Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

OLIS : 10-Sep-1999
Dist. : 13-Sep-1999

Or. Eng.

ENVIRONMENT DIRECTORATE
ENVIRONMENT POLICY COMMITTEE

Working Party on Economic and Environmental Policy Integration
Working Group on Economic Aspects of Biodiversity

ECONOMIC ISSUES IN BENEFIT SHARING: CONCEPTS AND PRACTICAL EXPERIENCES

81351

ENV/EPOC/GEEI/BIO(98)7/FINAL Unclassified

Or. Eng.

FOREWORD

The two papers contained in this report constitute the continuation of the work of the Working Group on Economic Aspects of Biodiversity on benefit sharing after the completion of the initial working paper "Issues in the Sharing of Benefits Arising out of the Utilisation of Genetic Resources" [OCDE/GD(97)193].

The first of the two papers, "Economic Issues in Benefit Sharing" is based on an initial paper prepared for the Working Group on Economic Aspects of Biodiversity jointly by Professor Timothy Swanson, School of Public Policy, University College London and Biodiversity Programme Director for CSERGE, Department of Economics, and Mr. Jan Horst Keppler, OECD Secretariat. It was substantially revised by Mr. Yann Guillaud, associate-researcher at the Research Centre on Contemporary Brazil (CRBC), Maison des Sciences de l'Homme, Paris, on the basis of the discussions of the Working Group at its Eighth meeting in La Paz, Mexico, 28-29 July 1998, and at its Ninth meeting in Paris, 19-20 November 1998, and on the basis of written comments.

The second paper "Practical Experiences: Case Studies on the Sharing of Benefits Arising out of the Utilisation of Genetic Resources" was prepared by Mr. Yann Guillaud. Several of the case studies had been prepared directly for the Working Group on Economic Aspects of Biodiversity. Several others had been prepared for the Secretariat of the Convention on Biological Diversity, Montreal, which has generously put them at the disposition of the Group. The two papers are presented in a single document, as the direct inclusion of the case studies sets in perspective the theoretical discussion on benefit sharing by on-going empirical experiences.

This report is released as an unclassified document under the responsibility of the Secretary-General of the OECD with the aim of bringing information on this subject to the attention of a wider audience. It is also available in French.

TABLE OF CONTENTS

ECONOMIC ISSUES IN BENEFIT SHARING

PRACTICAL EXPERIENCES: CASE STUDIES ON THE SHARING OF BENEFITS ARISING OUT OF THE UTILISATION OF GENETIC RESOURCES

EXECUTIVE SUMMARY

The three objectives of the Convention on Biological Diversity (UNEP, 1994) are:

> *the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding. (Article 1)*

It is the third objective — the fair sharing of the benefits arising from the use of genetic resources — that is probably the most elusive one, and the one that is the focus of this study. Achieving this objective is complicated by the number of different groups of actors involved, the fact that each group has its own aspirations and agenda, and the uncertainties of the quantitative estimates of the size of the benefits as well as of the relative contributions each group of actors makes to their realisation. Furthermore, benefit sharing is interlinked with other difficult and often contentious issues, including capacity building, technology sharing, trade, intellectual property rights, and distributive justice.

This study complements the previous OECD report "Issues in the Sharing of Benefits Arising out of the Utilisation of Genetic Resources" (OECD, 1997) by presenting in the first part of the report an economic framework for the examination of benefit sharing issues. In the second part of the report, the framework is used to analyse seven case studies on practical benefit sharing experiences involving OECD Member countries. All of these studies relate to benefit sharing arrangements in the pharmaceutical industry, which is one of the two main markets in which genetic resources are used as an input (the other main market is the market for agricultural seeds).

In this analysis, benefit sharing is essentially viewed as a problem of the definition of property rights over genetic resources, with the solution determined by bargaining between the providers and the users of these resources. The property rights to the genetic resources need to be clearly defined between these two parties. If they are not, the providers of genetic resources may restrict access to the resources out of a fear that they will not receive a share of the benefits arising from the utilisation of their resources, or that their traditional knowledge will not be recognised. Likewise, without a clear agreement as to their rights of access or that their intellectual property rights will be protected for any products developed from these resources, the users may in turn refuse to share benefits with the providers or even abandon natural product bioprospecting in favour of the development of synthetic substitutes. Economic analysis shows that either of these situations would be clearly inferior for both parties, and that some form of binding agreement is preferable.

Identifying the exact nature of such an agreement is more difficult, however, and will depend on the parties involved and the particular circumstances. Thus, this study does not attempt to provide any final answers on the issue of benefit sharing, but rather attempts to present the most important issues concerning benefit sharing in a consistent framework by linking the theory provided by economics with the results of the case studies on benefit sharing arrangements in the pharmaceutical industry.

This analysis highlights the importance of several issues. First, there is the fundamental issue of non-monetary benefits from the bioprospecting for pharmaceuticals, including the development of scientific and technical capacity. Thus, in a number of cases, pharmaceutical companies agree to train local researchers as partial payment for access to the resources. Second; the pre-condition of a benefit

sharing arrangement – although subject to changes over the course of a long lasting collaboration – for access to the resource is of utmost importantance. Finally, it can also be particularly useful to develop a trust fund, financed through the benefit sharing agreement, to integrate the collaboration into a wider development strategy.

Currently, most bio-prospecting experiences do not credit local and indigenous knowledge and practices other than a general recognition of their importance. The case studies described here represent a few examples where the providers and users of genetic resources have negotiated a more concrete and stable relationship for sharing the benefits arising from the use of these resources. However, efforts in this area are still just beginning, and further work is necessary to develop appropriate policies for governing benefit sharing.

ECONOMIC ISSUES IN BENEFIT SHARING

I. Benefit Sharing and the OECD Expert Group on Economic Aspects of Biodiversity

Of the three objectives of the *Convention on Biological Diversity* (UNEP, 1994), the conservation and the sustainable use of biological diversity and the fair sharing of the benefits arising from the utilisation of genetic resources, the third one is the most elusive one. Already the first two objectives present difficult challenges for policy makers. To achieve them a number of private and public interests have to be reconciled: the conservation of biological diversity can only be achieved if ambitions for increased economic progress are satisfied and sustainable use has to include considerations of public benefits during the pursuit of privately profitable activities.

However, the complexities of achieving a 'fair sharing of benefits arising from the utilisation of genetic resources', are even more intricate. This is due to the number of different groups of actors, each group having its own aspirations and agenda, and the uncertainties of the quantitative estimates of the size of the benefits as well as of the relative contributions each group of actors is making to the realisation of the benefits. In addition, benefit sharing is linked to complex issues such as capacity building, technology sharing, trade and intellectual property rights. Last not least, the issue of benefit sharing cannot be solved by technical or 'positive' analysis alone, but intricate questions of distributive justice have to be addressed.

Very schematically one can distinguish four different parties in the process of the utilisation of genetic resources: (1) the governments and the public of countries which supply genetic resources, (2) the private sector and local populations in these supplier countries, (3) private sector companies in industrialised countries and (4) the governments and the public of industrialised countries. Fair and equitable benefit sharing implies a balancing of the interests and contributions of those four parties in a manner which is politically acceptable and practically sustainable in the light of the institutional realities in the provider countries.

After having approached the issue from a general conceptual and legal point of view[1], the OECD Expert Group on Economic Aspects of Biodiversity is now approaching the issue with the help of economic concepts. While economic analysis alone cannot decide an issue such as 'fairness', it can clarify the motivations and contributions of the different actors and relate them by identifying the underlying web of incentives. In particular, the theory of rent and its distribution provides an indication about how benefits from the utilisation of genetic resources are generated and which minimum remuneration each factor has to receive in order not to endanger its participation in the process.[2]

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1 OECD (1997a), "Issues in the Sharing of Benefits Arising out of the Utilisation of Genetic Resources".

2 The fact that the value of a pharmaceutical product generated from genetic resources is larger than the costs of accessing the resources, processing them and marketing the final product creates a 'rent', *i.e.*, a surplus of value over costs (OECD, 1997a, 12). This rent is partly embodied in natural resources and partly embodied in the know-how of pharmaceutical companies. The beneficiaries of this rent are currently the companies themselves (in form of monopoly profits) and the consumers of pharmaceuticals (in form of consumer surplus). Rent in this context is henceforth used in the sense of social welfare over cost, independent of the question whether this welfare accrues in terms of monopoly profits or in terms of consumer surplus.

The issue of benefit sharing regards the problem to which extent the providers and the users of genetic resources are entitled to shares of the benefits. This question implies two distinct aspects: a positive and a normative one. This paper only deals with the positive dimension of the question and employs economic analysis to approach the issue. Thus basic concepts of the theory of rent and the theory of information are employed in order to explain the process of value generation. Also some indicative empirical estimates of the size of the market are provided. However, the all-important *normative* dimension is not discussed in this paper, i.e., it is explained how the allocation of property rights works, not how these property rights should be allocated.

The division of property rights will essentially be decided by bargaining between the Parties to the Convention on Biological Diversity. Simple economic analysis has little to bear on this topic as it is frequently impossible to assess the extent to which surplus value is generated by the genetic resources or by company know-how (OECD, 1997a, 12-13). However, economic analysis can show that such bargaining, including bargaining concluded in international forums such as the Conference of the Parties to the Convention on Biological Diversity is vastly superior to so-called "prisoners' dilemma" situation in which each side avoids to engage in mutually beneficial trades for fear the other side may renege on its commitment to benefit sharing.

Thus providers of genetic resources may fear that they will not receive a share of the benefits arising from the utilisation of their resources that their traditional knowledge will not be recognised and in consequence may restrict access. Users of genetic resources may fear to lose access rights to genetic resources and not to have their intellectual property rights protected and may hence refuse to share benefits with providers or would even abandon natural product bioprospecting to concentrate on the sole development of synthetic substitutes. Economic analysis can show that such a situation would be clearly inferior for both Parties, it cannot decide what the correct outcome should be.

Economics, here, is understood as an approach to social interactions which provides indications for improving well-being given scarce resources and alternative arrangements for their use. Markets are seen as a particularly efficient way to maximise private welfare through the efficient allocation of resources and the impetus for innovation they provide. However, due to the fact that it is not possible to privatise certain goods, such as existence values or contributions to economic development, markets need to be complemented by additional institutional arrangements in order to fully realise the combined potential of genetic resources and the ecosystems which surround them.[3]

Following the use of economic concepts in Chapters one to three, Chapter four will present an empirical overview of one of the two main markets in which genetic resources are used as input, the market for pharmaceuticals, is provided. The other main market, the market for agricultural seeds, will not be discussed. Although this activity is very important in terms of value and its links with biodiversity, the Work Programme of the Expert Group specifically demands:

> [...] *to leave aside issues with agricultural plant genetic resources, such as those being considered under the FAO International Undertaking on Plant Genetic Resources for Food and Agriculture* [...] (OECD 1997b, 12).

Such a distinction between genetic resources used for pharmaceutical, phytomedical and cosmetic products on the one hand, and, on the other hand, for food and agriculture is not just a question

[3] For a definition of existence values, see *infra* Box 1.

of organisations that are dealing with these topics, i.e. the Convention on Biological Diversity (CBD)[4] for the former and the Food and Agriculture Organization of the United Nations (FAO) for the latter. The distinction rather comes from the specific nature of pharmaceuticals, phytomedicals and cosmetics compared to food and agricultural products. Genetic resources for food and agricultural products have for many centuries, some would say millennia, been found, used, and improved. No botanic or economic analysis has been able to evaluate the respective contribution of the many cultivars, coming from many different sources, which were used to produce the final genome of a new variety.

Much less has it been possible to assign even qualitatively the contributions of each breeder in this long-lasting selection process of plants. Genetic resources for food and agriculture have therefore been essentially administered through institutional mechanisms close to the public domain and not through the market. Therefore, sharing bilaterally benefits arising from the utilisation of genetic resources for food and agriculture is neither relevant nor workable (Sontot, 1998). The context for agricultural genetic resources is far from the model where a provider and a user of a particular genetic resource are in direct relation such as is the case in the development of pharmaceutical, phytomedical and cosmetic products. The present paper deals exclusively with the latter, the sharing of benefits arising from the utilisation of genetic resources used in the production of pharmaceutical, phytomedical and cosmetic goods.

But even in this context, and in further keeping with the mandate of the Working Group on Economic Aspects of Biodiversity, this paper does not attempt to provide any final answers on the issue of benefit sharing (*ibid.*, 11), a consequence of its decision to avoid all normative questions. It attempts rather to present the most important issues concerning benefit sharing in a consistent framework by linking the theory provided by economics with the results of case studies on benefit sharing arrangements within pharmaceutical, phytomedical and cosmetic products development which are described in the second part of this paper.[5]

Clearly, the paper aspires to be useful to an ongoing debate rather than to pre-empt be providing any final answers. It is thus understood that it represents a compendium of selected and preliminary information that will need to be complemented by future works. There exist indeed a number of issues which are not taken into account here: relationships between governments and the private sector *inside* OECD Member countries non-Member countries; the activities of botanical gardens and other *ex situ* depositories of genetic biodiversity with respect to their own access and benefit sharing procedures; finally, the issue of traditional knowledge which is just beginning to be debated on the basis of Article 8j of the *Convention on Biological Diversity* is touched upon in passing rather than discussed in-depth.

More thinking and discussion is needed on all of these issues. Particularly important is the involvement of a wide range of different stakeholders in these discussions. In its future work, the Working Group aims to further strengthen its efforts in outreach and co-operation in order to continue to contribute to an open and vigorous discussion on *all* issues linked to the access and the sharing of benefits arising out of the utilisation of genetic resources.

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[4] It should be reminded that, in fact, the CBD deals about *all* genetic resources, but its discussion model is more linked to the context of pharmaceuticals than to the one of plant genetic resources for food and agriculture.

[5] See *infra*, "Synthesis of Case Studies on the Sharing of Benefits Arising out of the Utilisation of Genetic Resources".

