items have been licensed for the development of a new product. The company developing the product may have to pay for the use of each of these patents, adding to the cost of commercialization. When multiple patents are held by third parties, the royalty structure may make a deal financially unattractive.[20] When one company holds multiple patents involved in the process, determining final royalty allocation is simplified. For the purposes of this discussion, each patent owner's rights to the product should be understood and considered in the business decision to proceed with the BAA. (For a more-detailed discussion on royalty stacking, see the World Intellectual Property Organization's Web site.[21])

In addition to royalties, which are based on the overall success of product sales and licensing efforts on the company's part, the biodiversity collaborator also receives milestone payments. These payments are performance-based payments rewarding the biodiversity collaborator for competently executing its responsibilities. The milestone payment is pro-rated to the level of collaborator performance. In the example in Box 1, the maximum amount is established as a percentage of the annual funding that the biodiversity collaborator receives from the company and can be based on a range reflecting the degree of success or progress achieved by the biodiversity collaborator. Alternatively, the milestone can be based on the completion of stages toward product development. One of the drawbacks associated with this latter approach is that it is frequently predicated on the company's success and leaves the biodiversity collaborator with little ability to influence the amount of payment received. Hence the former option is sometimes considered the preferred approach.

The excerpt in Box 1 also provides two examples of nonmonetary benefits. These nonmonetary benefits address technology transfer and on-site training (both at the company's and the biodiversity collaborator's laboratories). In this case, the company is training the collaborator in both advanced scientific methods and in the use of its proprietary technology. In addition, the company encouraged the collaborator to send employees to the company for training. This not only improves the scientific capacity of the employees, but also gives the employees access to professional resources that may not be available in their own laboratories. The training that takes place in the biodiversity collaborator's laboratory is critical. Often collaborator laboratory infrastructure requires updating, and lab protocols need to be changed, with the guidance of the company, to support different equipment

Box 1: Typical Benefit-Sharing Section in a BAA

1. **Royalties**

For each calendar year during the term of this Agreement, The Company shall pay to Collaborator a royalty based on Product(s) sold by The Company, its Affiliates and/or licensees as follows:

On The Company direct sales:

(i) A% of the first X U.S. dollars (US$ X) in Net Sales of Product(s) sold by The Company;

(ii) B% of Net Sales of Product(s) sold by The Company in excess of X U.S. dollars (US$ X);

On revenue The Company receives from licensees:

(iii) C% of the first X U.S. dollars (US$ Y) in Product Sales Net Revenues that The Company receives, recognizes as revenues, or is otherwise entitled to receive (without duplication) in such calendar year;

(iv) D% of Product Sales Net Revenues in excess of X U.S. dollars (US$ Y) that The Company receives, recognizes as revenues, or is otherwise entitled to receive (without duplication) in such calendar year; or

(v) In the event that The Company's compensation from its licensees does not include royalty payments on sales of Product(s) by such licensee, then The Company shall further pay to Collaborator a royalty of E% of all license fees actually received by The Company in consideration of such a license, including, but not limited to, license issue fees, annual maintenance fees and sublicense revenue.

No royalties are due on products made available to third parties for testing only.

All royalties are subject to a royalty stacking provision and a pro rata share of products made using the company's proprietary technology.

2. **Milestones**

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

(i) 100% complete environmental/isolate sample data sheets submitted for all environmental samples received by The Company within five (5) business days of receipt of the sample each calendar year;

(ii) Providing DNA for each sample when requested (for soil samples ensuring that both DNA and soil are sent for each sample);

(iii) 100% compliance with The Company protocols for DNA isolation;

(iv) 100% compliance with shipping protocols;

(v) Fulfilling specific sample requests according to sampling capabilities of Collaborator;

(vi) Achieved maximum coverage of biotopes or habitats; and

(vii) Responds to requests in a timely and professional manner.

