

# Balancing Access and Benefit Sharing and Legal Protection of Innovations From Bioprospecting Impacts on Conservation of Biodiversity

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Biodiversity conservation, access and benefit sharing (ABS), and protection of intellectual property rights (IPR) linked to biotechnologies are all internationally agreed—but not necessarily compatible—objectives. The Convention on Biological Diversity aims for a balance between the needs and interests of owners of genetic resources and technology owners. Can current proposals for handling existing IPR legislation, such as disclosure of origin and certificates of legal provenance, contribute to finding a balance between the interests? Will the growing concern for legitimacy in international transactions with genetic resources be helpful to countries providing genetic resources for technological innovation or are the benefits too few? The article concludes that the success of establishing a multilateral system for access and benefit sharing still depends on compatible legislation in user and provider countries to counterbalance strengthened patent protection systems worldwide. Moreover, it is necessary to overcome the old schism between wildlife conservation and access issues in agricultural biodiversity to boost overall implementation efforts.

**Keywords:** *biodiversity; genetic resources; intellectual property rights; access and benefit sharing; international negotiations*

## Introduction

The Convention on Biological Diversity (CBD) constitutes an elaborate framework for balancing the objectives of biodiversity conservation in developing countries with the sharing of benefits arising from the use by industrialized countries of biogenetic material from these countries. Other international fora pursue more

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narrow objectives relevant to CBD objectives. Within the United Nations (UN) Food and Agricultural Organization (FAO), an international system has been developed that is aimed at securing access to a list of plant genetic resources to enhance plant breeding and food security. Agreements under the World Trade Organization and the UN World Intellectual Property Organization (WIPO) are primarily concerned with the protection of intellectual property rights relating to all technological inventions, including those in biotechnology. Biodiversity conservation, access and benefit sharing (ABS) from the use of genetic resources, and the protection of Intellectual Property Rights (IPR) to stimulate innovation are all internationally agreed objectives, but they are not necessarily compatible. The stakeholder debate and even much of the literature in this field tend to consider either ABS or protection of IPR as the priority concern. Taking the CBD framework as a point of departure, this article argues that the various objectives cannot be made compatible, but rather, a pragmatic balance must be sought between the needs of users and providers of genetic resources. As the goal for enhanced conservation—halting the loss of biodiversity—is still far from being achieved (Millennium Ecosystem Assessment [MEA], 2005), it is pertinent to inquire into the current state of proposals and measures aimed to contribute to such a balance in the various international fora.

Compared to the strong economic interests tied to IPR and ABS, biodiversity conservation produces less immediate economic benefits and conservation advocates are generally politically weaker stakeholders. Various interest groups recognize the economic potential of both ABS and IPR and are pursuing their interest in partly competing international negotiation fora. How do these international regimes promote synergy or conflict between these concerns and do they ultimately have the potential to encourage biodiversity conservation?

To tackle these questions, it is necessary first to assess how different policy objectives incorporated in different international agreements are being implemented nationally and what makes countries comply. To catch some of the nuances of how implementation can be assessed, I examine some of the main barriers and options for achieving a balance between said objectives by using a neorealist and an ideational perspective as simple theoretical frameworks that can help guide the analysis. The two perspectives, and the scholarly contributions associated with each of them, predict and identify different mechanisms and substantiating factors that determine outcomes. The neorealist view perceives states as unitary, rational actors and predicts outcomes in line with the interests of structurally dominant states determined by an abstract and always clearly identifiable national interest. Countries with a high level of technological development are best served by a system that grants them free access to genetic resources and at the same time provides protection of intellectual property rights that allows them to reap benefits from technological innovation. This system is primarily supported by the World Trade Organization (WTO) and WIPO. The more ideational-based approaches are based on the hypothesis that nonstate actors, such as international organizations and agreements (regimes), matter and promote learning processes and the generation and acceptance of common norms and

ideas (see Haas, Keohane, & Levy, 1993; Young, 1991).<sup>1</sup> Although states are likely to pursue what they perceive to be in their best economic interest, the learning process can change the view that countries have about the sharing benefits of using genetic resources, with countries providing those resources.

This article starts out with a description of the background and contents of the CBD objectives relating to conservation, access, and equitable sharing of benefits from genetic resources.<sup>2</sup> The aim here is to provide insight regarding the elements that need to be considered for a balance to be achieved. The next section discusses to what extent there has been interaction between the CBD and multilateral agreements under the FAO, WTO, and WIPO with respect to biodiversity-related subject matters. The third section looks at examples of implementation of provisions relating to benefit sharing, access to genetic resources, and protection of intellectual property rights at the domestic level among private firms and involving public actors. Positions of key countries in the current ABS negotiations taking place under the auspices of the CBD also are analyzed. The two theoretical frameworks introduced previously are used to analyze what drives outcomes in the debate and to shed light on what can be expected in the near future.