II. The Economics of Genetic Resources as an Input to Pharmaceutical Products

While genetic resources have many facets, it is probably fair to say that most likely there would be today no issue of benefit sharing if genetic resources were not an important contribution, as they have been in the past and might be in the future, to commercially valuable pharmaceuticals. However, genetic research is more and more conducted in laboratories these days as new combinatorial chemistry techniques can create thousands of slightly different molecules ready to screen in such a way that the sourcing and analysis of natural products cannot keep up (Macilwain, 1988, 536-537).

In some cases, technological options reduce the need for *in-situ* genetic resources and companies that encounter difficulty in gaining access to genetic resources are willing to invest in alternative technologies. Many companies already rely on *ex-situ* collections for samples for testing, as there is an abundance of yet untested material in such collections which are not concerned by the benefit sharing provisions (Article 15.3) of the *Convention on Biological Diversity.* However, also access to *ex-situ* collections are more and more linked to the introduction of benefit sharing arrangements. Many botanical gardens are indeed voluntarily beginning to apply the CBD like, for instance, the Royal Botanic Gardens, Kew which decided from 1 January 1998 forward to "make its best effort" to implement a benefit-sharing policy with source countries and users of genetic resources, including those resources acquired before the entry into force of the CBD, and whether the samples are used for research or commercial purposes (RBG Kew, 1997).

Whatever it may be, the contribution of *in-situ* genetic resources to the production of pharmaceuticals remains important in at least two ways. For one part, genetic resources contain *information* about successful genetic combinations, tested under rigorous evolutionary pressures, which can be profitably used in the production of pharmaceuticals and which so far has not been synthetically generated (see the Laird and Lisinge, the Ten Kate, Touche, and Collis and the Ten Kate and Wells case studies). This information is often enriched by information about the use of certain resources stemming from the knowledge of local and indigenous populations (see the Rosenthal case study). For the other part, *in-situ* genetic resources can be used, in sometimes considerable quantities as raw physical inputs into the production process of pharmaceuticals (see the Laird and Lisinge and the Ten Kate and Wells case studies).

Both aspects create their own difficulties from a policy-making point of view. The information aspect of genetic resources raises complicated questions of attributing the relative contributions to the final product, as well of defining and granting intellectual property rights. The physical input aspect raises equally complex but completely different questions about harmful by-effects on the surrounding ecosystem.[6] The relative weights of the information aspect and of the physical input aspect depend on the industry's ability to synthesise the inputs for final products and on the increasing use of deep-frozen cell samples as an alternative to harvesting "fresh" plant resources.[7]

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[6] Simpson & Sedjo (1994, 37) write following McChesney: "An initial sample may weigh 10 kilograms, but 100 kilograms may be required for preliminary evaluations, 100 000 for clinical trials, and many millions for eventual therapeutic use."

[7] For more information on the growing of different cultures from deep frozen cell samples, frequently gained from micro-organisms contained in open access resources such as earth and water, see *The Economist* (1998, 87-89).

Whether as raw materials or as genetically encoded information, genetic resources are part of a value creating process which generates large amounts of money (see next chapter for an empirical overview). For economists it has been more attractive to study the contribution of genetic resources in the same manner in which intellectual contributions to processes and products are considered. This allows to draw on a wide literature and to relate the issue to existing international agreements.[8]

It is useful to concentrate on the role of genetic resources as *information* in the research and development of the pharmaceutical industry as a starting point, even if it is only *one*, albeit an important one, part of the picture which has to be considered in order to arrive at solutions for benefit sharing. For this purpose, the pharmaceutical industry may be conceived of as continuing processes of research and development (R&D) rather than a set of static technologies. Genetic resources are crucial inputs into this R&D process. Frequently, it is not so much the tangible resource itself which is a useful input for the pharmaceutical industry, but rather it is the information to be gained from characteristics which have evolved within a living environment that is most likely to make a contribution.

Biodiversity *per se*, in a R&D perspective, is useful because of the manner in which the existing set of life forms have been selected within a living, contested system, which provides us with an already-vetted library of successful strategies in an evolutionary perspective. Much of the R&D process is focused on the screening of the strategies that are operational in nature, and their development for specific applications in an industrial context.

In certain circumstances, biodiversity in connection with indigenous knowledge operates as an alternative or precursor to the standard R&D process. It provides solutions which are already known to apply to important problems. The identification of medicinal plants and their applications gives a good example of this form of biodiversity input. Frequently, the fact that certain plants are biologically active has been noted previously by the local population. All that is required for an industrial application is to develop this information into a form capable of mass production along with the identification, the isolation and the testing of active ingredients, ensuring their safety for human use at various strengths and putting them into a usable form.[9]

Other times the information within nature requires substantial analysis and modification before it is incorporated within a final product. In this case, the information from biodiversity is best considered as a raw informational input into the R&D process. That is, it is only after it is combined with other forms of capital (scientists, specialised machinery) that the naturally-generated information is able to be developed into useful applications. An example of this form of biodiversity input into R&D would be the range of bacteria and micro-organisms screened for their activity and ultimately put to use in various industrial applications (see the Ten Kate, Touche, and Collis case study). Another example of this sort of input would be the screening of little-known plants for biological activity and the modification of any identified active molecules for use in the pharmaceutical industry (see the Laird and Lisinge case study).

This raw information may be brought into commercial use in one of two ways, either in the incorporation of the explicit information that specific genetic resources represent (the observed characteristic

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[8] The Agreement on Trade-Related Intellectual Property Rights (TRIPs) under the World Trade Organization (WTO) would be an example of such an agreement.

[9] Many of the already existing pharmaceuticals were derived within a process such as this, but it is believed that few pharmaceuticals will be so derived in the future on account of the exploitation or erosion of most local knowledge along with the development of combinatorial chemistry.

or phenotype) or alternatively by the use of the implicit, biological coding of that information (its genotype). That is, industry can either take note of the explicit information and make use of that information to develop new products incorporating that information without displacing the biological material, or the industry can make actual use of the coded (genetic) material that produces that effect and transplant it.

Pharmaceutical industries most often pursue the former strategy (making use of observed strategies in biological material), as opposed to agricultural industries which most often pursue the latter (Swanson, 1995). Pharmaceutical companies often screen diverse plant (and other) life forms in order to ascertain the presence of chemicals with biological activity, e.g., alkaloids in plants. However, if this information is identified to be of some useful purpose, then the pharmaceutical industry will usually focus on the synthesis of that activity within a laboratory environment from basic chemical constituents thus creating either a perfect substitute for the original genetic resource or a semi-synthetic product (see the Ten Kate and Wells case study).

II.1 The economics of information and innovation

Research and development (R&D) is the term used to describe the process by which new ideas are developed for application to the production of commercially valuable goods. Economists have long analysed the research and development process as one of information creation, application and diffusion (e.g., Arrow, 1962). Certain industries by their nature expend substantial proportions of their total available resources on the R&D process. For example, the pharmaceutical industries invest over 10 per cent of their investment in the development of solution concepts.

When R&D is a significant input into the production process within an industry, it is not always possible to obtain a reasonable rate of return on the product without an extended right of control over its subsequent use and marketing. If there is no exclusive right to control the subsequent marketing of the good, then the first purchaser of that good would have the right to re-produce the same product without expending all of the R&D resources required to produce it initially. This is problematic if the first seller invested large sums into the construction of the good, while the second only invested into copying it. In industries in which a substantial amount of the value produced is attributable to the information it contains, there would be no incentive to invest in this R&D in the absence of the capacity to control the marketing of its goods even after their transfer to others.

There is a great variety of rights denominated ‘intellectual property’: trade marks, copy rights, patents, plant variety rights, etc., to protect the interests of the provider of information. Many countries, including developing ones, have a patent system since at least the last quarter of the 19th century (UNCTAD, 1974). These rights allow a holder to obtain a reasonable rate of return on the good that is subject to the recognised right after it has left the possession of the right holder. Only with such protection is it interesting for the owner of information to provide it for the production of commercial products.

Applied to genetic resources this implies that genetic resources would not be provided to the pharmaceutical companies in the absence of adequate incentives for the protection of the information which is contained in them and, *vice versa*, the company would not invest in genetic resources R&D if it has not the adequate protection of the commercial product arising from it has invested many resources in the improvement of the natural active compound as it has already been stated in the introduction of this chapter. Such a logic holds then for all parties involved: traditional populations, governments and pharmaceutical companies. It is applied in theory and practice more easily for certain than others: for private companies intellectual property rights are rich and strong while these rights are yet to be more developed for traditional knowledge (see the Rosenthal case study).

Thus the impact of the introduction of an intellectual property rights (IPR) system would, in principle, lead to: (i) an increase in investment in R&D in the affected industries; and (ii) an increase in the investment in the other inputs (human, machinery and otherwise) required to undertake R&D in these industries. Since genetic resources constitute an input into the R&D process in the pharmaceutical industry, it would be anticipated that the introduction of an IPR system for genetic resources would have an impact on the rates of investment in these resources. The volume of genetic resources provided for pharmaceutical production should increase in response to the protection of the interests of the providers, specially local and indigenous populations providing traditional knowledge.

Roger Sedjo (1988) asks the question why society has so far not created property rights for species in the first place in his article "Property Rights and the Protection of Plant Genetic Resources". The question, and the three answers he provides, are revealing as they point towards the difficulties of establishing adequate property rights systems:

> *Three explanations come to mind. The first involves the ethical and legal view that since natural genetic resources are the creation of nature and not of man, they are a "common heritage" and should be freely available.*
>
> *A second is that, as with many other common property resources, at low levels of pressure on the resource no serious problem of resource degradation will occur. [...] Until quite recently it was probably true that for natural genetic resources as a group, the pressures of habitat destruction, particularly in the tropics, were not great enough to exceed the natural resiliency of the ecological system.*
>
> *A third explanation is that the inability of legal systems to define natural genetic resources precisely enough to award unambiguous property rights, together with the difficulties inherent in enforcing those rights and allowing for the capturing of the returns generated by that species, made these arrangements so complex and difficult as to preclude their application.* (Sedjo, 1988, 303-304)

Sedjo's arguments are important, even if one regards the first reason as a corollary to the other two, rather than as an independent one. The "common heritage" argument applies to all natural resources, including agriculture, and it has been quickly abandoned in cases in which resource degradation begins or the enforcement costs of private property rights have fallen relative to the expected gain. What has changed in the last two decades is precisely that pressures from competing land uses have grown (see Table 1) and enforcement costs have fallen with respect to the potential gains expected from the biotechnological transformation of wild genetic resources.

As genetic resources have become *scarce* in relation to the pressures of economic growth, its protection through the allocation of well defined ownership rights has become a necessity in order to, at least, realise its private and public use values. The previous chapter has discussed that this is not enough. But it is the first necessary condition on which all other considerations such as the protection of existence values, contributions to public goods such as economic development and the like have to build.

Table 1: Increasing Pressures on the Land

(Area of arable land and permanent crops in 1 000 ha)

	1961	*1996*	*Per cent change*
Africa	155 272	197 972	27.5
Asia[a]	436 258	512 475	17.5
Latin America and Caribbean	102 265	161 961	58.4
Oceania	34 789	54 869	57.7
North America	225 709	222 500	-1.4
Europe[a]	151 365	135 392	-10.6
USSR (former)	239 800	226 158	-5.7
World (developing)	675 567	853 183	26.3
World (developed)	669 894	658 147	-1.8
World (total)	**1 345 461**	**1 511 33012.3**	

[a] Not taking into account the relevant part of the former USSR.

Source: FAO (1998)

II.2 Impacts of IPR structures on the provision of genetic resources

Thus, property right systems are no forgone conclusion, but must be carefully designed and properly structured. Otherwise, it is possible that it results only in investments in some forms of inputs (e.g., synthetic substitutes, *ex-situ* conservation of genetic resources), and not in others. In particular, this refers to investments (or the lack thereof) into *in-situ* conservation which is the form of investment into genetic resources most likely to fulfil the three objectives of the *Convention on Biological Diversity* which has therefore accorded special attention to *in-situ* conservation it in its Article 8.

The continuing erosion of genetic resources at the field level, despite the introduction of IPR regimes at the market level of the industry, may be viewed as symptomatic of a failure to define these regimes adequately. It is, nevertheless, difficult to attribute this erosion exclusively to a failure of IPR regimes alone. Many other factors, including poor execution of IPR, population pressures, corruption, alternative higher value use etc., equally contribute to genetic erosion. These factors are, however, largely outside the remit of the *Convention on Biological Diversity* and will therefore not be the focus of the discussion.

It is important to consider the reasons why existing IPR regimes fail to generate incentives for investments in the assurance of an ongoing flow of genetic resources to the R&D sectors that require them. There are essentially two reasons for the fact that existing incentive systems do not accord enough protection for the providers of genetic resources to invest into *in-situ* protection: first, the returns on the information contained in genetic resources does not reach those who decide on land-use patterns; and second, the returns on the information from genetic resources are lower than expected, since their value as an input into the

production of pharmaceuticals is less than expected. Of course, this regards only the private value of genetic resources and does not refer to their existence or option values (see Box 1 for more details).

Concerning the first reason, it has to be said that the nature of genetic resources makes it difficult to determine the exact contribution of each participant in the process.[10] For instance, the knowledge and practices of local and indigenous populations, which are frequently known to groups of people rather than individuals are difficult to handle in existing property right patterns formed to protect the interests of individual legal entities, such as single persons or companies. Barriers of communication between providers and users make it difficult to perceive mutual needs. For instance, some potential investors invest in substitutes such as *ex-situ* collections because of the unreliability of the supply of sufficiently high-quality specimen. The second point will be discussed in Chapter 4.

The vesting of a property right at the wrong level of an industry can be sufficient to break the normal link between the use of an input and the incentives for its conservation. Genetic resources are an important input into industries in which intellectual property rights are applied. Does the incorrect assignment of property rights diminish the incentives to invest in the supply of biological diversity? In general, economic theory holds that the level of the industry at which a property right is held should not matter, as the parties should be able to enter into contracts to move complete or partial 'ownership' to people with the appropriate knowledge, communication facilities and the ability to supply appropriate quality levels of biological resources.

