ISSUES IN THE SHARING OF BENEFITS ARISING OUT OF THE UTILISATION OF GENETIC RESOURCES

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris

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This paper was prepared by Ms. Kerry ten Kate, Royal Botanical Gardens, Kew, UK, and Mr. Jan Horst Keppler, OECD Secretariat, for the Expert Group on Economic Aspects of Biodiversity. Following the Programme of Work of the Expert Group, it aims at the clarification of the issues surrounding the sharing of benefits from the utilisation of genetic resources.

A first version of this paper was presented at the Sixth Meeting of the Expert Group on 23-24 June 1997 in Paris. The present version has been revised on the basis of the discussions at the Sixth Meeting and of written comments submitted subsequently by Member countries. It constitutes the first of a series of elements of the work of the Expert Group on benefit sharing. Work in preparation includes a study of the economic aspects of benefit sharing. Discussions about empirical experiences of Member countries with benefit sharing, as well as about additional work are currently under way.

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ISSUES IN THE SHARING OF BENEFITS ARISING OUT OF THE UTILISATION OF GENETIC RESOURCES

CHAPTER 1. INTRODUCTION

1.1 The context of the OECD project on benefit-sharing

The Mandate of the OECD Expert Group on Economic Aspects of Biodiversity [ENV/EPOC/GEEI/BIO(97)1] states that the Group as part of its activities during the period 1997-1998 should

... explore the issues surrounding the sharing of economic benefit resulting from the utilisation of genetic resources including the issues of access to commercially valuable genetic resources and the transfer of technology or technological knowledge.

The Programme of Work formulated by the Expert Group at its first meeting on 3-4 January contained further information on the scope and nature of this work. It was decided that a study of the issues connected with the sharing of economic benefits from the utilisation of genetic resources of wild species will be undertaken under the supervision of the Expert Group. It was clearly stated that the study would not aim at providing any specific policy guidance. The study would instead aim at providing a service to discussions going on in other fora by clarifying the issues at stake, not to participate in these discussions.

The study would concentrate on biotechnological and pharmaceutical products to be derived from genetic resources, including phytomedicines, agricultural chemicals, biological control agents and molecular research tools, and leave aside issues connected with agricultural plant genetic resources, such as those being considered under the FAO International Undertaking on Plant Genetic Resources for Food and Agriculture.

It was agreed that the first part of the study would present the conceptual issues connected to economic benefit sharing and describe the special nature of the issues surrounding the utilisation of genetic resources. This part of the study would also take careful account of the discussions in other fora on this issue. It was further agreed that a second part of the study would provide an overview of existing empirical work on the utilisation of genetic resources. It would refer the various estimates of the commercial potential of products directly and indirectly derived from the utilisation of genetic resources and indigenous knowledge.
1.2 The Convention on Biological Diversity and benefit-sharing

The third objective of the Convention on Biological Diversity (CBD) is the ‘fair and equitable sharing of the benefits arising out of the utilization of genetic resources’, the other two being the conservation of biological diversity and the sustainable use of its components.1 The CBD was opened for signature in June 1992 at the United Conference on Environment and Development, entered into force on 29 December 1993 and has now been ratified by 167 countries and the European Commission. The Convention may broadly be interpreted as an instrument to promote the equitable exchange of access to genetic resources and associated knowledge for finance, technology and participation in research.

The rationale for benefit-sharing is threefold: equity and the conservation and sustainable use of biodiversity. The obligation to do so arises in the context of access to genetic resources and the context of the knowledge, innovations and practices of indigenous and local communities.2 The scope and nature of access, what constitute ‘benefits’, and whether, when and how they should be shared are for national authorities to determine and for the parties to individual transactions to agree.3 The circumstances vary enormously, but benefit-sharing will generally take place in the context of scientific research, such as ethnobotany and taxonomy, and the development of products such as pharmaceuticals and other products dependent on the application of biotechnology. Benefit sharing thus has links to a sphere of private profits and benefits as well as to another sphere of public benefits, where positive spillovers from private activities contribute to the building of capacity and the transfer of technologies, as well as to economic development and the conservation of biodiversity.

This double nature of the issue of benefit sharing requires that both governments and the private sector have a role to play in its solution. While governments have to set the framework conditions for the private sector in order to maximise its contribution to the achievement of public policy objectives such as the conservation of biodiversity, the challenge to achieve this will only be met, if a vigorous private sector is allowed to prosper. This interaction defines the problems but also the opportunities connected with benefit sharing and has also influenced the references to benefit sharing in the Convention on Biological Diversity.