### **Looking Back: Biodiversity in International Negotiations**

Some knowledge of the historical negotiation process is necessary for understanding different viewpoints between users and providers of genetic resources and also for exploring the scope for a balanced implementation of provisions. There is broad political and scientific consensus about the need to stop and reverse the loss of biodiversity, and the international response goes back to the early 1970s with the Ramsar Convention for wetlands, the Convention on Migratory Species (CMS), and the Convention on Trade in Endangered Species of Flora and Fauna (CITES). The current rate of species extinction is extremely high compared to the natural average rate, not least in developing countries in the South (Heywood, 1995, p. 232; MEA, 2005; Wilson, 1988). Similarly, there is a rapid loss of genetic diversity in domesticated plants, with potential risks for food security (Food and Agriculture Organization [FAO], 1998). At the same time, economic interests linked to biotechnologies using genetic resources are soaring. For instance, it is estimated that U.S. biotechnology generates annual revenue of U.S.\$13 billion (Chambers, 2002) and the estimated value of products derived from genetic resources worldwide is between U.S.\$500 and 800 billion (ten Kate & Laird, 1999). The combined effect of these two trends has been a greatly enhanced interest in intellectual property rights and access to genetic resources. Another effect is that stronger links have been forged between acknowledged value and acknowledged loss.

The novel trait of the CBD compared to earlier species and habitat-oriented conventions is its comprehensive scope. The international debate on the CBD did not focus solely on conservation—a Northern concern—but also on the issues of

distribution and equity (Koester, 1997). The power and interest constellation characterizing the negotiation phase of the CBD (1989-1992) can be better understood by considering the following five factors. As indicated by the dates of cited sources, these five factors influenced the debate during the CBD negotiations and still characterize the issue area.

First, the main bulk of terrestrial species diversity is found in tropical areas in poor parts of the world (United Nations Environment Programme [UNEP], 1995). Second, genetic resources constitute important input factors for biotechnology and are of critical importance to agriculture, pharmaceutical, and chemical industries. Wild relatives of domestic crops provide genetic variability that can be crucial for overcoming disease outbreaks or adjusting to climatic changes (Kloppenborg, 2004; Kloppenborg & Kleinman, 1987). Species may contain genetic compounds that may be used in pharmaceutical products with great commercial value. Bioprospecting refers to the activity of searching for potentially valuable genetic resources and biochemical compounds in nature (World Resources Institute [WRI], 1993). Making any accurate assessment of the potential value of such genetic resources is difficult due to the fact that still little is known about the extent of the world's biodiversity. For example, microbial diversity and the diversity of marine species are largely unknown; the deep sea may rival tropical forests in species diversity (Haefner, 2003; Laird & Wynberg, 2005; Swanson, 1995, p. 105).

A third important element is how several biotechnological inventions build on food and medicinal plants that originate in the South as well as on traditional knowledge about valuable properties of plants or animal products. For more than a hundred years, plant material was collected free of charge and stored in international gene banks (Barton & Siebeck, 1992; Kloppenborg, 2004; Mooney, 1983). A much-cited case from medicine is the Rosy Periwinkle (*C. roseus*), a native plant of Madagascar. Since this story appeared in *New Scientist* in 1992, it has made a considerable impression on environmental and developmental circles, even though its integrity on some points has since been challenged. The drug reportedly generated an annual U.S.\$200 billion, none of which was returned to the country of origin (Gehl Sampath, 2005, p. 23). Traditional knowledge has been found to increase the success ratio of bioprospecting by 400% (Gehl Sampath, 2005). Screening results from Shaman Pharmaceuticals revealed that of the samples that displayed promising chemical activity, 74% directly correlated with the original ethnobotanical use, that is, traditional knowledge (Sheldon & Balick, 1995, p. 59). Fourth and also related to technological innovation, the development of modern biotechnology coincided with increased privatization of agricultural and pharmaceutical research in the 1970s. This brought about an economic incentive to introduce patent protection coinciding with a technological capability to apply patents in the field. Biotechnology made it possible to fulfill the legal patent criteria for inventions involving biological material (Crespi, 1988). A fifth factor influencing the power constellation in negotiations relates to the difficulty to provide similar legal protection to traditional knowledge

as to commercial innovation. This problem is accentuated by patenting being a very costly affair, largely dominated by multinational corporations (Gleckman, 1995). In the late 1980s, developing countries held only about 1% of all patents in biotechnology, and by 2005, that figure had increased to only 4% (United Nations Development Programme [UNDP], 2005, p. 135; World Commission for Environment and Development [WCED], 1987).

All of these factors combined to increase the awareness of an existing imbalance between users and providers of genetic resources. This is the background for developing countries' claim for national sovereignty over genetic resources. They argued that there is an inequity inherent in the fact that, for all practical purposes, their genetic capital was still considered a Common Heritage of Mankind, freely accessed by all (Raustiala & Victor, 2004; Rosendal, 1991). At the same time, they themselves must pay an increased price for access to improved breeding materials and medicines as these become subject to patent protection. This perception of the situation was disputed at the time. The United States initially wanted the CBD as a conservation treaty only (Andersen, 2006), fearing that linking the packages of conservation and benefit sharing would hamper negotiations on a biodiversity convention (Porter, 1993; Rosendal, 1991). Putting a price tag on biodiversity might disclose how profits in the agricultural and pharmaceutical sectors in the North are extracted from genetic resources from the South. Likewise, environmental and wildlife management nongovernmental organizations (NGOs) such as the International Union for Conservation of Nature and Natural Resources (IUCN) and the World Wide Fund for Nature (WWF) feared that no conservation agreement would be reached, either for wild or domesticated species, if the latter were to be included in the negotiations (Rosendal, 1991, p. 33).