A firm might, for instance, purchase lands or acquire certain use rights and thus capture a part of the value of the genetic resources found through bioprospecting against some kind of arrangements. The purchasing land option is sometimes advocated in "debt-for-nature-swaps" programmes (see the Moran case study, 1). The frequently cited INBio project in Costa Rica supported by the funding of the pharmaceutical company Merck which therefore secured its supply of samples or the implementation of conservation measures through the purchase of *Prunus africana* at a guaranteed price by the phytomedical company Plantecam-Medicam (see the Laird and Lisinge case study) are examples of companies acquiring certain use rights on the resource.[11]

A widespread application of this approach would raises a series of important questions. For instance, the 'banking' of large areas of the world's natural land area by large multinational companies based in a few western countries is not in accord with the appropriate function of land rights and the necessity of assuring local economic development, although trust funds are frequently a part of such arrangements. Indigenous people, who would be the 'owners' of the land, might not ask appropriate prices or not be fully aware of the implications of a complete sale. Their exclusion from substantial areas of land by foreign landowners for purposes of maintaining its 'naturalness' would be conceptually and politically difficult to

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[10] Attempts exist to estimate the contribution of wild genetic resources with the help of so-called 'R&D production functions' consisting of the output 'new products' and the inputs 'human capital (scientists), physical capital (machinery) and wild genetic resources'. An empirical study based upon the record of plant breeding at the International Rice Research Institute estimated that approximately 35 % of the production of modern new varieties has been attributable to the genetic resource (Evenson, 1995).

[11] The first arrangement in 1991, on a two-year basis, included the payment in advance by Merck of US$ 1.135 million and a confidential percentage of royalties should a commercial product arise from the 10 000 samples supplied by INBio (see the Guillaud case study, 6). This two-year payment in advance amounts to 0.09 % of one year of Merck's research and development expanses (Simpson & Craft, 1996, 15).

defend. It would also run counter to the letter and the spirit of the *Convention on Biological Diversity*, in particular its Article 8j.[12]

The question of the ownership of biodiversity resources includes the need to realise investment opportunities, but goes beyond it by including questions of national sovereignty, natural heritage and global existence values. This fact makes the treatment of the question so difficult. Instead of talking about 'property rights', it might be more useful to treat ownership of complex goods such as genetic resources or biodiversity as emanating from a bundle of different *use rights*, all allocated according to different criteria and therefore access rights.

This recognises that almost any resource consists of a bundle of attributes which can contain private as well as public values. For example, privately owned land has a public good element by being part of the national heritage and identity. This element would be destroyed by large-scale foreign ownership for a genetic pool reserve with the exclusion of access for local population. Access rights are thus one of the most important types of use rights in connection with genetic resources. Therefore, henceforth the focus will be on access rights rather than general property rights.

However, the analysis of the problem of benefit sharing from the point of view of IPR systems highlights one important point which will not go away: those who decide on the use of land will need adequate incentives in order to preserve natural habitats. Otherwise, alternative uses such as agriculture are more attractive. Final incentives will have to include the returns on the commercially valuable information contained in genetic resources, but will also have to include the return on those services which biodiversity-rich ecosystems renders to wider communities such as nation states or the global community at large.

[12] A half-way solution in so-called debt-for-nature swaps involves the establishment of domestic organisations to hold the land rights, rather than holding them in the foreign organisations that had acquired them.

III. The Global Pharmaceutical Industry and Wild Genetic Resources – Empirical Estimates

Before entering into the discussion of a well-known empirical study of the value of pharmaceutical products derived on the basis of wild genetic resources, some information on the pharmaceutical industry itself is necessary. The global market for pharmaceutical products (in-patent drugs and generic out-of patent drugs) was estimated to be US$ 188 billion in 1992 and around 225 billion in 1995 with rapid growth in the last three years. These numbers *exclude* over-the-counter drugs (which can be sold directly to consumers without prescription) which would add almost another 20 per cent.[13]

In 1990, OECD countries produced 73 per cent of global prescription drugs (in value terms) and consumed 72 per cent of them. Employment in the pharmaceutical industry in OECD countries totalled 940 000 in 1991. As mentioned, the pharmaceutical industry is one of the most research-intensive industries, ranked only behind aerospace and before computers or electronics, which is an indicator of its reliance on a steady flow of new products and new information derived *inter alia* from *in-situ* genetic resources. The relatively rapid turnover of drugs is also due to the limited extent of patent protection which usually does not extend beyond 10-11 years at the time the product is marketed. In the period from 1973-1992, research and development expenditures almost doubled from 7 to 12 per cent of production in a representative sample of twelve OECD countries. This figure rises to 16 per cent for the large multinational companies which dominate the industry.

The global pharmaceutical industry is highly concentrated with the ten largest firms holding close to 36 per cent of market share in 1995. This figure has certainly increased in the meantime as the industry has been subject to an accelerating trend of consolidation. Consolidation is driven by two trends: first, the highly increasing cost of developing complex drugs for degenerative diseases (e.g., arthritis, cancer, Alzheimer's disease) and new viruses (e.g., Aids); and second the reliance on very few patent-protected products for the major share of profits. The top three-products commonly account for around half of the sales in a certain market and individual leading products hold over 20 per cent of the market in Europe.

Size allows firms to spread the large risks inherent in the development of very few, but highly profitable drugs. The focus on this last dimension of the industry – its highly profitable sale of very few pharmaceuticals – has influenced the debate about benefit sharing and has given rise to a bias of over-estimating potential benefits. This has skewed the objectives of some potential suppliers of genetic resources in the direction of hoping to 'hit gold' rather than to establish themselves as long-term providers of intermediate products, as the very small number of such profitable pharmaceuticals was not enough taken into account. Indeed, a rough estimate of the probability of a sample leading to a marketed pharmaceutical product is only around 1 for 250 000 (Macilwain, 1988, 535).

The continued ability to extract transitory monopoly benefits has been assured for pharmaceutical companies by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) which obliges (WTO, 1998) developed Member countries since 1 January 1996

[13] The information about the global pharmaceutical industry is based on the study by Tarabusi & Vickery (1996). Following their study, the information provided here about the global pharmaceutical industry refers only to "ethical" (prescription) drugs and will exclude over-the-counter drugs, if not otherwise indicated.

(Article 65.1) – with further delays of four years for developing Member countries and Member countries in transition from a centrally planned into a market economy (Articles 65.2 and 65.3) and a ten-year delay for the least-developed Member countries (Article 66.1) – to accord protection of pharmaceuticals from the moment of patent application ("pipeline protection").

The importance of wild genetic resources to the pharmaceutical industry is not easy to assess in a definite and unequivocal way. Due to the manipulations of the original raw material at different stages of the research and manufacturing processes, its contribution varies in each case and average assessments can be perilous, not least because different assessments assume different degrees of substitutability of either the genetic resource itself or of the scientific know-how embodied in its further processing. Nevertheless, some serious studies have been undertaken and allow at the very least to provide indications for boundaries inside which the "true" value of the contribution of wild genetic resources has to be sought. Of course, it is quite evident that no such "true" value exists, as assumptions about relative substitutability and future contributions to combat as-of-yet-unknown diseases are necessarily hypothetical.

In 1993, the assets of United States pharmaceutical companies in developing countries were about 10 per cent. An interesting statistic in this context is that foreign direct investment in the pharmaceutical industry has greatly increased in the United States, Europe and Japan but has remained relatively stagnant in the category "Rest of the World" throughout most of the 1980s. Foreign direct investment in the "Rest of the World" was about 28 per cent of the total in 1980 and about 15 per cent in 1988, in a period when total volumes of investment in nominal terms tripled (Tarabusi and Vickery (1996), 93).

Clearly, these numbers do not permit any simple conclusions, as financial flows might not correspond precisely to the "true" contributions of developing countries as providers of inputs. When making investments in OECD non-Member countries, which constitute the vast majority of the "Rest of the World" category, labour and capital costs, access to infrastructure and to markets have to be weighed against possibly lower access costs to genetic resources. While such aggregate numbers do not permit any firm conclusions, they might nevertheless serve as a warning from overestimating the relative value of easy access to biodiversity-rich land for the pharmaceutical industry.

III.1 The "value" of wild genetic resources used as inputs in the pharmaceutical industry

Concerning estimates of the potential size of benefits, a substantial literature exists. These estimates can vary by several orders of magnitude due to differences in treating arguments such as public good values, marginal versus average values, uncertainty and others. A discussion of one of the most recent studies, which has the benefit of being informed of the results, assumptions and discussions concerning previous studies, can perhaps provide a better feel for such estimates and their implications for benefit sharing.

David Simpson and Amy Craft (1996) working on the assumption of global annual sales of US$ 300 billion estimate that gross industry profits (revenues minus operating costs) amount to some 25 per cent of total sales, or US$ 75 billion. This is the amount of the rent, the combined surplus over costs. It is due to a combination of research ingenuity and the uniqueness of genetic resources. While Chapter 4 will discuss the issue of rent sharing in some more detail, at this point only the following points shall be made: first, the pharmaceutical industry does indeed seem to be able to create large value above normal operating costs and; second, economic theory would predict that in the absence of agreements the major share of the rent will go to the party which provides the most unique (least substitutable) factor whether this be the owners of genetic resources, scientists, marketers or share-holders.

Discounted at 3 per cent per year, an annual rent of US$ 75 billion would give a net present value of *all* future rents of US$ 2.5 trillion. This would lead according to the authors under certain assumptions regarding the substitutability of different pharmaceutical products from different species and the number (which is assumed to be ten million) of species on which pharmaceutical research can be performed to an expected social value around a maximum of US$ 170 000 with a best estimate of about US$ 33 000 for the marginal species as a potential source of new pharmaceutical products (Simpson and Craft (1996), 12-16).[14]

Then, Simpson and Craft (*ibid.*, 16-17) ask the question what would happen to the social welfare linked to the pharmaceutical industry if a major shock such as a severe climate change should lead to the disappearance of a great number of species. Because of the assumed substitutability of species in the production of pharmaceutical products, the answer is: not much. Even the permanent loss of 25 per cent of all species would amount in this set-up to a net present loss of US$ 111 billion in welfare, only about 4 per cent of the net present value of all future rents or 0,01 per cent of the world product annualised at the same discount rate of 3 per cent.

The authors, on this basis (*ibid*., 18-20), then calculate implied marginal land values for 18 biodiversity "hot spots" according to the number of expected endemic species per hectare and arrive at values reaching from US$ 29 - 2 888 per hectare. These numbers are in the vast majority of cases not enough to acquire land publicly for the purpose of conserving genetic biodiversity on the basis of its potentialities in terms of new pharmaceuticals as private land-values like in California's Floristic Province or in South-Western Australia (two of such biodiversity "hot-spots" mentioned) are considerably higher.

The final results of the paper are ambivalent. The authors willingly discuss the stylised nature of their assumptions, for instance, the assumption of far-reaching substitutability which gives a too low value to major new breakthroughs such as, say, a cure for cancer, and take care to point out that there can be:

> *[...] any number of other aesthetic, ethical, ecological, and even spiritual reasons for which biodiversity [and by implication its conservation] may be important [...]* (Simpson and Craft, 1996, 3).

Such reasons, however, seem to refer to the *non-substitutable* nature of natural resources. If every species, every genetic resource is unique, the distinction between average and marginal values becomes meaningless. The assumption of substitutability with respect to the use of genetic resources as inputs into the production of pharmaceuticals gives rise to very low values that can be justified for spending on the prevention of species extinction due to climate change.

The example shows how difficult it is to come up with "correct" numbers, as they depend on assumptions, qualifications and questions asked. OECD (1997a, 28) provides an overview of different empirical estimates for *inter alia* the values of single species (successful or untested) to the pharmaceutical industry, the value of sales derived from natural products or the value of land for medicinal plants with estimates varying by two orders of magnitude or more. The most important question regards the distinction between average and marginal values.

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[14] This estimate deals about how much is a species worth on the margin (and not on average which would give US$ 250 000 instead of US$ 33 000), that is to say how much a small change in the total number of species would affect the welfare.

The marginal value of a species regards its likely contribution to the well-being of present and future generations in terms of its potential to serve as raw material or input for a valuable pharmaceutical product. The average value of a species regards the contribution of *all* species divided by the number of species. The numbers differ widely, with average values being the higher ones (see footnote 14), as the loss of any one particular species would not constitute a major loss as enough other possible contenders continue to exist. The loss of the last few species (which would have a very high marginal value assuming equal likelihood for each species to have valuable properties) is, despite growing pressures on biodiversity, only a remote possibility.

Which one of the two sorts of estimates of the value of a species is now the correct one? The answer depends on the question. A species' marginal value is relevant if the question is: how much shall the global community invest in order to prevent its extinction? If the benefit per hectare of biodiversity-rich land is higher than alternative land-uses (only in rare cases), this land should be preserved for the conservation of biodiversity. If the benefits are lower than alternative benefits from logging, agriculture or development, then these alternative uses shall be pursued.

Authors such as Simpson, Sedjo and Reid (1996) are quick to point out that their valuation take *only* into account the value of biodiversity for pharmaceutical purposes and that consideration of existence values and other biodiversity-related services might lead to higher valuations and to different land-use decisions. This shows the limits of sectoral economic reasoning and the necessity of a wider perspective given the multi-dimension nature of biodiversity.

A species' average value is interesting in the context of the question: how much money should accrue to the owner of a random wild species with a potential to serve as an input for the production of a pharmaceutical production? The average value of a species can be understood as the total economic rent of pharmaceutical products divided by the number of species. Of course, this presumes that *all* the rent should go to the holders of biodiversity resources and no payment should be made, beyond the cost to solicit their contribution, to scientists, the holders of patents and owners of pharmaceutical companies.

Any discussion about the right value of genetic resources thus has to distinguish between marginal and average valuations depending on the context. Even then, there is no one right value, as pay-offs from different species not only display a wide variance but are also wholly unpredictable in their dependence on technologies, existing diseases and consumer demand. This is not to say that the estimates are of no value. Their orders of magnitude allow the following fundamental conclusion on the basis of the most likely estimates: *the gains from the use of genetic resources as inputs for pharmaceutical products alone and hence the willingness of private pharmaceutical companies to pay for its protection will not be sufficient to cover the cost of the conservation of biological diversity without additional incentive measures provided by the public sector taking into account the existence and option values (see* infra*) of genetic resources and their surrounding ecosystems.*

IV. The Double Nature of Genetic Resources

Genetic resources have a double nature. As discussed, they are a useful input into the production of commercially valuable pharmaceuticals and hence their ownership can provide legal tender, private value. However, this captures only part of their true value. Genetic resources are also elements of larger ecosystems which have a general value for many people, both within and outside of the country in which the ecosystem is located.