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

3. The Company shall also provide Collaborator with training in technology for the molecular phylogenetic analysis of different habitats, including the following techniques ("Technology"): a) techniques for nucleic acid extraction from environmental samples; b) techniques for generating gene libraries; c) techniques for PCR cloning of genes directly from environmental samples; and d) information technology for DNA analysis.
4. Additionally, Collaborator may designate employees, at its sole discretion and expense, to visit The Company's facilities for purposes of training in the technology for an equivalent of one person for one month's time (for example, two people for two weeks, four people for one week, etc.).

Source: Excerpted and generalized from a redacted Diversa BAA that was submitted by the University of Hawaii to the Office of Information Practices in the State of Hawaii.

and supplies. It is also not uncommon for the biodiversity collaborator to improve protocols for the company and provide training and education in the opposite direction. This further enhances the biodiversity collaborator's probability for increasing its share of the benefits. While a superb example of a highly desirable and valuable nonmonetary benefit, it is not often available due to confidentiality requirements within companies.

4. POTENTIAL PITFALLS OF BIODIVERSITY ACCESS AGREEMENTS

The above guidance is meant to provide a practical framework highlighting the major issues for consideration when constructing a BAA. It has been distilled from more than a decade of experiences of companies and biodiversity collaborators. However, no discussion of BAAs could be complete without a cautionary note on the business and political circumstances under which the BAA will be created and implemented. These factors are as important as any listed above, and failure to adequately deal with them could prove fatal for the BAA. They can also add substantially to the costs of creating a BAA as they require significant time, effort, and resources to resolve. A brief discussion of these issues is presented below.[22]

4.1 *Valuation versus negotiation*

Given that there is no established market for biodiversity resources or databases with details of other BAAs, valuation of the biodiversity resource will ultimately come down to discussions between the biodiversity collaborator and company. As with all negotiations, parties are well advised to understand the motivations and interests of their negotiation partners. Biodiversity collaborators and companies will need to have the overarching goal of making cooperation work, and will have to be flexible enough to incentivize their partners (and to respond to any incentives partners offer) fairly, in the context of the agreement.

From the collaborator's point of view, the best knowledge to have when negotiating for monetary benefits would be the level of profit that the company expects. In practice, this figure would be very difficult for the collaborator to obtain. Companies will be reluctant to share projections for many reasons, not the least of which is their desire to maximize profit. Even the best projections of future profit are just that, projections, and subject to varying degrees of risk, only a portion of which can be mitigated. Moreover, a corporate proclamation of an attractive potential profit will provide incentive for other companies to compete, possibly reducing the value of their future profit. Regardless of the reasoning, collaborators are unlikely to get an accurate picture of the expected profits from the deal.

Companies, too, would do well to study the terms of any previous BAAs available, especially those concluded with the intended biodiversity collaborator. Information about which nonmonetary benefits a collaborator would value would enhance the company's position and relieve some of the pressure to negotiate away projected profit.

Ultimately, the parties will either identify the right mixture of monetary and nonmonetary benefits to be distributed in the BAA, or lose patience with or confidence in their partners and walk away from the negotiating table without an agreement.

4.2 *Politics and perception*

Although the mechanics and structure of negotiating BAAs have become somewhat clearer over the past decade, not much has been clarified when it comes to the difficulties in politics and perception that companies face when attempting to create BAAs with biodiversity collaborators. Although biodiversity permit systems may be in place, the proposal of a BAA almost always creates controversy. Once a company states that it would like to create a BAA and establish a new standard for securing genetic resources from around the world, the most common response is for the governing authority to move extremely slowly, fearing that it will be accused of authorizing an inequitable agreement that undervalues their biodiversity and does not support their country's development. This problem can be further complicated by watchdog groups that consider the private sector to be inherently corrupt. No matter what benefits

the company offers, such groups will criticize the deal as inequitable to the biodiversity collaborator. Ironically, this reaction reflects negatively on the very companies that are taking the lead in supporting the CBD. Unfortunately, those companies wishing to construct BAAs based on the principles of international conventions are seen in the same light as those companies that continue their research without any benefit-sharing arrangement and without permits. All of this has created an atmosphere in which life science corporations have been given every incentive to avoid engaging in bioprospecting and divulging or sharing any information about such endeavors. This actually makes it more important for biodiversity collaborators to seek out companies that are willing to take the step towards building a new approach to discovering products from nature, an approach that respects the economic interests and property rights of the nation providing the biodiversity (genetic resources).