## **Establishing the CBD**

Nevertheless, in the words of the executive director of the United Nations Environment Programme (UNEP), Mostafa Tolba, at the time of the CBD negotiations, it was important that "a balance should be struck between the legitimate rights of germ plasm owners and technology owners, recognizing the needs of both" (Tolba, 1998, p. 144). He concludes that the prompt approval by 157 countries of the convention after very difficult negotiations is an indication that such a balance must have been accomplished in the text (Tolba, 1998, p. 159). The CBD seeks to find a balance through three main objectives: (a) conservation, (b) sustainable use of biodiversity; and (c) fair and equitable sharing of benefits arising out of the utilization of genetic resources. Equitable sharing is regarded as a prerequisite for achieving the objectives of conservation and sustainable use.

The CBD was signed at the UN Conference on Environment and Development in Rio de Janeiro in 1992. With a view toward the use and equitable sharing of benefits, the CBD seeks to counterbalance the expanding patent regime by exchanging

the Common Heritage principle with that of national sovereignty over genetic resources (Koester, 1997; Rosendal, 2000). The CBD was largely formulated as a compromise between access to technology and access to input factors—genetic resources. In article 16.5, the Parties are asked to ensure that intellectual property rights do not run counter to the objectives of the CBD. Through article 15.7, the CBD Parties have accepted the aim of “sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial utilisation of genetic resources with the Party providing such resources.” Article 15.2 encourages Parties to “create conditions to facilitate access to genetic resources for environmentally sound use.” Without access, it is presumed there will be fewer benefits to share. Without benefit sharing, it is suggested that there will be fewer resources conserved for future use. Hence, prior informed consent (Article 15.4) and mutually agreed terms (Article 15.5) are meant to guide access to genetic resources. Since signing the CBD in 1992, the Parties spent 10 years negotiating access and equity, resulting in the voluntary Bonn Guidelines (2002) on access and benefit sharing (ABS). The guidelines suggest concrete measures on the following:

- How to include the principles of prior informed consent (PIC) and mutually agreed terms (MAT) in bioprospecting agreements,
- How to deal with traditional knowledge (TK) on an equitable basis,
- Disclosure of holders of traditional knowledge and country of origin in patent applications, and
- A certification system for trade in genetic resources.

The emerging consensus in the CBD negotiations was boosted by the coherent negotiating stance of developing countries as a block, many of whom harbor great biodiversity. On the other side, the industrialized countries, with their growing biotechnology sector, were concerned about maintaining free access to genetic resources. The CBD stipulates both open access to genetic resources as well as that developing countries have the sovereign right over their genetic resources and should share in the benefits derived from using them in commercial products.

An open question explored in the following is whether the agreement on access and benefit sharing (ABS) is more than a symbolic victory for the South. The CBD aims to enhance ABS to strengthen incentives for biodiversity conservation in developing countries. This CBD objective for conservation has later been translated into a goal of halting and reversing the loss of biodiversity by 2010 (UNEP/CBD/Conference of Parties to the United Nations [COP6]/Decision 26, The Hague, the Netherlands, 2002). However, the general verdict on implementation of this goal is not good. On one hand, the percentage of protected areas has doubled from 6% or 7% to 12% since 1990; on the other hand, the quality of protection is still contested (MEA, 2005, p. 11). In 2005, the Millennium Ecosystem Assessment concluded that especially poor countries are not getting any closer to reaching the objective of conservation and sustainable use

of biodiversity (MEA, 2005). Although rates of habitat loss are decreasing in temperate areas, they are projected to continue to increase in tropical areas (MEA, 2005, p. 14). Although most countries in the South acknowledge global environmental threats, including the loss of biodiversity, under real-world circumstances, they have limited capacity to deal with such problems. The South has argued that it is the responsibility of rich countries to assist them in dealing with environmental problems.

### **Interaction Between Multilateral Agreements: Current State of Balance**

Scholars studying implementation of multilateral environmental agreements increasingly take interaction between international agreements into account. Interaction indicates the idea that effective implementation of one convention may affect the implementation of another (Oberthür & Gehring, 2006; Rosendal, 2001; Young, 1996). A better understanding of potential synergies and incompatibilities is thus important for implementation of various international provisions. The next section discusses two other sets of multilateral agreements, which interact with the CBD in the issue area of genetic resources. The relationship between the CBD, Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), and WIPO and the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA) illustrates the problem of incompatible objectives within overlapping issue areas, or regime complex, in the words of Raustiala and Victor (2004).