The utilisation of genetic resources has thus to pay attention that, during the process of extraction, the surrounding ecosystem does not suffer harm, the rights of indigenous people are respected and contributions to economic development are made. These aspects links genetic resources to issues of general welfare, public goods, option and existence values (see Box 1 for more detail).

As a public good, biodiversity and with it the genetic resources that are a part of it cannot be conserved to a desirable extent in the absence of some form of policy action due to the fact that markets for 'natural heritage', 'national treasures', 'scenic beauty' and 'global environmental benefits' do not exist. Box 1 contains a series of arguments for the values of such goods. The involvement of governments, in complement of private activities, to implement sustainable uses of biodiversity is thus a necessity.

In practice, this can take the form of providing incentives for the private sector to render the prospecting for and the use of genetic resources sustainable. These incentive measures can be either positive, such as a tax break or a subsidy, or negative, such as a penalty for unsustainable use in form of a tax, the forfeiture of a performance bond or a regulation.

However, international co-operation in the imposition of incentive measures for sustainable and fair use is required. Many bioprospecting companies are world-wide operating multinational companies and certain genetic resources are frequently available in more than one supplier country. This limits the ability of any one supplier country to impose such conditions of sustainability or fairness. Thus, a close collaboration among provider countries could play an important task as, therefore, governments of the user countries.

A particular role is played by the requirement that benefits arising out of the utilisation of genetic resources be shared fairly. Without going into a detailed discussion of what would be constituted by a 'fair' sharing of benefits, one can state that a 'fair' sharing of the benefits is a politically agreed upon division of the benefits which differs from the division which would prevail in the absence of government intervention in an unregulated open access regime for genetic resources.

Unregulated open access has to be distinguished from an *open access* regimes in general, in the sense that unregulated open access leads to rent dissipation and a depletion of the resource which is not the case in an institutionally regulated access, often called 'open access regime' such as, for instance, the Consultative Group in International Agricultural Research in which public or private researchers can gain free access to its *ex-situ* collections without any IPR restrictions *providing* that these users make similarly neither claim on the ownership nor extend IPR over the genetic material transferred.

Box 1: Public goods – Fundamental, Existence and Option Values,

Public goods are goods which have value although no private markets for them exist, thus without government intervention too little of them would be provided. This is due to the fact that they are either very large, such as infrastructure, require the complex co-ordination of many different opinions, such as education or defence, or that they cannot be privatised in principle such as biological diversity. Even if certain elements of biodiversity (commercial plants and species) are privatised, other aspects of biodiversity such as its variety *per se*, its aesthetic and 'existence' value, are public goods. Other public goods connected to genetic resources are economic development and capacity building.

Does this mean the private sector has no role to play in the provision of public goods connected to biodiversity? To the contrary, privately profitable uses of biodiversity are essential to its protection from pressures of competing economic activities. The settlement of well-defined ownership rights will vastly improve the protection of biological diversity from a situation of unregulated open access. However, governments have to assure that private uses of biodiversity fully contribute to the conservation of its qualities over the long-term, i.e., assure 'sustainable use'.

In deciding on the appropriate *levels* of public good provision (or, in the case of biodiversity, protection) economists have developed the following concepts which are expressions of the value of public goods in general which can also be applied in the case of genetic resources.

Fundamental values: while economic theory is based on marginal analysis aiming at static equilibria and assuming substitutability between different goods, this raises important theoretical and practical problems when applied to the natural environment where dynamic issues, complementarities and non-substitutabilities are central (Botkin, 1990). However, the principle of monetisation to recall the importance of ecosystems for the economy (e.g., Costanza *et al.*, 1997) can be useful when thoroughly applied (Pearce, 1998), bearing in mind that the functioning logic of ecological systems is supporting human and economic systems and not the opposite (Passet, 1979).

Existence values: people, especially in industrial countries, value global ecosystems and biodiversity for their pure existence. The knowledge that the tropical rain forest, or most of its species, is still there provides them pleasure, even if they might never do as much as look at a picture of it. In practice, existence values are closely linked to (non-marketed) aesthetic enjoyment and to the provision of fundamental global services such as maintaining an oxygen/carbon-dioxide equilibrium.

Option and quasi-option values: option values refer to use values of certain goods which are currently not realised but *might* be realised at some point in the future. Thus governments with a long-run perspective might preserve genetic resources whose current use values are to too low for private companies to be interested in them. Option values are closely related to the *precautionary principle* as a *safety first* attitude. Quasi-option values refer to possible future usefulness on the basis of as yet unknown information (Arrow and Fisher, 1974). Given the inexhaustible nature of biodiversity constantly challenging the limits of the scientific understanding, a risk-averse attitude which keeps open the possibility of using a resource even if it never materialises can be well justified (Conrad, 1980).

Fundamental values, existence values, quasi-option values and option values are expressions for the value of biodiversity (public goods in general) beyond its immediate commercial values which can frequently be privatised and may efficiently be allocated by markets. They, therefore, require some additional incentive measures in order to be fully realised.

In economic terms, the sharing of benefits is referred to as "rent sharing". Rents are receipts for the final product (e.g., for pharmaceutical products) beyond the costs needed to produce it. These costs of production are, on the one hand, the costs of accessing, harvesting and transporting genetic resources themselves and, on the other hand, the costs of the expertise, the research facilities and the marketing know-how of pharmaceutical companies. A rent is a surplus from the receipts after the costs of access, as well as the costs of scientists, laboratories and advertising campaigns, have been deducted.

The question concerning the fairness of benefit sharing is then simply: who will get how much of the rent? All partners have probably good claims to it. The provider country can claim that it should receive the rent as the value of the product was "contained" in genetic resources over which its sovereignty is settled. The user company can claim that it should receive the rent as the value of the product was "unlocked", in a quite uncertain and risky process, only by its expertise which is however frequently legally protected by intellectual property rights.

But if both parties have a good claim to the rent, why not just let them fight it out by themselves in tough bargaining sessions or in the market place? The reason is that this would lead consistently to very one-sided outcomes which would be considered as "fair" only by a limited number of people. This is due to three facts which distribute bargaining power asymmetrically among participants in the bargaining process:

a. If on one side of the bargaining table a limited number of industry players (oligopolists) are opposed to a multitude of fairly similar supplier countries on the other side of the table, the theory of imperfect markets states that the rent will inevitably go to the oligopolists with virtually nothing going to the, more or less, competitive suppliers.

b. Bargaining strength is not only measured in numbers; the ability to use the international court system in case of disputes and the fact that a whole body of law on the protection of intellectual property exists compared to only a few tentative attempts to protect ownership of genetic resources beyond general declarations of intent, would again skew any bargaining in favour of companies processing genetic resources, as opposed to countries providing them.

c. Closely related to the previous point is the fact that the inputs other than physical biological resources which user countries might be providing into the process, such as indigenous knowledge about the effectiveness and location of certain resources may suffer from a limited "tangibility" of their value[15], in the sense that their values are not sufficiently codified, accepted and protected in international legal frameworks. The task of the expert is to "translate" these values into the language of international negotiations.

Of course, one possibility, entirely consistent with economic theory, would be to match market power with market power, *i.e.*, to represent a united front of supplier countries in form of a cartel of genetic resource providers.[16] The most prominent example for such a solution is the successful cartel of diamond producers. However, many other attempts of creating cartels have failed due to difficulties of

[15] See Munasinghe (1992, 229).

[16] Such an approach is presented in Vogel (1997). This approach raises the interesting economic question to which extent the *Convention on Biological Diversity* in itself performs the function of a relatively benign cartel continuously involved in negotiations with user countries of genetic resources. However, even such institutional meta-analysis could uncover some structural similarities to the objectives of more traditional cartels, the Convention process displays few of the tools used by industrial cartels such as supply restrictions and artificial price raising.

enforcing trust and discipline amongst its Members. However, even if such an adversarial approach were feasible and even if it could achieve a particular idea of "fairness", it is uncertain whether it would be able to contribute to that other aspect which links genetic resources to a sphere of wider public concern mentioned earlier – the sustainable use of biological diversity as a whole.

An additional aspect which links the prospecting of genetic resources and the sharing of benefits to a wider sphere of public interests beyond immediately marketable private interests is constituted by the issues of capacity building and technology transfer, which are addressed under the *Convention on Biological Diversity* in its Articles 16, 18 and 19. In economic terms these issues can receive different, even if linked, interpretations:

a. The transfer of technology relevant to the processing of genetic resources and the building of human and technical capacity can serve to capture a higher share of the rent in the supplier country by retaining certain value-adding steps inside its own jurisdiction thus strengthening its claim over the rent (see the Ten Kate and Wells case study). In final consequence, one day indigenous pharmaceutical companies might be able to manufacture and market products based on wild genetic resources themselves, thus making the distinction between provider and user countries obsolete.[17] But this would not signify the end of benefit sharing arrangements as compensations for the use of genetic resources will require continuing attention.

b. The transfer of technology and the building of capacity can also be interpreted as a contribution to the economic development of a country in general (see the Guillaud, Laird and Lisinge, Moran and Rosenthal case studies); in this case the transfer of technology would constitute only a side payment from countries with an advanced technological base to less developed countries as part of the overall rent sharing process.

c. As mentioned above, pharmaceutical countries from user countries and supplier countries are involved in bargaining processes over the sharing of rent (see the Swiss case study); while pharmaceutical companies due to their restricted number and the good protection accorded to their intellectual property rights possess some degree of monopoly (oligopolistic in fact), and hence bargaining power, supplier countries, in absence of international accords dispose over very little monopoly power. The transfer of technology can assure that the bargaining power of user countries is not further enhanced by an exclusive possession of technologies necessary to process genetic resources.

In one sense or another, capacity building and technology transfer are means to address the asymmetries mentioned between suppliers and users of biodiversity. Concrete elements of such capacity building are attempts to develop standardised access legislation or internationally agreed prior informed consent (PIC) procedures which obviate the need for each country to build up an infrastructure of monitoring and negotiating access and benefit sharing (see all the case studies).

Such PIC procedures can, for instance, include on the side of the provider country a designated national authority, definition of scope, full information, the granting of licences, the imposition of user fees or the allocation of exclusive bioprospecting rights as a permanent property over the samples; on the side of the user country it can include legislation to deter unlawful collection, imposition of record keeping obligations, requirements to co-operate in national patenting legislation (Hendrick *et al.*, 1993,

[17] Walter Reid (1994, 54) writes on this topic: "If bioprospecting is not to repeat the sad history of previous ventures based on exporting raw materials from the developing world, policies must be put in place to foster the development of domestic biotechnology capabilities."

253-255). Access legislation in several countries, such as those of the Andean Pact, Australia, Brazil, Cameroon (see the Laird and Lisinge case study), Costa Rica, Gambia, India and Malaysia (see the Ten Kate and Wells case study) or the Philippines, are designed to provide a legal and, in some cases, also an institutional framework to organise these processes.[18]

In summary, whether to achieve the 'fair' sharing of benefits, the sustainable, non-destructive use of genetic resources or the transfer of technologies and the sharing of benefits arising out of the utilisation of genetic resources requires the involvement of governments of user countries, interested in the sustainable use and extraction of genetic resources and its preservation for possible future uses, as well as the governments of supplier countries, interested in the fair sharing of the benefits and the transfer of technology and the building of capacity for future economic development.

Needless to say, it also involves those directly taking part in the prospecting and the processing of genetic resources, local populations and pharmaceutical companies. It is easy to see that local populations have an interest in a fair sharing of the benefits which might accord to them a share of rents stemming from genetic resources. Any sharing of benefits, however, has to proceed on the principle specified in Article 3 of the *Convention on Biological Diversity* stressing that:

> *States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources [...].* (UNEP, 1994)

National interests, including both governments representing these States and their indigenous and local communities, have then to be taken into account in the benefit sharing arrangements.

Last but not least, the international pharmaceutical companies have an interest in a 'fair', *i.e.*, informed by political and social considerations, sharing of the benefits arising out of the utilisation of genetic resources. How can this be? Are they not the main beneficiaries of an unregulated free access for all? Undoubtedly, but the prospecting of genetic resources is not a zero sum-game, in which one side's gain is automatically the other side's loss.

Much rent can be dissipated in fruitless struggles with hostile immigration and customs officials; the securing of a continuing supply of high-quality materials requires trained and well-motivated ground-staff who will want to participate even to some small degree in the sharing of final profits beyond a subsistence wage (see the Laird and Lisinge case study); legal security, the sensitivity of pharmaceutical companies to a commercial boycott due to their dependence on a few products for their rents (see the Guillaud case study) and the assurance of long-term availability of supplies which are not being snatched up by a lucky competitor can outweigh any short-term considerations of maximising its relative share of the benefits (see the Swiss case study).[19]

Clearly, this does not mean that there is no conflicts and that no massive differences in interests remain among the different parties involved. However, economic theory can provide some useful arguments towards a co-operative model to aim for a 'fair' sharing of benefits as opposed to an adversarial model. Box 2 contains a hypothetical example of just how such a co-operative model might look like for illustrative purposes. In practice, many other examples are thinkable as it is demonstrated by the synthesis

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[18] For more information on access legislation, see Convention on Biological Diversity (1995 & 1996).

[19] David Simpson & Roger Sedjo (1994, 40), amongst others, insist on the importance of the high quality of sampling and recording in the considerations of bioprospecting companies. Efficiency wage theory would provide rationales for paying workers higher than marginal wages, if difficult to monitor diligence is an important work requirement. The argument can be extended to other aspects of benefit sharing.

of case studies (see below the second part of the paper). Indeed, these experiences are not completely following such co-operative steps as they are primarily the fruit of private initiatives, although often supported by government institutions. The hypothetical example is thus more forward looking assuming the existing of a coherent international effort which provides some guidance towards a fair sharing of benefits stemming from the utilisation of genetic resources.