Another complicating factor is that parties to the CBD have been slow to implement legal frameworks that facilitate legal access to their biodiversity and provide guidance on accepted or preferred benefit-sharing arrangements. Furthermore, the measures taken to date have been diverse in terms of their scope and their clarity. Compared to those countries that have created a simple, efficient approach, countries that have chosen a more cumbersome, comprehensive approach have generally had little participation from bioprospectors. Nonetheless, many countries remain without any legal frameworks to govern bioprospecting, allowing some companies to engage in bioprospecting without securing legal access to collect environmental samples and without providing associated equitable benefits.

The case of politics and perception is similar to that of benefit sharing in that both parties must demonstrate a willingness to make the BAA and successive agreements work. This requires each party to set aside short-term self-interest.

4.3 *The shortcomings of business as usual*

In addition to the practical challenges of negotiation and politics, there are several issues with current research sampling practices that will continue to grow in importance as more BAAs are concluded and the market for products developed as a result of the BAAs develops further. Often, samples collected for research purposes will be "contaminated" with types of biodiversity other than the target type. This unintended transfer of genetic material may constitute giving away potentially valuable (with respect to its potential for commercialization) biodiversity. Another issue that will become increasingly contentious is that limiting access to biodiversity may have a detrimental effect on scientific research. While these issues may not surface in a BAA between a company and its biodiversity collaborator in the near term, they will certainly have to be addressed in the longer term for the sake of scientific advancement and the conservation of global biodiversity.

4.4 *Addressing the pitfalls*

Many of the problems identified above could be mitigated or eliminated by improving the information available to parties to the BAA as well as to the larger pool of stakeholders interested in the outcomes of these agreements. Parties to the BAA want to know that they are being fairly treated. Collaboration partners want to understand the fair value of access and local value-added processing. Companies need to understand the amount and composition of compensation required to create the BAA. Companies can face higher commercialization costs in the absence of this information. The relative lack of standard information on BAAs can engender feelings of mistrust not only among the parties to the BAAs but also in stakeholders outside the agreement. Standards for creating BAAs, based on the experiences of many biodiversity collaborators and companies, would give the parties to the agreement a reliable and acceptable framework to aid decision making, negotiations, and communications about the agreements. These standards could even extend beyond the terms of the BAA to include model legislation and regulations to provide consistency to the legal and administrative environments in which BAAs will be created. Standards for BAAs could address the longer-term issues

as well by explicitly discussing the rights and responsibilities of researchers and providing guidance on accessing IP-protected biodiversity for noncommercial purposes.

Participation by NGOs may be one way to address these issues. The main benefit of NGO involvement would be credibility. NGOs operating independently as neutral third parties can build trust among partners on both sides of the BAA. This neutrality could satisfy stakeholders outside the BAA, concerned with broader issues of biodiversity conservation and continued access to biodiversity for scientific research. NGOs would be able to leverage the expertise and experience of governments, research organizations, other NGOs, and companies globally to provide standards that are broadly applicable.

An example of an NGO making progress in this direction is the E. O. Wilson Biodiversity Foundation. Through the creation of its BioTrust, envisioned and initiated by one of the authors, Jay Short, the foundation seeks to ensure fair terms between countries and companies for access to biodiversity while preserving the biodiversity resources. BioTrust consortium establishes strategic relationships predicated on the notion that all countries (especially developing counties) contain wealth in the form of biodiversity and that they should be compensated for its exploitation. Saddled with the burden of long-term stewardship, most countries are currently without a financial incentive to continue.