#### **The ITPGRFA of the FAO: Ensuring Access to Seeds for Plant Breeding**

Historically, seeds were treated as a Common Heritage of Mankind (CHM), as apparent in the long traditions in collecting plant material free of charge and storing it in international gene banks. The advent of patents and plant breeders' rights brought about monetary restrictions on systematically bred plant material and developing countries put the contested issue on the FAO agenda in 1979. The FAO Parties agreed on an International Undertaking for Plant Genetic Resources in 1983, which established that all seeds should be subject to the CHM principle—freely accessible to all—be they wild, traditional cultivars, gene bank collections, or systematically bred material (Rosendal, 1989). Six years later, the Undertaking was renegotiated to waive the CHM principle for patented plant material. As a result, the contested issue found its way into the CBD negotiations. Because the CBD did not explicitly address and resolve the problem for plant genetic resources in gene banks, the access issue returned to FAO.

In 2001, FAO established the ITPGRFA. The Treaty aims to secure access to seeds from a specified list of the most central food plants. The material, it is agreed,

must remain freely available and not become subject to patents “in the form received” from the FAO multilateral system, that is, international gene banks (Article 12.3). This is meant to contribute to securing farmers’ rights to use and reuse their seeds and to retain access to breeding material (Andersen, 2006).

### **WTO/TRIPS and WIPO: Innovation Through Strengthened Intellectual Property Rights**

The WTO was established in 1994 along with TRIPS. The WTO negotiation process—the General Agreement on Tariffs and Trade (GATT) Uruguay Round from 1988 to 1993—coincided with that of negotiating the CBD. The aim of the TRIPS Agreement is to stimulate technological innovation through harmonization and strengthening of domestic patent legislation by all WTO members. The TRIPS does not create a single, universal patent system. It aims to harmonize, strengthen, and expand the scope for patent protection in domestic patent legislation in member countries.<sup>3</sup> As multinational corporations seek patent protection around the world, they depend on each country’s patent office to grant patent rights in a uniform manner. The TRIPS Agreement laid down the ground rules for what must be protected by some kind of intellectual property right, including plant varieties and pharmaceuticals.

National patent legislation is largely drawn from international conventions, administered by WIPO. WIPO is presently negotiating a stronger version of harmonization of IPR systems: The draft Substantive Patent Law Treaty (SPLT) aims to achieve international harmonization on patent applications, core terms, and patent criteria (Tvedt, 2006). It is by strengthening and expanding the patent system to the new field of biotechnology that these regimes interact with the other objectives of access to, benefit sharing, and conservation of genetic resources (see Tolba, 1998, p. 144).

### **Institutional Interaction and the Balancing Act**

Learning through norm diffusion may account for the fact that the CBD objective of benefit sharing is now taking center stage in a number of international arenas.<sup>4</sup> The Conference of Parties to TRIPS has been instructed in the Doha Ministerial Declaration (Dutfield, 2001) to examine the relationship of its provisions with those of the CBD. The main focus has been on the issue of disclosing the origin of genetic resources used as a basis for inventions when applying for patents. Moreover, UNESCO is addressing traditional knowledge and intellectual property by developing model provisions on the protection of folklore. WIPO also has taken up the discussion of protection of traditional knowledge in its Intergovernmental Committee on IPR, Genetic Resources, Traditional Knowledge, and Folklore.

Looking at incentives for innovation through intellectual property rights, there are, at first glance, several indications that the TRIPS agenda has not been overly persuasive worldwide. First, the TRIPS Agreement is in itself open ended, leaving it

to the WTO member states to decide on the legal protection of plant varieties.<sup>5</sup> Each country may choose to take environmental and socioeconomic considerations into account, and plants and animals may be exempted from patenting altogether (Article 27[3] [b]). Second, most of the least developing countries have so far not complied with TRIPS and they have been granted an extended transition period for doing so. Several newly developed countries have seen it in their interest, however, to comply with TRIPS to gain market access, attract foreign direct investments, and avoid trade sanctions (Sell, 2002). Third, the WTO Doha Round is fraught with contentious and unresolved North-South issues, of which TRIPS is only one among many. India highlighted IPR and access to medicines and vaccines, disclosure of origin of genetic resources, and relationship to the CBD as the main TRIPS-related issues that needed to be resolved for a successful outcome of the WTO Ministerial Conference in Hong Kong in December 2005, a meeting that ended in failure.

The diffusion of norms to other international institutions can be seen as a sign that a convergence in policy objectives is emerging. Looking beyond negotiation agendas and examining the actual behavior that results from negotiation outputs, however, a neorealist model provides the best explanation.