Box 2: A Hypothetical Example of Benefit Sharing with Regulated Access

In a particular case of prospecting for biological resources the following actors might be involved: G_{dev}, the government of a supplier country, most likely a developing country; L, the local populations in that country possessing knowledge about the properties and locations of potentially interesting plants; P, a pharmaceutical company interested in bioprospecting in an area under the jurisdiction of G_{dev}; and G_{ind}, the government of the country in which P is incorporated, pays taxes and sells most of its products, and which is most likely to be an industrialised, developed country. After initial contact has been made and interest in bioprospecting is confirmed, fair and sustainable benefit sharing could proceed according to the following manner:

1. G_{dev} and G_{ind} are already settling in an international forum such as the Conference of the Parties to the Convention on Biological Diversity what constitute sustainable practices and a 'fair' sharing of the benefits such as capacity building and transfer of technology, fee payments and royalties, ownership of samples and patent protection.

2. P signals its intent to bioprospect to G_{ind}.

3. G_{ind} induces P to adhere to fair and sustainable practices; possible incentive measures in this context could be:
   - legal constraints according to its national legislation on sustainable bioprospecting;
   - a non-binding but widely publicised certification process;
   - support for sustainable practices in form of tax reductions for profits from the receipts on products developed with the help of sustainably harvested biological resources;
   - penalties such as forfeiture of performance bonds for engaging in unsustainable practices.

4. G_{ind} signals to G_{dev} that P has received "clearance" after agreeing to adhere to sustainable practices.

5. G_{dev} guarantees access to P under a limited number of reasonable conditions.

6. P engages with G_{dev} and L into the details of bioprospecting and benefit sharing clarifying issues such as sample quality; in-kind contributions and capacity building.

7. Bioprospecting proceeds; benefits are shared according to the agreements mentioned under 1.

8. After conclusion, a report is deposited with an international organisation, such as the Secretariat of the Convention on Biological Diversity for verification and comparison of experiences.

This is a hypothetical example. At this point, the choice of particular incentive measures is secondary. The important point is that successful benefits sharing have to take into account the interest of *all* the stakeholders in the process: those of G_{dev} and L to facilitate economic development, the sustainable use of their genetic resources and a fair return for their biological and cultural assets; those of P in access and a high quality of biological inputs; and those of G_{ind} in the conservation of biodiversity and a stable international framework for business.

V. Conclusions

Any discussion about the economics of sharing of the benefits arising out of the utilisation of genetic resources has to take into account the following fact which defines the context of benefit sharing: any continuation of unregulated open access regimes for areas with high biological diversity, whether on the national or on the global level, would lead to the depletion and destruction of the commercially valuable genetic resources *as well* as of the surrounding ecosystem with its fundamental, existence, option and quasi-option values. Resource depletion would be virtually assured due to competing pressures for land use from economic sectors such as agriculture, logging or industrial development projects.

Benefit sharing agreements have to insert themselves into a logic which takes into account the double nature of biodiversity – its private and its public value. The use of genetic resources as inputs for the production of profitable pharmaceutical products displays a strong structural similarity to the value of information in industrial production. Adequate protection of the generators of information (inventors, scientists and designers) as well as of the owners of valuable genetic resources is necessary to guarantee the maximum of possible returns for individual companies, indigenous and local populations as well as for the economy as a whole.

The logical alternative to unregulated open access (see p. 14) is the allocation of well defined ownership rights which include the whole range of ownership going from access, use and exclusive private property rights. In this context, far-sighted pharmaceutical companies might, for instance, acquire tracts of biodiversity-rich lands. Their outlays would be commercially justified up to the amount of all future expected profits generated by the genetic resources of the respective area. If such property or use rights are tradable, economic efficiency in private good terms alone could be achieved.

But, as a solution to benefit sharing issues such acquisitions would be, however, inadequate due to a series of reason discussed in the preceding chapters:

- First, bargaining over correct prices among providers and users would be skewed by asymmetries in the bargaining skills and information.
- Second, the utilisation of genetic resources is explicitly expected to contribute to the building of indigenous and local populations' productive capacity and to assist the provider country in furthering economic development.
- Third, and maybe most importantly, at least from an OECD perspective, the utilisation of genetic resources has to be linked to the sustainable use of the whole of biological diversity. A benefit sharing regime which would maximise the private value of genetic resources, but would not maximise their public value and the existence value of the surrounding ecosystem or would restrict access to the public would correspond neither to the letter, nor to the spirit of the Convention on Biological Diversity.

When considering the necessary elements of benefit sharing along with the efforts to conserve and sustainably use the whole of biodiversity, the following general considerations have been identified. First, provider countries have to develop the appropriate capacity to engage in bargaining on a level playing field with the users of genetic resources over adequate benefit sharing. While there exist no one-size-fits-all solution, it is clear that such capacity includes the aspects of information, institutions and legal

infrastructure.[20] While to some extent the process of the *Convention on Biological Diversity* is in itself part of this capacity building, through sharing of information, advising and offering models for co-operation, its achievements have to be complemented by processes in both provider and user countries.

Second, one of the fundamental elements of all activities which are part of the paradigm of sustainable use is their *conditionality*. Like other activities utilising elements of biodiversity, the main activity underlying the sharing of benefits arising out of the utilisation of genetic resources like bioprospecting has to adhere to certain conditions which maximise its contribution to the global public values of biological diversity. Other than the actual *sharing* of potential profits, *i.e.*, the transfer of financial assets, this includes the non-destructive use of the surrounding ecosystems, the respect for the traditions and knowledge of local and indigenous populations, the sharing of information and the transfer of technology. Only the adherence to such conditions would guarantee the fundamental, existence, option and quasi-option values of biological diversity as a public good.

Concretely, the inclusion of these wider objectives into benefit sharing processes are supported by the development of procedures which enforce prior informed consent (PIC) for bioprospecting companies, by the development of standard contracts and by the further sharing of experiences with access and benefit sharing agreements in a standardised format as requested in Article 6 of Decision IV/8 of the Fourth meeting of the Conference of the Parties to the Convention on Biological Diversity held from 4 to 15 May 1998 in Bratislava, Slovakia (see Annex 1).

In the last instance, an economic analysis of the benefit sharing issue confirms that any viable solution will have to take into account the interests of *all* stakeholders. And these stakeholders do not only comprise pharmaceutical companies and the governments of provider countries. They comprise indigenous people in biodiversity areas and the governments of user countries, many of them OECD Member countries which transmit the double interest of their citizen to have access to genetic resources *and* to preserve global public good values.

The organisation of the cost and benefit flows between the different groups of shareholders is ultimately the challenge of benefit sharing policy. "Fairness" of benefit sharing is not so much based on an idealistic notion of re-distribution, but on the correct assessment of the relative contributions to common gains, whether they are measurable in monetary terms (such as proceeds from pharmaceutical products) or accountable as part of the global natural heritage (such as existence values), In addition, fairness implies to provide all participants in this global exchange with equal access to the international decision-making bodies and to equal endowments of legal and bargaining skills.

A final word of caution, whatever the "true" value of genetic resources, the proceeds from their utilisation, whatever the partition of the rent will turn out to be, are unlikely to be high enough to cover the costs of conserving areas with biodiversity-rich ecosystems large enough to be compatible with the desired conservation of global public goods. Some incremental financing, whether through tax breaks for bioprospecting companies adhering to sustainable practices and benefit sharing, direct transfers or other means from parties interested in such global benefits (amongst them OECD Member countries) to parties bearing the cost of sustainable, as opposed to unsustainable use, will most likely be necessary. In practice, payments for rents stemming from the private value of genetic resources and payments for maintaining the

[20] Although this paper concentrates on the case of developing countries as genetic resource providers and developed ones as users, the latter countries are also providers of resources, mainly through their national park networks (see the Ten Kate, Touche and Collis case study). Therefore, benefit sharing is also an issue *inside* developed countries.

public value of entire ecosystems might not be always distinguishable from the point of view of the individual recipient. For policy-making purposes, however, it is useful to distinguish the different components.

Timothy Swanson (1997, 110) develops an example of such an approach in some more detail in connection with internationally tradable development rights. In the example, choices between ecologically sustainable and unsustainable development can be influenced through the acquisition of such rights in return for certain land use restrictions such as clearance or burning. However, the essential logic that conditionality requires appropriate incentives applies generally:

> *To the extent that the international community wishes to reduce the development intensity away from the local optimum (of high intensity conversion and use), then it must be willing to provide a stream of [...] payments to compensate for the forgone development and to pay for the additional factors required [...].* (Swanson, 1997, 111)

To the extent that benefit sharing shall equally contribute to general policy goals, be they economic development, sustainable use of biodiversity or "fairness", a similar compensation for incremental costs will be necessary.

A first step into such an organisation of flows could be a more precise assessment, quantitative *and* qualitative, of the desired objectives in terms of public good conservation. The issue of benefit sharing will not be solved in the perspective of a zero-sum game between pharmaceutical companies and provider countries. Economic analysis as well as common sense indicate, once more, that only a solution that maximises total benefits, private and public, of *all* stakeholders will be environmentally, institutionally and economically sustainable.

ANNEX 1:
Text of Decision IV/8 "Access and benefit-sharing"
adopted by the Fourth Meeting of the Conference of the Parties
to the Convention on Biological Diversity[21]

The Conference of the Parties

1. *Requests* the inter-sessional open-ended meeting referred to in decision IV/16, paragraph 2, to explore options for access and benefit-sharing mechanisms and to start work on paragraph 10 of decision IV/15 and to make recommendations for future work;

2. *Requests* the Executive Secretary to invite information from Parties and relevant organizations in time for the inter-sessional meeting in respect of those *ex-situ* collections which were acquired prior to the entry into force of the Convention on Biological Diversity and which are not addressed by the Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization, to help the inter-sessional meeting to make recommendations to the fifth meeting of the Conference of the Parties for future work on resolving the issue of such *ex-situ* collections, with due regard to the provisions of the Convention;

3. *Decides* to establish a regionally balanced panel of experts appointed by Governments, composed of representatives from the private and the public sectors as well as representatives of indigenous and local communities, operating in accordance with decisions II/15, III/11 and III/15, under the Conference of the Parties and reporting to its next meeting. The mandate of this panel would be to draw upon all relevant sources, including legislative, policy and administrative measures, best practices and case-studies on access to genetic resources and benefit-sharing arising from the use of those genetic resources, including the whole range of biotechnology, in the development of a common understanding of basic concepts and to explore all options for access and benefit sharing on mutually agreed terms including guiding principles, guidelines, and codes of best practice for access and benefit-sharing arrangements. These options might address, *inter alia*, the elements set out in the annex to the present decision;

4. *Requests* the financial mechanism to give special emphasis to the following programme priorities to fund initiatives by eligible Parties:

(a) Stock-taking activities, such as, for example, assessments of current legislative, administrative, and policy measures on access to genetic resources and benefit-sharing, evaluation of the strengths and weaknesses of a country's institutional and human capacity, and promotion of consensus-building among its different stakeholders; and, for those developing country Parties that have identified arrangements for benefit-sharing as a national priority;

(b) Formulation of access and benefit sharing mechanisms at the national, sub-regional and regional level including monitoring and incentive measures;

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[21] In the interests of speedily informing interested readers of the results of the fourth meeting of the Conference of the Parties (Bratislava, Slovakia, 4 to 15 May 1998), the Secretariat of the Convention on Biological Diversity has made available the texts of the decisions adopted on the final day of the meeting. These are advance unedited versions, and are subject to editing and correction as required. The final texts of the decisions will be included in the full report of the meeting currently under preparation.

(c) Capacity-building for measures on access to genetic resources and sharing of benefits, including capacity-building for economic valuation of genetic resources;

(d) Within biodiversity projects, other specific benefit sharing initiatives, such as support for entrepreneurial developments by local and indigenous communities, facilitation of financial sustainability of projects promoting the sustainable use of genetic resources, and appropriate targeted research components;

5. *Invites* all relevant organizations and the private sector to support efforts by Parties and Governments to develop and promote legislative or administrative measures, policies and programmes which facilitate the distribution of benefits arising from the use of genetic resources on mutually agreed terms and to update the Executive Secretary on a regular basis regarding their activities and experiences;

6. *Requests* the Executive Secretary:

(a) To explore the possibility of linking the clearing-house mechanism with relevant international and other organizations to access publicly available information on intellectual property rights which are based on biological resources and to report on the progress made on this matter to the Conference of the Parties at its fifth meeting;

(b) To compile information on access and benefit-sharing arrangements and to disseminate such information in a standardised format through the clearing-house mechanism;

(c) To facilitate the exchange of information related to access and benefit-sharing through appropriate means such as the clearing-house mechanism;

(d) To prepare a background document on the review of implementation of measures to promote and advance benefit-sharing arrangements, based on the experiences submitted by Parties, Governments and relevant organizations.

Annex

1. Prior informed consent in provider countries for access to genetic resources and research and development.

2. Clear, established mechanisms to provide such consent, including, *inter alia*, legislative, administrative and policy measures, as appropriate.

3. Reference to the country of origin, where available, in relevant publications and patent applications.

4. Mutually agreed terms including on benefit-sharing and intellectual property rights and technology transfer, where appropriate.

5. Efficient permitting and regulatory procedures that avoid burdensome procedures involving high transaction costs.

6. Incentive measures to encourage the conclusion of contractual partnerships.

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SYNTHESIS OF CASE STUDIES ON THE SHARING OF BENEFITS ARISING OUT OF THE UTILISATION OF GENETIC RESOURCES

I. Introduction

The various case studies on the sharing of benefits arising out of the utilisation of genetic resources synthesised in this section of the paper have either been submitted to the Secretariat of the Convention on Biological Diversity (SCBD) on the occasion of the Fourth meeting of the Conference of the Parties to the Convention (Laird and Lisinge; Moran; Ten Kate, Touche, and Collis; Ten Kate and Wells), or have been prepared for the OECD Working Group on Economic Aspects of Biodiversity (Guillaud; Rosenthal; Swiss Federal Office for Foreign Economic Affairs, and Swiss Federal Institute of Intellectual Property).