By acting as an honest broker using a master agreement that binds the interested parties to a quid pro quo relationship, BioTrust ensures the fairness sought by the parties to the access agreement and the continuation of biodiversity conservation. Under this model, companies, as well as academic and research institutions, can sample and analyze genes, small molecules, and proteins, but a portion of revenues produced from any resulting products flows back to the country of origin for purposes of conservation. BioTrust participants agree to participate in capacity building through technology access and/or education for source nations.[23]

5. CONCLUSIONS

The experience of companies and countries in creating BAAs to share access to microbial biodiversity offers lessons that can be adapted for use with agrobiodiversity. These lessons will help interested parties bridge the gap between broad international guidance on the commercial use of biodiversity and the practicalities of deal making. Just as important as any technical aspect of deal making is the commitment of both parties to a sustainable and rational use of biodiversity in a way that encourages commercial development and protects the unique resource. Both parties need to conduct the due diligence on each other to foster the trust required for cooperation.

Companies should devise a set of operating principles based on the CBD and provide partners with real incentives for cooperation, which should include both equitable monetary and nonmonetary benefits. Countries must develop, clarify, or streamline administrative and permit procedures to encourage the sustainable, commercial use of biodiversity. They must also have the resolve to operate in a principled manner, consistent with international consensus (CBD). Both parties should be willing to engage in open debate with domestic and international critics to demonstrate the value of making progress in this field, despite having limited knowledge about the market potential of biodiversity-derived products.

There are a number of practical challenges to concluding BAAs. Many of these challenges could be addressed by improving information available to all stakeholders. NGOs could play a critical role in facilitating fair access to biodiversity for commercialization while preserving scientific access to biodiversity for research purposes. ■

CHARLES COSTANZA, *Consultant, 1304 North Avenue, NE, Atlanta, GA, 30307, U.S.A. chuckcostanza@yahoo.com*

LEIF CHRISTOFFERSEN, *Associate, E. O. Wilson Biodiversity Foundation, 10190 Telesis Court, San Diego, CA, 92121, U.S.A. leif@eowilson.org*

CAROLYN ANDERSON, *President, Capia IP, 10190 Telesis Court, San Diego, CA, 92121, U.S.A. Carolyn@Capiaip.com*

JAY M. SHORT, *Founder, President, and Chairman, E. O. Wilson Biodiversity Foundation, 10190 Telesis Court, San Diego, CA, 92121, U.S.A. jshort@eowilson.org*

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8 See *supra* note 2.

9 For the sake of clarity, the term *biodiversity collaborator* is used to describe the country granting access, as well as its institutions, universities, and researchers. The term *company* is used to describe any corporation, NGO, university, or research organization that could commercialize biodiversity or genetic resources.

10 Contact information for the National Focal Points for Access and Benefit Sharing can be found on the CBD Web site at www.biodiv.org/world/map.aspx. Once at that Web site enter the name of the country for the list of the National Focal Points for each country. See, also in this *Handbook*, chapter 16.2 by C.G. Thornström.

11 See *supra* note 9.

12 There are 188 parties to the Convention out of a possible 195. The nation states that have yet to ratify the CBD and become members are 1) Andorra, 2) Brunei Darussalam, 3) Holy See (Vatican), 4) Iraq, 5) Somalia, 6) Timor-Leste, and 7) the United States.

13 Uniqueness in this chapter means a resource has not been commoditized in a particular place or situation.

14 This text was excerpted and generalized from a redacted Diversa BAA that was submitted by the University of Hawaii to the Office of Information Practices in the State of Hawaii.

15 Tides Center/Biodiversity Action Network. 1999. Access to Genetic Resources: An Evaluation of the Development and Implementation of Recent Regulations and Access Agreements. *Environmental Policy Studies Working Paper No. 4*. Columbia University School of International and Public Affairs, p. iii. www.biodiv.org/doc/case-studies/abs/cs-abs-agr-rpt.pdf.

16 See *Supra* note 7.

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22 The authors will address these issues and strategies for dealing with them in a forthcoming paper.

23 For more information on the E. O. Wilson Biodiversity Foundation, visit itsWeb site at www.eowilson.org.