First, there are no indications that technologically dominant parties will accept disclosure of origin in patent applications concerning genetic resources. WIPO, with its 180 member states, is becoming increasingly important for strengthened IPR systems. Similar to TRIPS, this arena also is used to negotiate standardization of patent criteria in the members' domestic legislation. The dominant parties in this arena seek to bring the scope for patenting further than did TRIPS, and there is very little inclination among the developed countries to open up for additional patent criteria, such as the proposal on disclosure of origin (Tvedt, 2005). It is uncertain how, if at all, the WIPO negotiations on folklore and traditional knowledge will affect these other WIPO negotiations on a draft SPLT (Rosendal, 2006b).<sup>6</sup>

Second, it is most important to consider bilateral activities outside of TRIPS. The United States, European Free Trade Association (EFTA), and European Union (EU) are signing bilateral trade agreements with an increasing number of developing countries. These bilateral agreements are frequently referred to as "TRIPS plus" agreements because they demand stronger and wider patent protection compared to TRIPS (Dutfield, 2001). TRIPS plus agreements tend not to include any transition period for complying, whereas the period of IPR protection is prolonged (El-Said, 2005). In addition, TRIPS plus agreements tend to limit the grounds for allowing the use of compulsory licensing of medicine, and in several cases, they do not allow for plants and animals to be excluded from the patent laws of signatory countries. This threatens access to affordable medicines and valuable breeding material (Choudry, 2005). These treaties are negotiated by states and will most benefit the dominating transnational corporations in the life sciences (Pistorius & van Wijk, 1999).

Third, the bilateralism so far sanctioned by the CBD when it comes to implementing benefit sharing arrangements on "mutually agreed terms" only adds to imbalance:

An important indication of the asymmetric power relations appears as the international trade with genetic resources is left to bilateral agreements (TRIPS plus) between those primarily providing and those primarily using these resources. The least developing countries generally have low negotiating power in bioprospecting deals, stemming from several sources: First, only few countries have the necessary administrative capacity to monitor bioprospecting deals (Svarstad & Dhillon, 2000). Genetic resources are not sold in bulk so their value lies in qualitative traits (e.g., such as oil and minerals). Second, negotiation power is likely to remain low due also to the fact that biological material does not necessarily follow political borders (Schroeder, 2000). The rosy periwinkle also is found in Jamaica, illustrating the problem of identifying providers of genetic resources as a basis for benefit sharing. The country of origin cannot always be identified and thus the question of what country should benefit from bioprospecting deals may be difficult to resolve, adding to the weak negotiating position for stakeholders (Fowler, 2001).

In sum, the main bulk of the evidence from the bi- and multilateral level would seem to support the conjecture drawn from a neorealist view—norms count but power decides. The rapid growth of bilateral trade agreements is a strong indication that industrialized countries, pushed by strong multinational corporations, have succeeded in advancing their goals for strengthened IPRs and patent systems.<sup>7</sup> An important proposed user measure—disclosure of origin of genetic resources—has yet to be accepted internationally and integrated in patent legislation in user countries. The bilateral implementation provisions so far stipulated in the CBD on benefit sharing are not helpful in terms of empowering poor countries in bioprospecting deals. Moreover, although the CBD does include a number of important norms and principles aimed at such empowerment and equity, the CBD is poorly equipped with enforcement mechanisms compared to the WTO system (Rosendal, 2006a). Still, we know little about implementation in terms of the behavior of public and private actors in bioprospecting deals. A closer examination of positions in the ABS debate in the CBD also may shed light on the prospects for future bioprospecting deals. This will be further explored in the next section.

### **Looking Ahead: The Implementation Phase**

Today, five main arguments can be identified that affect the discussion on negotiating concrete steps for implementing access and benefit sharing:

The first argument is that too rigorous an application of intellectual property rights causes imbalance by undermining equity. Some speculate whether the effect from IPR systems may indirectly weaken indigenous and local groups in their efforts to achieve bilateral agreements on bioprospecting (Gebhart, 1998). Fauchald (2001) points to the problem that strengthened IPR systems in the developed countries are undermining the economic value of the original genetic resources. There are, as yet,

no alternative models to IPR laws for protection of traditional knowledge. The knowledge in its traditional form and the nonsystematically bred cultivars hardly fulfill general patent criteria. On the contrary, it is disputed whether traditional knowledge (e.g., of medical properties of a certain plant) constitutes prior art; hence, misappropriations occur (World Intellectual Property Organization [WIPO], 2005). In effect, it is argued that patenting may be incompatible with the CBD policy objective of equitable sharing of benefits (Correa, 1999; Egziabher, 1999; Hendrickx, Koester, & Prip, 1993).

A second argument is that too rigorous an application of intellectual property rights causes imbalance by undermining access to genetic resources. The uneasy relationship between ABS and IPR systems concerns not only benefit sharing but also the question of access to improved breeding materials in agriculture and to vaccines and medicines from the pharmaceutical sector. Since the time of the Chakrabarty case in 1980, patents in biotechnology have become increasingly broad and the patent criterion of the inventive step has been lowered in tune with a narrow practice of looking for prior art (Barton & Berger, 2001; Safrin, 2004). Barton and Berger (2001) conclude that "it may be very expensive or difficult for the public sector to gain access to patented technologies or to use protected varieties for research in developing new applications for the smaller crops or subsistence farmers." Regarding the pharmaceutical sector, Médecins Sans Frontières (MSF, 2001) argues, "In fact, patents may actually hamper medical research in developing countries. Patents are often owned by private companies or research institutions that during the period of protection put limits on research knowledge. Molecules that could be promising for the treatment of neglected diseases are consequently not easily accessible for research."