However, despite the fact that the studies submitted to the CBD follow the structure the Secretariat requested when it called for case studies, all of the studies collected here differ significantly in scope.. Thus, some describe a particular arrangement established between collaborators regarding a particular genetic resource (Laird and Lisinge) or a type of genetic resource (Moran; Ten Kate, Touche, and Collis), while others are more general and analyse policy-orientation around a particular product development (Ten Kate and Wells) or of a funding institution promoting benefit sharing (Rosenthal). Finally, one paper discusses a pilot benefit sharing scheme currently being established (Guillaud), while the Swiss paper (Swiss Federal Office for Foreign Economic Affairs and Swiss Federal Institute of Intellectual Property) presents the actual behaviour of various Swiss companies, universities and research institutes involved in the international exchange of genetic resources and possible incentives to promote benefit sharing.

Following, roughly speaking, from the most specific to the most general of these case studies, an overview of each is presented, followed by answers to a number of specific questions for each case study. Despite the different scopes of the case studies, the policy orientation described is, basically, based on experiences of benefit sharing arrangements undertaken by the United States, either co-ordinated by its governmental bodies (the US National Cancer Institute and the National Institute of Health) or undertaken in the United States itself. Indeed, the Moran, the Ten Kate, Touche, and Collis, the Ten Kate and Wells, the Rosenthal, and partly the Laird and Lisinge case studies concern the United States as a user party; while the other part of the Laird and Lisinge, the Guillaud, and the Swiss case studies involve France and Switzerland as the users of genetic resources.

To a certain extent, this reveals the global importance of American pharmaceutical companies, but it also reveals how closely linked the question of benefit sharing is to the national co-operation policies in user countries. Despite the focus on the US experience, the different case studies provide a rich and varied picture. The experience and the evolution of US policy on bioprospecting arrangements – in particular the organisation of a deeper co-operative product development and technology transfer with providers – is of much interest.

Several issues come into focus: the fundamental issue of non-monetary benefits from the bioprospecting for pharmaceuticals; the pre-condition of a benefit sharing arrangement – although subject to changes over the course of a long lasting collaboration – for access to the resource; and the importance of a trust fund to integrate the collaboration into a wider development strategy. At the current time, most

bio-prospecting experiences do not credit local and indigenous knowledge and practices other than a general recognition of their importance. Efforts in this area are still just beginning, and there are no clear policy recommendations for implementing benefit sharing strategies between the users and providers of genetic resources for the pharmaceuticals, phytomedicals, and cosmetics industries, other than depending on the good will of private companies.

If possible, in the future, other OECD country experiences should be added to those described below in order to deepen the analysis, and to further enlighten policies aimed at the fair sharing of benefits arising from the utilisation of genetic resources.

II. Overview of the Case Studies

The Laird and Lisinge case study. This study makes a comparison between two benefit sharing arrangements taking place in Cameroon which are based on particular genetic resources: *Ancistrocladus korupensis*, a forest vine with no reported local use, but of potential pharmaceutical importance against the human immunodeficiency virus (HIV); and *Prunus africana*, a hardwood species whose bark has limited traditional medicinal use locally, but whose greatest demand is as a phytomedical treatment for prostate hyperplasia in Europe with total sales estimated at US$ 150 million per year. This comparison reveals that the research and development collaboration – which is essentially a – non-monetary benefit sharing arrangement – is of crucial importance in *pharmaceutical* bioprospecting as the odds of developing a commercial product (and so the payment of royalties to local communities under a monetary benefit sharing arrangement), are very slim; while in *phytomedical* product development, traditional knowledge is often a direct lead, but an affordable and reliable source of raw material is required so that the product can serve as the basis for a sustainable income-generating activity.

In the *A. korupensis* case, the institutions involved are: on the provider side, the Korup National Park (where the original collection took place in 1987), the University of Yaounde and the Government of Cameroon (basically the Ministry of Environment and Forests, and the Prime Minister's Follow Up Commission for the Exploitation and Conservation of *A. korupensis*); on the user side, the United States National Cancer Institute (NCI), the Missouri Botanical Garden, and Purdue University.

The NCI Letter of Collection was discussed in 1992 and signed in 1993 with the University of Yaounde, but was then revoked by the Government of Cameroon upon deciding that a university was not a suitable institution to defend national interests. No other agreement has been signed. While the NCI no longer pursues research and development into the anti-HIV michellamine B derived from the vine because of its toxicity, it still considers it as a potential promising compound.

In the *P. africana* case, the institutions involved are: on the provider side, the Mapanja and Bokwongo villages, the Mount Cameroon Project, and the Ministry of Environment and Forests; on the user side, the French owned Plantecam-Medicam company, which is the main purchasing company for that resource in Cameroon. The Mapanja and Bokwongo Village Traditional Councils signed in 1997 an agreement to generate higher benefits to the villages by supplying Plantecam with barks harvested sustainably.

The Moran case study. This study examines a pilot programme in Nigeria to test the feasibility of using an independent trust fund (whose draft constitution is attached to the case study) in benefit sharing agreements for phytomedical bioprospecting. The institutions involved are: on the provider side, local traditional healers' organisations, the Nigerian-based non governmental organisation Bioresources Development and Conservation Programme (BDCP) , which is working on pharmaceutical leads against tropical diseases, and the University of Nigeria; on the user side, the American company Shaman Pharmaceuticals which uses ethnobotany to develop phytomedical products, and the Healing Forest Conservancy (HFC), an American non governmental organisation created in 1990 by this company to promote long-term survival of tropical forest biodiversity.

The BDCP, in close co-operation with HFC since 1990, facilitated the creation in 1997 of a long-term trust fund, the Fund for Integrated Rural Development and Traditional Medicine. This was financed by the HFC through a US$ 40 000 donation to fund capacity building so that bioresources are viable to achieve health care improvement and sustainable development. To date, Shaman has not developed a commercialised product.

The Ten Kate, Touche, and Collis case study. This case study describes the benefit sharing arrangement between the United States Yellowstone National Park (YNP), provider of thermal micro-organisms, and the American Diversa Corporation, which works on enzymes produced in extreme conditions which are of particular interest for pharmaceuticals, agriculture, and biotechnological products. In its negotiation, YNP was helped by the American non-governmental organisation World Foundation for Environment and Development to clarify issues for this bioprospecting pilot programme.

The contract signed in 1997 settles an initial five-year Co-operative Research and Development Agreement (CRADA), although benefit sharing and reporting obligations extend beyond the termination of this agreement. This was the first time that a United States National Park developed a programme to enable it to obtain a share of research-generated benefits arising from the use of its resources. Under the arrangement, to gain access to extremophilic micro-organisms as well as other genetic resources in the Park, and to be able to use specimens collected earlier for product development, Diversa provides the YNP with an up-front payment of US$ 20 000 per year for five years, to be offset against any future royalty payments received under the agreement, and the company transfers equipment and training to the Park staff.

The Ten Kate and Wells case study. This study gives an overview of the policy-orientation of the United States National Cancer Institute (NCI, one of seventeen American National Institutes of Heath) in the sharing of the benefits arising from the utilisation of genetic resources. The first introduction of benefit sharing issues by the NCI took place in 1988 with the development of the Letter of Intent (LOI), used for the first time with Madagascar in 1990. There was little room in the LOI for any value-added for the provider country other than the training of a scientist at the NCI, the receipt of research results, and royalty payments should the sample give rise to a product licensed by the NCI as it cannot commercialise products itself.

The LOI was revised in 1991, and in 1992 became the Letter of Collection (LOC), introducing more value-added to the provider country through the transfer of technology and capacity building for drug discovery and research. Finally, in 1995, the Memorandum of Understanding (MOU) was developed which further enhances the value-added for the provider, and is increasingly used as the partnership model. The MOU establishes that the provider country undertakes all collection work, primary screening, and isolation of active compounds, instead of going through an NCI contractor and exporting the sample. Where these techniques are lacking, the NCI equips the provider country. The NCI undertakes anti-cancer and anti-HIV screens and repatriates the results to the provider within three months, publication is made jointly and the NCI will not distribute material to third parties without the consent of the provider. Royalties and compensation are directly negotiated between the provider and the licensee.

The case study presents this evolution through a comparison of the development processes of two products: the anti-HIV compounds Calanolide A and B isolated in 1992 from the collection of samples of the tree species *Calophyllum lanigerum* and *Calophyllum teysmannii* from Sarawak (Malaysia), and the anti-tumour semi-synthetic drug Topotecan, whose natural active compound

Camptothecin comes from the tree species *Camptotheca acuminata* obtained from China by the United States Department of Agriculture in 1911, 1927, and 1934.

In the case of Calanolides, the institutions involved are: on the provider side, the State Government of Sarawak (basically the State Forestry Department), and the company Sarawak-Medichem Pharmaceuticals; on the user side, the NCI, the University of Illinois at Chicago, which has been conducting for the NCI the collection of samples in Sarawak since 1987 under a Sarawak Collection and Export Permit, and the American company Medichem Pharmaceuticals. The collaboration is organised through three agreements: the LOC between the NCI and the Sarawak State Government, the five-year Co-operative Research and Development Agreement (CRADA) between NCI and Medichem, and the 50:50 joint-venture between the Sarawak Government and Medichem Pharmaceuticals. The product Calanolide A is currently in phase II clinical tests and Calanolide B is in pre-clinical tests.

In the case of Topotecan – because there was little regulation of access to genetic resources at the time of the collection of *C. acuminata* – there was no formal arrangement with China as the initial provider. Supply of Camptothecin between the mid-1980s and the early 1990s came from Chinese and Indian pharmaceuticals, and currently it comes from an international broker, sourcing it from Brazilian plantations. The USDA sent plant extracts to NCI for anti-tumour testing in 1957, but the agreement cannot be recalled. The American non-profit Research Triangle Institute succeeded in isolating Camptothecin in 1966 under an NCI contract, but trials were terminated in 1972 due to product toxicity.

In the mid-1980s, the NCI set up a National Co-operative Drug Development Group (NCDDG), which provided the framework for a collaboration among the American company SmithKline Beecham (SB), Johns Hopkins University, and the Universities of Florida and Virginia. This NCDDG worked on Topoisomerases which are critical to cell replication, and therefore of great interest for cancer research. Through that participation, SB also worked on Camptothecin and its ability to inhibit a particular Topoisomerase. SB continued independently its work on Camptothecin, and developed Topotecan from it in 1986 and filed an exclusive patent. Clinical trials began in 1990 in collaboration with NCI, and the product was approved in the United States in 1996 and marketed as Hycamtin-R®.

The Rosenthal case study. This study presents the International Cooperative Biodiversity Groups (ICBG) Program, a United Sates Government funded initiative to promote the sharing of benefits arising from the utilisation of genetic resources with the aim to improve human health through the discovery of natural products having medicinal properties, to conserve biodiversity through the raising of the values of natural resources, training and infrastructure building, and to promote sustainable activities.

The study gives the basic guidelines developed by the ICBG, which was established in 1992 by three United States agencies: the National Institute of Health, the National Science Foundation, and the United States Agency for International Development, but the latter has since withdrawn from the programme. In 1993 and 1994, the ICBG awarded co-operative agreements (rather than grants) to a principal investigator at a United States university or research institute for financing the work of five groups, each for a five-year period, in Suriname, Costa Rica, Argentina-Chile-Mexico, Peru, and in Cameroon-Nigeria. The principal investigator then forms one or more contracts to organise the members' collaboration between American and provider country universities, environmental organisations, and pharmaceutical companies.

The Guillaud case study. This study describes the benefit sharing scheme, called Biodivalor, proposed by the French non-governmental organisation Pro-Natura International (PNI), and financed up to FF 7 million by the French Government (French Development Bank and State Secretariat for Co-operation). Its feasibility has been tested since 1996 in Gabon, but as no information is available at this time, the paper only describes the framework of Biodivalor. While pharmaceuticals, agrochemicals, food, cosmetics, and aromas are covered in this benefit sharing arrangement, it is most applicable for pharmaceuticals and cosmetics because of the specificity of benefit sharing arrangements in the agro-food industry.

PNI, in collaboration with a local scientific institution, serves as an intermediate between a bioprospector and a provider country for the supply of samples, and ensures that parties satisfactorily fulfil their undertakings. At the centre of the agreement is a trust fund, the Special Ecodevelopment Fund, which is financed by the full profits generated through the sale of samples, sold at the international price, and at least 50 per cent of the royalties should the sample give rise to a commercialised product.

The Swiss case study. This study presents a review of the current situation of benefit sharing issues dealt with by Swiss companies, universities, and research institutes involved in the international exchange of genetic resources. It is based on a questionnaire jointly formulated by various representatives of these institutions which agreed to collaborate on the study. The main result of the completed questionnaire is that experts from industry as well as from universities attach a great importance to free access to genetic resources in the guarantee of freedom of research, while a restrictive policy of granting access is seen as having possible negative effects for the transfer of technology and the attractiveness of natural substances, particularly for the chemical and pharmaceutical industries.

The study therefore concludes that a non-compulsory code of conduct represents the most promising instrument to implement incentives for further co-operation between the providers and users of genetic resources, and constitutes the most flexible mechanism for addressing complex questions relating to the facilitation of access to genetic resources and the aim of sharing benefits, yet allows the greatest possible participation from industrialised as well as developing countries.

III. The Practice of Benefit Sharing: Answering the Relevant Questions

In order to better organise the information contained in the seven case studies, eight questions were formulated regarding the different experiences with the sharing of benefits arising from the utilisation of genetic resources. These questions follow those formulated by the Expert Group on Economic Aspects of Biodiversity in the document "Procedures for the Provision of Empirical Material on the Sharing of Economic Benefits from the Utilisation of Genetic Resources" [ENV/EPOC/GEEI/BIO(97)5]. Through these questions, the information contained in these studies about the different aspects of benefit sharing are easily accessible in a comparative format.

III.I At which point was benefit sharing introduced?

Overview. In nearly all cases, benefit sharing arrangements are introduced after the extraction of material has taken place. This can be explained by the innovating dimension of such arrangements in bioprospecting. However, with the introduction of a benefit sharing framework, such as the ICBG or Biodivalor, benefit sharing arrangements are becoming a pre-condition to bioprospecting, although this does not mean that these arrangements are not subject to change; as bioprospecting itself is a dynamic process.