Third, it is argued, improved access may undermine conservation. In the field of bioprospecting and the search for pharmaceutical and chemical components, the effects of access itself also are contested. On one hand, access to wild resources is a prerequisite for both innovation and ensuing benefits for sharing. A well-functioning access regime may hence provide an incentive for conservation. On the other hand, unrestrained access may undermine conservation if it leads to excessive harvesting of scarce resources. This problem is not really resolved if the end products are derived from synthetic processes or from plantations because that also would provide few incentives for conservation. The primary conservation incentives are hence likely to be linked to ecosystems where the large diversity of organisms and their potential benefits are still unknown (Sheldon & Balick, 1995). This argument is less widely applied in the negotiations.

A fourth argument is that too much focus on benefit sharing causes imbalance by undermining access and innovation. Some claim that emerging ABS legislation can hamper both bioprospecting and biodiversity conservation, as scientific examination of tropical species is being hindered by cumbersome access regimes (Grajal, 1999). For instance, a proposed ABS regime is found to be extremely costly for biotechnology

research, with an estimated loss of U.S.\$79 billion throughout 20 years in the EU alone (Pacific Research Institute for Public Policy [PRI], 2005). From the agricultural sector, it is similarly argued that this type of regulation will reduce access to important genetic material for plant breeding for food and agriculture (Fowler, 2001). This concern was among the driving forces to establish ITPGRFA (Adhikari, 2005; Andersen, 2006).

And finally, it is argued that fair and equitable benefit sharing is unrealistic and hence inadequate as an incentive for conservation. First, a common inquiry is how it will be possible to establish the country of origin of the material that formed the basis of a marketable product. Second, a company may claim that the product has been modified from its naturally occurring state or from the original traditional use and, hence, is no longer the original material to which benefit sharing applies. This raises a number of questions, such as what impact new disclosure requirements about country of origin in patent legislation may have on innovation, how a new disclosure requirement may transfer benefits, and whether it may actually promote ABS in an effective manner. Related to this, some argue that the emerging legal regimes to regulate access to genetic resources in the South may be based on unrealistic expectations of benefits (ten Kate & Laird, 1999). The argument is that most multinational seed corporations are self-sufficient, with breeding material for most of the commercial crops (ten Kate & Laird, 2000).

The above discussion has shown that there are certainly links between access and benefit sharing, conservation, and protection of private property rights, although the causality between them is much disputed. Right or wrong, the fate of the ABS objectives will be important for how the providers of germ plasm interpret their success and failures and, in turn, how they will view the legitimacy of carrying out their international obligations with a view to conservation.

## **Implementation Activities at National and Corporate Level**

Looking at implementation activities at the corporate and domestic levels, are the objectives implemented in a balanced manner or are some of the objectives doing better than others? The answer to these questions will be significant for the future legitimacy of biotechnology and future efforts to conserve biodiversity. The answer also depends on where you look, and the next section briefly reports on the fate of these objectives in the private and public sector, as seen from two different perspectives.

A number of trends and examples can be found on both decreasing and increased balance. It is not difficult to find examples of norm diffusion in bioprospecting deals (Laird, 2000). Here, there is an increased acceptance of ABS legislation, including the CBD principles of prior informed consent and mutually agreed terms, as well as concern for the rights of holders of traditional knowledge (TK) through disclosure of origin and certification. The first and only synthesis report on case studies on benefit sharing for the CBD (UNEP, 1998) concluded that all aim at equitable sharing;

however, no benefits had yet been derived from commercialization of a product. This is supported by the finding that the principle of equitable sharing of benefits is increasingly accepted among larger and socially responsible companies that are users of genetic resources (Laird & Wynberg, 2005, p. 5).

The effect of this trend will, however, depend on developments regarding the fifth argument: Whether there may be benefits to be shared will partly depend on how great the interest in access to natural resources is. In a thorough study of the varying needs and interests for wild genetic resources among biotechnology and seed sector companies, Laird and Wynberg (2005) find that the pharmaceutical sector is experiencing a dwindling interest and reliance on natural resources due to increased use of a synthetic, chemical approach and a reduced emphasis on infectious diseases. They argue, however, that this may change because the fight against infectious diseases is not over once and for all (p. 10). Similarly, for industrial biotechnology, natural resources dependency is expected to resurface because natural enzymes are biodegradable and hence more environmentally sound than are synthetic chemicals (p. 16). The seed sector and crop protection in particular still use wild genetic resources (p. 22), although there is uncertainty about the future value of these resources. In summary, across the board, there is no conclusive evidence that the various sectors will not experience an increased need for access to natural, wild genetic resources.

A recent study by Støen, Dhillion, and Rosendal (in press) reports on an increased interest in doing bioprospecting in the North. The pharmaceutical sector turns to prospecting and bioprospecting in their own backyard (e.g., unknown marine resources). Here, the multinationals face less stringent ABS regulations because no developed country has established strict ABS regulations. The trend could seem to be based on the fourth argument—benefit sharing obstructs access—and the end result may be to do business elsewhere and avoid the problem altogether. Laird and Wynberg's findings indicate, however, that it is the cumbersome and lacking administrative capacity that surrounds ABS legislation that creates mistrust in the industry sector rather than the idea of equity itself. This insight is corroborated by Gehl Sampath (2005, p. 165), who also points to capacity building as a means of improving ABS in practice.

Comprehensive ABS legislation has so far only been established in developing countries as a reaction to the expanding scope of IPR regimes and based on arguments one ("patents undermine equity") and two ("patents undermine access"). Even though there is great diversity of technological capacity in developing countries, as well as diversity in their biological richness, ABS legislation is becoming a common feature here. Close to 50 developing countries and regions around the world are in the process of enacting various types of ABS legislation (see <http://www.biodiv.org/programmes/socio-eco/benefit/measures.aspx>).

Moreover, they maintain the need to improve patent search practices to enhance novelty and prior art; this is to avoid traditional knowledge being patented by

multinationals (Ruiz, 2005, p. 20). Similarly, although developed countries hardly constitute a homogeneous block in this issue, they share the common characteristic of lacking established ABS legislation. Australia has established access regulation but it does not include regulation of benefit sharing. Norway, with its very small biotechnology sector, has one of the most far-reaching proposals so far on acquisitions of genetic material from abroad, requiring that such resources must be handled according to ABS legislation in the providing country (Norwegian Ministry of Environment [NOU], 2004, p. 28).

Meanwhile, the CBD parties continue the discussions on a multilateral system on ABS.<sup>8</sup> A recent development in the benefit-sharing discussion is the idea of issuing so-called certificates of legal provenance (CLPs). The concept refers to the "history of custody of the material, described since its access, including the changes it has suffered" (Fernández, 2004). As such, CLPs may become relevant for aiding the tracking and documentation of genetic material and knowledge in bioprospecting and, hence, solve part of the problem of origin discussed in argument five above ("fair and equitable sharing of benefits is impossible"). The CLP proposal stipulates that all patent applications should carry a certificate regarding where and how genetic resources have been appropriated as a prerequisite to patents. At the Granada ABS meeting in 2006, the Like-Minded Megadiverse Countries (LMMC),<sup>9</sup> the Latin American and Caribbean Group (GRULAC), and the African Group were able to operate as a coalition because they all preferred a legally binding regime on ABS.

There are some different positions among developing countries. Brazil, similar to most of the megadiverse countries in the LMMC group, advocates the widest possible scope for such provenance certificates. A few countries with fast-growing research capacity, such as Mexico, prefer a narrower scope. Some observers point to the fear that such certificates may turn out to be political boomerangs by being too effective in illuminating domestic equity issues and by empowering indigenous groups and holders of traditional knowledge in developing countries (Støen et al., in press). This may in the end prompt more developing countries to shy away from pushing too hard for provenance certificates. Still, the issue is one where the G77 coalition has been able to develop a strong common position (see Miller, 1995; Najam, 2005; Williams, 2005).

Developed countries are less coherent in their positions. Some, such as Australia, Japan, and Canada, do not see the need for a new international instrument and prefer a narrow scope without reference to CLPs. Others, such as the EU, Norway, and Switzerland, go further in identifying options for enhancing the balance between ABS and IPR systems. Switzerland has proposed an amendment to WIPO's Patent Cooperation Treaty and the EU supports a requirement to disclose the origin or source of genetic resources under both TRIPS and WIPO.

The role of plant genetic resources for food and agriculture in the future ABS regime remains a crosscutting source of controversy. Many large agricultural countries (both developed and developing) prefer to deal with this issue in the FAO ITPGRFA and in the International Union for the Protection of New Varieties of

Plants (UPOV) fora rather than under the CBD. This can be traced back to the line of argument four (“benefit sharing may undermine access”) and the belief that leaving plant genetic resources out of the CBD regime on ABS would simplify matters. Mega-diversity countries with an eye on bioprospecting deals tend rather to oppose references to ITPGRFA.<sup>10</sup> They fear that too much emphasis on access would compromise equity issues in the ABS negotiations.

Either way, the generation of benefits from the use of genetic resources is dependent on the existence of appropriate policies and institutions in the country providing genetic resources as well as compatible legislation in the user countries (Fauchald, 2001; Hendrickx et al., 1993; Rosendal, 2000; Svarstad & Dhillion, 2000). This compatibility is one of the main challenges in developing a multilateral system for ABS. The alternative—bilateral bioprospecting deals—is likely to be most problematic for countries with a low technological base (Støen et al., in press). The catch is that a multilateral system may have serious problems making one size fit all.