The Laird and Lisinge case study. In the *A. korupensis* case, the benefit sharing agreement was introduced in 1992, after the screening and the identification in 1990 of the promising compound by the NCI, as a result of the necessity to ensure a large-scale supply of raw plant material for the research and development process. In the *P. africana* case, the agreement arose from the effort to correct the unsustainable harvest of the resource as the Mount Cameroon increased supply of the resource after its exhaustion in the North West Province.

The Moran case study. The trust fund, which organised concretely in 1997 the sharing of benefits, was created long after the first discussion and financial support of the University of Nigeria by Shaman in 1990, the 1993 research and plant export permits drawn up by the government, and the mutual agreement (not discussed in the case study) established among Shaman, the Nigerian scientists, BDCP, and local villages.

The Ten Kate, Touche, and Collis case study. YNP and Diversa discussed the establishment of a CRADA for three years before it was signed. During that time, Diversa worked in the Park under Research Specimen Collection Permits, which excluded commercialisation possibilities. But when the CRADA was signed, Diversa gained the right to use previously collected samples for commercial purposes, so it can be considered that the benefit sharing took place, to some extent, after extraction and screening were already done.

The Ten Kate and Wells case study. In the case of Calanolide, the benefit sharing arrangement was made after the collection, and the negotiations took place at the same time as the screening and isolation activities. In the case of Topotecan, no benefit sharing arrangement are in place.

The Rosenthal case study. All of the benefit sharing arrangements were made before the beginning of the research, but as the research and development process is dynamic, all agreements have been modified since, based on experiences and the technical and political developments.

The Guillaud case study. The Biodivalor contract was developed prior to any bioprospecting taking place, and it links access to genetic resources to a benefit sharing agreement.

The Swiss case study. Under material transfer agreements (MTAs), the timing of the sharing of monetary and non-monetary benefits is agreed to in accordance with the needs of the parties on the basis of mutually agreed conditions. This allows for a degree of flexibility in the interest of the parties, and in the agreement on objectives. Generally, MTAs contain concrete principles for benefit sharing. Genetic resources needed for research are acquired by pharmaceutical and plant protection industries through private screening companies, which are mostly situated in the United States. It is usually required that resources are acquired in accordance with the relevant rules of the Convention on Biological Diversity. For the research on seed products, there are practically no commercial contacts with developing countries, the only agreements are the transfer of materials to developing countries. With regards to foodstuffs, contacts are primarily made through local representatives situated abroad or universities and research institutes, but no data is given in the study on when such agreements have been settled.

III.2 Which type of contractual relationships were formed?

Overview. In all cases, the relationship formed around bioprospecting projects results in a long-term collaboration beginning with scientific co-operation and continuing through the long lasting prior informed consent (PIC) process of all partners, in particular local and indigenous communities. The benefit sharing arrangement describes duties, the field of co-operation, and compensations for all partners, and can take diverse contractual forms depending on each situation as governmental institutionalised procedures (types of contracts) are fundamental at this stage.

The Laird and Lisinge case study. In the *A. korupensis* case, in terms of the access to the resource by the NCI, the resource collecting is done by the Missouri Botanical Garden, and the research on the cultivation at Korup by Purdue University, the NCI Letter of Collection (LOC) provided for the provision of test results, research exchanges, royalties, and other forms of compensation including equipment, infrastructure support, and transfer of technologies to Cameroonian collaborators. Despite the revocation of the LOC, collaboration continued but no agreement was signed because of a failure to clarify the respective responsibilities of the Cameroonian stakeholders.

However, the adoption of the 1994 Forestry law and the 1996 Environmental Management law requires respectively that royalties be paid, and that scientific research and collection benefit the country. It was later stated by Cameroon that an agreement should include such benefits as the return of research results, that propagation and cultivation research should take place at Korup (and only in Cameroon), training in plant taxonomy, and assistance in the evaluation of new natural products and the authentication of traditional medicines.

In the *P. africana* case, the first relationship between villagers and Plantecam was established when the village granted permission to the company for collection over a period of two years for a payment of FCFA 125 000 . Given the massive illegal harvesting that was occurring, discussion began in 1994 of the possibility of bringing the villagers under Plantecam's license for bark collection, and a participatory study was undertaken on gathering and identification of common ground for the set-up of a

gathering system. The licence agreement was signed in 1997, and guarantees the company will purchase from each village a monthly maximum of 10-tonnes of sustainable bark, with payments to the gatherers based on the price received before by middlemen, and with 7 per cent of this revenue diverted to finance a Village Development Fund.

The Moran case study. At the beginning of the collaboration and during research expeditions, Shaman provides specific up-front compensations through small grants and small-scale project development funding in response to the immediate needs of country and community collaborators. Long-term compensation will be available through royalties paid by Shaman, and channelled through the HFC, should a product be commercialised. The arrangement specifies that such royalties would be divided equally among all collaborators Shaman ever worked with, regardless of the origin of the plant sample or traditional knowledge used.

The Ten Kate, Touche, and Collis case study. A CRADA relationship organises the way a private company contributes money and expertise to a federal laboratory (i.e. any research institution operated by the Federal Government) in order to augment its own expertise and in exchange for technology and rights, by means of a license, in any resulting useful discovery arising from the research.

The Ten Kate and Wells case study. In the case of Calanolide, the benefit sharing arrangement operating inside the United States is organised by a CRADA between the NCI and the private company Medichem, while the benefit sharing arrangement between the State of Sarawak and the NCI takes the form of a LOC, and between the State of Sarawak and Medichem it is through the creation of a joint-venture. In the Topotecan case, all collaboration takes place inside the United States, and the benefit sharing agreement was established under an NCDDG, which is intended to encourage synergistic interactions between novel ideas within academia and cutting edge research within industry. The NCI provides core funding and, if required, technical assistance. Under such an agreement, if an innovation is developed the rights to it are held under a joint patent, and therefore include a sharing of the downstream royalties. However, because SB independently investigated Camptothecin derivatives to get lower toxicity, greater solubility, and better selectivity than Camptothecin itself, SB is not linked under that agreement.

The Rosenthal case study. The research and development process is the core of the relationship between providers and users. In Costa Rica (insects study), the organisational approach is a one contract model among all members (basically Cornell University, Bristols-Myers Squibb Pharmaceuticals, and the National Biodiversity Institute of Costa Rica). At the other extreme is a wheel of bi-lateral contracts for the group including Chile, Argentina, and Mexico (arid land plants study) at the centre of which is the University of Arizona, and the company Wyeth-Ayerst American Cyanamid.

In Suriname (rainforest plants study) and in the group involving Cameroon and Nigeria (also a rainforest plants study) the approach is also bi-lateral, at the centre of which is the Conservation International-Suriname and the Bedrijf Geneesmiddelen Voorzietring Suriname, and the Bioresources Development and Conservation Programme in the Cameroonian-Nigerian case, with the responsible company again being Bristols-Myers Squibb in Suriname and Shaman Pharmaceuticals in Cameroon-Nigeria. But in the Suriname and Cameroonian-Nigerian cases, these institutions have separate contracts for the agreement about collections and benefit sharing on the one hand, and the commercial research and development agreement on the other hand.

Finally, in Peru (traditional medicinal plants study), the bi-lateral arrangements take the form of a triangular relationship: first there is the biological collecting agreement (between the Aguaruna Peoples

and Washington University); second, the license option agreement (between Washington University and Monsanto-Searle Pharmaceuticals); and, last, the know-how license (between Monsanto-Searle and the Aguaruna).

The Guillaud case study. The Biodivalor contract seeks to implement a long-term relationship among PNI, a provider scientific institution, and industrial users to whom an initial limited exclusivity is given which can be extended on request by the user company. With the creation of the trust fund, local communities are also included in the contract, but so far only as recipients of local development projects.

The Swiss case study. Material transfer agreements are the most frequently used means to share the benefits resulting from the use of genetic resources. In the case of industrial relationships, the Swiss pharmaceuticals, plant protection, and foodstuff industries are, in general, already making provisions concerning disclosure of research results, up-front or fixed fee obligations and benefit sharing requirements or royalty payments to providers. A fee per sample is arranged in the first place, and the firm acquires exclusivity for the use of the resources for a given period of time. After the product development, the provider will be entitled to a share of the profits. In the case of academic research projects, there are no contractual conditions regarding the sharing of benefits. However, for projects which have reached a certain degree of maturity, and which may perhaps be of commercial interest, appropriate agreements are negotiated.

III.3 What were the monetary and non-monetary benefits involved?

Overview. For all cases in which providers and users are in direct contact, benefit sharing agreements contain monetary and non-monetary components. As most of the collaborations are fairly recent, the most important benefits so far have been non-monetary. In addition, non-monetary benefits are also predominant because they are independent of research results which, for pharmaceuticals, do not often result in a commercial product.

On the provider side, non-monetary benefits generally include training and capacity building, the transfer of bioprospecting, screening, isolation, and pre-clinical tests technologies, the sharing of research results, a co-authorship on these results, support of the providers' priority medical research areas and, frequently, the creation of a trust fund to finance local development projects. On the user side, non-monetary benefits include access to the genetic material for research, access to local and indigenous knowledge, collaboration with skilled local partners, the utilisation of local infrastructure, co-authorship of research results and innovating techniques, and a positive public image. Monetary benefits include, for the provider, an up-front or some kind of fee per sample payment, the payment of the salaries of the local collaborators by the users in some instances, and in all cases royalties should a product be commercialised.

A greater share of the monetary benefits can be gained by the providers if a joint-venture has been established with the user party, but a certain level of technical and economic capacity is required on the side of the provider party. On the user side, monetary benefits will come from the sale of the product should the research succeed, and if a joint-venture is established with the provider party, the user will benefit from the sums invested by the provider.

The Laird and Lisinge case study. In the *A. korupensis* case, the benefits so far have come from the research and development process and are non-monetary. For the provider country, they include: training in collection and agronomic techniques (including for the benefit of local communities),

infrastructure for nurseries, research results, investment in potential income-generating schemes should royalties result from the development of a commercial product which could lead to sustainable collection and cultivation of the resource, and capacity-building necessary to realise access and benefit sharing objectives. In the *P. africana* case, the benefits are both monetary and non-monetary.

Monetary benefits, for local communities, come from the increase in the payments made to gatherers, compared with payments when they sold their bark harvest to middlemen, and the creation of a Development Fund (which already amounted to FCFA 1 million just 5 months after its creation) and, for the government, there is an increase in export tax revenues sourced from a sustainable activity. Non-monetary benefits include the monitoring of the harvest area by all project members (including local harvesters), training in sustainable harvest methods and in financial accounting and management, and infrastructure improvements such as a water project financed by the Development Fund.

The Moran case study. Monetary and non-monetary benefits channelled through this arrangement amount to US$ 200 000. Monetary benefits include donations to the trust fund and a donation to a village to support a community-based medical plant forest reserve, while non-monetary benefits include financial support to the organisation for ethnomedical workshops, training programmes for Nigerian scientists, provision of field research material to BDCP, and the supply of school materials and the payment of schoolteachers' salaries in two villages. Future monetary benefits will be distributed by the trust fund as follows: at least 50 per cent (but no more than 70 per cent) of available funds to traditional healers' organisations and community development projects, 10 per cent (but no more than 15 per cent) to national universities and other national institutions, and 10 per cent (but no more than 15 per cent) to the sponsoring entity (in this case the BDCP) for further conservation and development activities.

The Ten Kate, Touche, and Collis case study. Monetary benefits include the up-front payment of US$ 100 000, to be paid over five years and to be offset against any future royalty payments to the Park under the agreement. For subsequent royalty payments by Diversa, laws governing a CRADA imply that royalties should be shared by the Park with the United States National Park Service. This would be used to reduce the tax burden for upkeeping the Park. Non-monetary benefits – amounting to US$ 75 000 per year over the five-year agreement – include donation of equipment and training of the Park's staff on projects that are not necessarily linked to the research purpose of the agreement.

Non-monetary benefits for Diversa include non-exclusive access to the genetic resources of the Park, the expertise of the Park's staff in conservation and the sampling of materials, and the database of the YNP on its ecosystems. Should a commercial product be developed from the samples collected under the agreement or those collected before the agreement was settled, Diversa will receive monetary benefits. The World Foundation for Environment and Development has thus far received US$ 28 000 from the Park for its assistance, as well as having gained notoriety.

The Ten Kate and Wells case study. In the case of Calanolide, non-monetary benefits have been the most important ones until now. Such benefits shared under the LOC arrangement include, for the provider country, the training of scientists in screening and isolation techniques, the transfer of screening technology, research results from the NCI, and the conservation and sustainable use of *C. teysmannii*, rich in Calanolide B, by the University of Illinois at Chicago which received funds from the NCI and logistical support from the Sarawak Government. The NCI gained access to Calanolides-rich species.

Under the CRADA, the NCI benefited from inputs by Medichem Pharmaceuticals, which in turn gained exclusive rights to develop NCI-patented Calanolides A and B. This exclusivity will give rise to

monetary benefits on products that are marketed in the future (to be shared with Sarawak-Medichem on a 50:50 basis), although this could change depending on future investment patterns. The University of Illinois at Chicago will also receive co-authorship royalties based on the amount received by Medichem Pharmaceuticals. In the case of Topotecan, non-monetary benefits to the NCDDG partners include the research process on Camptothecin and the ability to inhibit a particular Topoisomerase, while all monetary benefits arising out of the commercialisation of Hycamtin-R® (derived from Topotecan) are kept by SmithKline Beecham.

The Rosenthal case study. Monetary benefits include: advance payments in the form of access fees (such as fees per samples or lump sum, etc.) which have been established in three of the five groups, and royalties (as a percentage of earnings from sales) should a product be commercialised. Non-monetary benefits include research participation and results sharing, equipment, training, and infrastructure building, including in some priority research areas for uses outside the direct purpose of the collaboration. Each of the five groups use some combination of such non-monetary benefits.

The Guillaud case study. Both monetary and non-monetary benefits are covered in the contract. Monetary benefits include payments for samples and royalties should the sample give rise to a commercialised product. Non-monetary benefits include the information by the user company on all the research and development stages, capacity-building in the scientific institution of the provider country, as well as the financing of local sustainable development projects by the trust fund. The user company benefits from the access to the resource and the confidentiality of its supplies.