### **Concluding Remarks: Prospects for Conservation**

There has been slow and incremental progress on development of a multilateral regime building on the ABS objectives. In comparison, there has been a more rapid strengthening of IPR objectives, not least through bilateral trade agreements (TRIPS plus). Meanwhile, the link between conservation and ABS issues is primarily upheld by the CBD rather single-handedly. This would seem to reflect the situation that conservation has less powerful stakeholders than ABS and IPR, which have a more easily recognized economic potential.

Part of the ABS-IPR debate is paradoxical. Countries and corporations from the North tend to argue that there is no money in bioprospecting (argument five), and ABS legislation in the South is criticized for undermining access and innovation efforts (argument four). This argumentation seems to build on an inherent contradiction. On one hand, it is argued that agribusiness and the pharmaceutical industries are virtually self-sufficient in genetic resources for their innovations, in effect leaving few benefits to be shared with developing countries. At the same time, complaints are increasingly being raised that the rapidly spreading access restrictions in the South constitute serious barriers to technological innovations. If the latter were indeed the case, the potential for reaping benefits would seem to be greater.

The normative impact of the ABS argument is readily observed in bilateral bioprospecting deals at the corporate level, but there is still quite some way to go in terms of establishing a multilateral regulatory framework. This is not for lack of proposals; there are several calls for changes in IPR legislation to balance the needs of users/IPR and providers/traditional knowledge: This includes the call for disclosure of the origin of genetic material to confirm that it has been acquired according to the principles of prior informed consent and mutually agreed terms. The aim is to stop misappropriation of traditional knowledge by strengthening the search for prior art

before a patent is granted. Disclosure would be a necessary, although as the problems related to identification of country of origin illustrated, far from sufficient legal step in user countries. A similar aim is sought with the current proposal for CLPs of genetic resources as a prerequisite to patents. The success of a multilateral system such as this will first of all depend on compatible legislation in user and provider countries to balance strengthened IPR systems in user countries. Since the early phases of CBD negotiations, user countries have nevertheless come a long way in realizing the need for the reciprocity through such a system.

Another challenge to the creation of a protocol under the CBD on a multilateral ABS system stems from the different needs and interests related to the provision of domesticated as opposed to wild genetic resources. The divergent interests that relate to wildlife conservation and management of agricultural biodiversity date back to the agenda-setting phase of the CBD negotiations, when the IUCN and the United States feared that such a package would raise the conflict level and hamper conservation of biodiversity. Similarly, as seen in argument four, there is still concern that access to plant genetic resources may suffer due to ABS legislation. If environmental and developmental NGOs were to have a positive impact on biodiversity conservation, the old dispute between wildlife conservation and provisions of agricultural biodiversity would need to be laid to rest. This needs to be further explored because there is an unfortunate inconsistency between the need for a multilateral system and the pitfalls of choosing a one-size-fits-all solution.

The main objective of the CBD to promote biodiversity conservation is hardly possible without dealing with the complex equity issues reflected in the ABS debate. Again, it is useful to view this issue against the backdrop of the trends in global environmental governance, where an increased acceptance of the concerns of developing countries is noted (Najam, 2005; Williams, 2005, p. 54). The idea of sustainable development has become an integral normative element of global environmental governance, and the development of a multilateral ABS system will likely be an important new element in support of more equitable distribution of costs and benefits of global biodiversity conservation.

## Notes

1. See Hansenclever, Mayer, and Rittberger (1996) for various branches (power based, interest based, and knowledge based) within what may broadly be called regime theory.

2. The Convention on Biological Diversity (CBD) defines genetic resources as genetic material of actual or potential value.

3. Patent legislation is of a national character, and patent protection is applicable only in the country where it has been granted. One exception is the European Patent Convention (EPC) of 1973, which applies in the European Community.

4. Schram Stokke (2000) defines "normative diffusion" as a situation where principles and regulations that have been found to be effective in a regime within one issue area are adopted by another regime.

5. Granting Plant Breeders' Rights under the International Union for the Protection of New Varieties of Plants (UPOV) is one form of this, but in principle, countries can decide if they want UPOVs, Plant

Breeders' Rights (PBRs), or to develop a sui generis system adjusted to their own specific needs in plant breeding.

6. The Substantive Patent Law Treaty (SPLT) negotiations have currently broken down (April 2006) because the parties were unable to agree on the agenda for future work.

7. There is a rather high correlation between dominating countries and key economic interests in the global economy: The United States is dominating the biotechnology industry, accounting for 78% of global company revenues, followed by Europe at 14% (Ernst & Young, 2005).

8. The fourth meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing (ABS) of the Convention on Biological Diversity (CBD) met from January 30 to February 3, 2006, in Granada, Spain. References to this meeting build on personal communication with Morten Walløe Tvedt (February 8, 2006) and the authors' interpretations of *Earth Negotiations Bulletin* (ABS-4 highlights, February 6, 2006).

9. The 17 countries are Bolivia, Brazil, China, Colombia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Philippines, Peru, South Africa, and Venezuela.

10. See *Earth Negotiations Bulletin* (ABS-4 highlights, February 6, 2006).

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