The Swiss case study. Typical material transfer agreements are long-term co-operation contracts that include compensation – by the user of the resource – for research work and costs arising from infrastructure provision, salaries, insurance, and transport. Such agreements generally contain concrete criteria principals for the sharing of benefits based on monetary participation, the research contribution leading to the identification of the active substance, the commercial significance of the product, and the geographical extension of protection over the intellectual property rights. Due to the relatively small chance of developing a commercialised product based on the research and development process, non-monetary benefits (sharing research results, training, technology transfer, and capacity-building) play a more important role than monetary ones. Monetary benefits, in the first place, take the form of a fee per sample payment and, in the case of product commercialisation, generally a one-time payment (ranging from US$ 1 to 5 million), rather than a royalty payment, as this would require the disclosure of sensitive production and commercial data.

Furthermore, if research institutes participate in the development of the product, the monetary share has to be divided between these institutes and the provider of the genetic resource, with the latter receiving between 50 and 65 per cent of the monetary benefits shared by the user company. For the pharmaceutical industry, material transfer agreements are basically sales contracts (with a fee paid per sample), rather than co-operation agreements. Private screening companies, mostly American-based, supply the desired substance and are not interested in the transfer of technology.

III.4 How was the agreement integrated in wider development strategies?

Overview. The most powerful condition for successfully integrating bioprospecting into a wider development strategy is the creation of a trust fund financed by bioprospecting activities. Such funds may finance local development projects which are not necessarily linked to the conservation of biological diversity, but should be ecologically sound as well as addressing local needs, inlcuding active

participation of the local population in the project decision process. Training and capacity building, as well as support of the providers' priority research areas outside the direct purpose of the collaboration, are also part of a wider skill raising and infrastructure improvement strategy integrated in the benefit sharing arrangements.

The Laird and Lisinge case study. In the *P. africana* case, the creation of the Village Development Fund gives the opportunity to finance basic infrastructure improvements.

The Moran case study. The up-front compensations are largely used to support forestry and other small-scale development projects, as well as laboratory equipment for scientific research on plants that are used locally to treat parasitic diseases. One of the objectives of the trust fund is to finance activities that help alleviate poverty through community development initiatives, and information and education provision for indigenous groups and rural families, particularly women and children.

The Ten Kate, Touche, and Collis case study. As a pioneer experiment, this benefit sharing arrangement could serve as the basis for fund and skill raising strategies for other United States National Parks. However, since such parks have no populations living in them, this strategy does not contribute to a wider local development strategy.

The Rosenthal case study. The possibility that collaborators can undertake research other than for the direct purpose of the arrangement (such as on important local diseases), as exists in all five ICBG agreements and ensures that these agreements are integrated into a wider development strategy. Each of the five arrangements have established, or are associated to, a trust fund – a powerful mechanism for undertaking local development actions. Thus, in Suriname, the trust fund is used to fund training and marketing for traditional non-timber forest craft products, while in Cameroon-Nigeria it is used to fund the rebuilding of a local clinic and the cultivation, preparation, and storage of herbal medicines.

The Guillaud case study. The basic purpose of Biodivalor is to integrate a wider development strategy into bioprospecting through the creation of a trust fund. For a project to be financed by this fund, the project must hold an interest for the country's population, be sustainable and not endanger forest conservation, provide employment and resources to the local population and, if possible, promote local training. Therefore, local development projects financed by the fund are not necessarily linked to bioprospecting and biodiversity conservation itself.

III.5 How were intellectual property rights taken into account?

Overview. In most cases, the right to patent an innovation or a commercial product is given solely to the private pharmaceutical company, as the case studies examined mainly cover situations in which United States research laboratories are the resource users, and these are not licensed to proceed to commercialisation. However, under such contracts, prior consent by the resource providers, and the provisions made by the benefit sharing arrangement, have to be respected by the holder of the intellectual property right (IPR). Benefit sharing arrangements in some cases also stipulate the right of providers to file patents for all inventions resulting from their participation. In the case of a joint venture with the resource user, the IPR is then shared between the user and provider.

The Moran case study. Peculiarly, neither the trust fund nor the case study take into account any property rights regime regarding the samples collected, and no explanation is made of how traditional knowledge would be protected and recognised if a commercialised product should be patented, although

the case study indicates that no single paradigm will work in all situations. The only point that is made clear is the need to recognise territorial rights for indigenous groups and their authority to deny or permit access by outsiders to their resources.

The Ten Kate, Touche, and Collis case study. All specimens collected under research permits from any United States National Parks belong to the Parks, so the specimens sampled in the YNP and transferred to Diversa's laboratories for research are still owned by the Federal Government. As a result, the transfer of samples by recipients to a third party is subject to approval by the National Park Service. However, CRADAs do not deal with intellectual property rights, so Diversa is free to patent any innovations based on such specimens and to sell the resulting products.

The Ten Kate and Wells case study. In the case of Calanolide, the NCI-patented Calanolides in 1993, and Medichem obtained an exclusive worldwide license for it in 1995. In 1996the joint-venture Sarawak-Medichem was founded, and through this the patent is shared between Medichem Pharmaceuticals and the Sarawak State Government. In the Topotecan case, because no commercial organisation was interested in Camptothecin before SmithKline Beecham (SB), it was freely available from the NCI, so SB could conduct its research process on Camptothecin derived Topotecan and exclusively patent it and commercialise it under Hycamtin-R®.

The Rosenthal case study. All group members have rights to file patents (joint patent ownership or exclusive licensing arrangements) for any inventions resulting from their participation. The agreements between collaborators and the compensations should be clearly stated and may vary.

The Guillaud case study. It is the sole prerogative of the user to file patents covering inventions arising from a sample provided by the supplier. However, any license issued under such a patent must include a clause referring to the product development agreement (priority of provision, sharing of information, payment of royalties, control and audit).

The Swiss case study. In the case of a product development, the company holds the right to patent the innovation, but the rights can be transferred (through a license agreement, for example) to the supplier partner if the user company does not want to use the invention itself. In the case of the pharmaceutical industry, there is a practice of behaving cautiously with research partners in developing countries due, for the most part, to a lack of protection of intellectual property rights.

III.6 How were indigenous and local communities' knowledge and practices handled?

Overview. In all but one of the cases examined there are no special provisions for handling indigenous and local communities' knowledge and practices. The sole recognition of their participation in bioprospecting activities is through gaining their prior informed consent, proceeding to some kind of payments, and the establishment of a trust fund. The innovative orientation of the Peruvian ICBG is to implement a know-how license in the benefit of local or indigenous communities. With such a license, the licensee explicitly recognises its use of an indigenous knowledge or practice that is generally not patentable.

The Laird and Lisinge case study. In the *P. africana* case, the benefit sharing arrangement is a general recognition of the need to benefit local communities which live in the area and manage local forests to ensure a sustainable supply of the resource, but no specific provisions are made to settle some form of know-how license.

The Moran case study. The participation of traditional healers' associations and village communities is central in the arrangement. Shaman recognises this by making up-front payments to traditional healers and villages for their participation to the bioprospecting, and by being members of the trust fund.

The Rosenthal case study. The know-how license is an agreement that provides the licensee with exclusive or non-exclusive rights to use informal knowledge that is not generally patentable, but is important for the utilisation of an associated technology. It is a mechanism for recognising and protecting indigenous and local communities' knowledge and practices. The Peruvian ICBG has incorporated such an innovation into its bioprospecting agreement. Full disclosure and informed consent of indigenous and local communities are required for all ICBG bioprospecting in the lands of the people covered by the agreement.

The Guillaud case study. There is no specific handling of traditional indigenous or local communities knowledge other than the funding of local development projects that favour biodiversity conservation. In fact, local communities are not explicitly members of the management committee for the trust fund.

The Swiss case study. There have been no agreements that cover the use of traditional knowledge of local indigenous groups in the plant protection industry because the genetic material generally comes from universities or research institutes. At the university level, in the search for potentially active substances, the knowledge of indigenous ethnic groups and local healing practices play an important role. Contacts with local medicine men and women and the study of traditional healing practices are necessary for a directed search for new and effective natural materials. In the case of micro-organisms, however, the knowledge of such groups plays practically no role at all. Finally, for the foodstuff industry, procurement of genetic resources comes from *ex-situ* publicly accessible collections, so there is only a limited amount of contacts with indigenous groups. Even when a sharing of benefits is agreed in favour of indigenous or local communities, Swiss companies and research institutes have no real possibilities for tracking the actual use of the contributions in the recipient country.

III.7 Which international trade aspects were important?

Overview. Generally, the provider is recognised by the benefit sharing arrangement as the preferential source of raw or processed material for operations undertaken in collaboration, throughout the process from research to commercial production purposes. In the case of ICBG sponsored agreements, the ownership of samples stays with the provider, while in the case of Biodivalor, the sale of the sample transfers its property to the user to whom an exclusive use right is given over the resource for a limited period of time.

The Laird and Lisinge case study. In the *P. africana* case, the company will only purchase bark from the villages' Prunus Harvesters Unions.

The Ten Kate and Wells case study. In the case of Calanolide, the Sarawak Government has exclusive rights to supply *C. teysmannii* latex rich Calanolide B.

The Rosenthal case study. Unless it is otherwise stipulated in the agreement, biological samples and associated information collected under an ICBG sponsorship is the property of the source

country institutions. For all follow-up analysis and product development of a lead compound, the source country and/or the communities participating to the arrangement should preferentially be the first source of raw or processed materials.

The Guillaud case study. Under the Biodivalor contract, should a commercial product arise from a sample sold to a user company, priority should be given to the provider country to supply, preserve, and cultivate the biological resource in their country. An exclusive use right is associated with a sample sold to a user for a limited period of time. If the user is interested, this exclusivity can be prolonged depending on development research results given to the provider.

The Swiss case study. Swiss Industry has had very little negative experience with discrimination over access. However, in joint projects, restrictions are often agreed to in connection with some areas of research. A potential problem could occur with respect to the exclusivity agreements from the private screening companies. The risk of reliance upon these companies is, however, small. A possible danger of discrimination against Swiss industry is greatly reduced by the fact that Swiss transnational companies are strongly represented in the US. Likewise, on the university level, there have only been a few isolated cases of discrimination. Countries possessing genetic resources normally have a financial interest in making their plants available for research. In cases where there is discrimination by a given country, there is often the possibility of procuring the exact same plant in a neighboring country. With the exception of quarantine regulations and phytosanitary requirements, which differ from country to country, neither industries nor universities have been confronted with problems relating to the import or export of genetic resources. From the viewpoint of industry, however, the often uncontrolled and sometimes illegal border-crossing traffic in genetic resources, particularly between developing countries, poses a considerable potential risk.

III.8 What were the impacts on the conservation and sustainable use of biodiversity?

Overview. Except in the case of *P. africana* where the benefit sharing arrangement has had a direct positive impact on the resource, the natural resources involved in the case studies were not endangered. However, these arrangements certainly have a positive impact on the resource as all of them contain a provision to ensure its *in-situ* conservation, although on-going research to develop sustainable supply techniques and *ex-situ* propagation is, sometimes, also sought.

It is too early to develop a clear idea of the impact on the surrounding ecosystem of the benefit sharing arrangements studied. Nevertheless, training and capacity building, the creation of a trust fund to finance sustainable development projects, and the raising of the value of natural resources through bioprospecting are certainly facilitating the implementation of an environmentally sound development strategy.

The Laird and Lisinge case study. In the *A. korupensis* case, the research done on the sustainable supply of this resource to industry will be useful in case it is of economic value. In the *P. africana* case, the development of quotas limiting harvest quantities, coupled with progress in the living conditions of the local population and the research and training in sustainable harvesting methods, have greatly reduced illegal and unsustainable harvests.

In the *A. korupensis* case, the support to infrastructure development in the Korup National Park can be employed to address other conservation priorities. In the *P. africana* case, its sustainable commercial exploitation and the efforts to cultivate it could generate benefits for local communities

through providing incentives for conserving the species and alternative income-generating activities based on sustainability.

The Moran case study. By linking local development projects to the conservation of medicinal plants, the benefit sharing arrangement may be a strong incentive to reduce agricultural land conversion and sustainably exploit the forest.

The Ten Kate, Touche, and Collis case study. The monetary benefits received by the YNP from Diversa are paid to a special account specifically used for the conservation of microbial biodiversity, scientific research, data management, and public outreach and education. In order to be granted an access permit to the resource, the applicant must demonstrate that the research activities will not have serious impacts on the ecosystem. Moreover, sourcing of micro-organisms for biotechnology applications often has less environmental impact than, for example, sourcing plant materials which requires larger material quantities and an ongoing supply.

The Ten Kate and Wells case study. In the case of Calanolide, both *Calophyllum* species are common in Sarawak and are not endangered. However, the Sarawak Forestry Department banned their felling in 1993 due to their potential importance. As it was not possible to relocate the original specimen which was used to produce Calanolide A, and as other samples were less productive, synthetic production of this compound is the only option. However, due to the high concentration of Calanolide B in the latex of the species *C. teysmannii*, its *in-situ* conservation and *ex-situ* propagation for industrial production is highly desirable.

In the case of Topotecan, as only small amounts of Camptothecin is needed to produce SB's product and as *C. acuminata* comes from plantations, this product development has no effect on the *in-situ* conservation of *C. acuminata*, and the research on Camptothecin has favoured *ex-situ* conservation in the United States. The far richer source of Camptothecin, was discovered in India in 1970 but un-patented, and is sourced from the native Indian tree *Nothapodytes foedita*. Demand for this has pushed the Indian Government to ban its export, and its access in the wild now requires a permit from the forestry authorities.

The Rosenthal case study. For all ICBG sponsored research and development, the agreement must specify how a sustainable source of the material used will be developed. The key question for a positive impact on the surrounding ecosystem is that local communities, private companies, and the natural resource policies of both developed and developing country governments ensure both short- and and long-term benefits from bioprospecting. It is clearly too early to know how much bioprospecting benefit sharing arrangements will contribute to biodiversity conservation.

The Guillaud case study. All activities under the contract must provide measures to promote the conservation of local biodiversity, in particular through the trust fund.

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