Genetic resources in the context of the Convention on Biological Diversity

Article 2 of the Convention provides some definitions pertaining to the ‘fair and equitable sharing of the benefits arising out of the utilization of genetic resources’. Thus ‘genetic resources are defined as ‘genetic material of actual or potential value’, whereby ‘genetic material’ means ‘any material of plant, animal, microbial or other origin containing functional units of heredity’. Always according to Article 2 of the Convention, the valuable ‘genetic resources’ are, together with organisms, populations and biotic components of ecosystems, part of ‘biological resources’. While the Convention on Biological Diversity as a whole is concerned with biological resources in general, its third objective concerning benefit sharing exclusively addresses genetic resources.

1 See Article 1, below.
2 According to Articles 15 and 8(j), respectively.
3 Article 15(1).
4 Article 15(4).
The value of genetic resources derives from their use in the production of commercial products. Pharmaceuticals constitute the most important product group that contains a large number of individual products which are partly or completely derived from genetic resources. Of all product groups under consideration, this one has the biggest market and is of the biggest importance. There exist, of course, many pharmaceutical products that are not derived from genetic resources, as there exist many products derived from genetic resources that are not pharmaceuticals. The latter category comprises bio-polymers, bio-pesticides, bio-fertilisers, cosmetics, perfumes, food and beverage additives (e.g., sweeteners, colorants, preservatives), inputs for bioremediation projects and others.

In some cases, commercially valuable goods are also derived from ‘parts of organisms’ rather than from genetic resources proper. While the sharing of the benefits from their utilisation in some instances may display similar characteristics and problems as the ‘fair and equitable sharing of the benefits arising out of the utilization of genetic resources’, for reasons of consistency with the Convention of Biological Diversity they are not included in the following discussion which will only concern ‘genetic resources’ as defined in the Convention.

**Articles of the Convention and official documents relating to benefit sharing**

While the Convention clearly states the ‘fair and equitable sharing of the benefits arising out of the utilization of genetic resources’ as one of its objectives, none of the words ‘fair’, ‘equitable’, ‘share’, ‘utilization’, ‘commercial’ or ‘benefit’ is defined in the CBD, although each is used at least once. ‘Benefit-sharing’ is explicitly mentioned in the context of the provisions on the knowledge, innovations and practices of indigenous and local communities (Art. 8(j)), and on access to genetic resources (Art 15). These, in turn, are explicitly linked to the provisions on access to and transfer of technology (Art. 16), the handling of biotechnology and distribution of its benefits (Art. 19), financial resources (Art. 20) and the financial mechanism (Art. 21). The result is that the Convention provides a number of indications of how to accomplish benefit-sharing throughout its web of Articles (see Table 1).

Consideration of related items at the Third Meeting of the Conference of the Parties has provided directions in which the future discussions of this item may be conducted. The most directly relevant decision is III/16 on transfer of technology. Combined with Decision III/22 on the medium-term programme of work for 1996-1997, they set out that the benefit-sharing is to be considered in the framework of issues related to biotechnology as contained in Article 19 and access to and transfer of technology as envisaged in Articles 16 and 18. Furthermore, the discussion of the latter will have a focus on biological diversity of inland waters, following the thematic approach. In addition, Decision III/15 on access to genetic resources calls for information on policy measures and guidelines for activities covered by Article 15, and in particular, on access and benefit-sharing. The Executive Secretary to the CBD is requested to prepare a note summarising such information.

Decision III/17 on Intellectual Property Rights (IPR) encourages case studies of the impacts of IPR on the achievement of the Convention’s objectives, including, *inter alia*, in facilitating technology transfer and in arrangements by which interested parties may determine access to and share equitably the benefits of genetic resources or knowledge, innovations and practices. Furthermore, Decision III/14 on implementation of Article 8 (j) requests the Executive Secretary to produce a background document

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5 Benefit: (10 times) Preamble (3 times); 1; 8(j); 15(7); 16(4); 19 (title); 19(2); 20(2) sharing: (9 times) Preamble; 1; 8(j); 15(7)(twice); 20(2); 21(2) (NB last two are ‘burden-sharing’) benefit-sharing (together): (4-5* times) Preamble; 1; 8(j); 15(7); 19(2)* (‘*access’ to benefits); fair: (4 times) 1; 15(7); 16(2); 19(2); equitable: (5 times) Preamble; 1; 8(j); 15(7); 19(2); commercial: (once) 15(7); utilization: (6 times) 1; 8(j); 15(7); 21(1); 21(2) (twice).
containing, inter alia, the consideration of the linkages between Article 8(j) and related issues, such as technology transfer, access to genetic resources, IPR, alternative systems of protection, incentives and Articles 6, 7 and the remainder of Article 8. All these decisions of the third meeting of the COP together call for considerable amount of information that is relevant to the consideration of benefit-sharing.

Table 1

<table>
<thead>
<tr>
<th>‘Benefit-sharing’ in the various articles of the Convention on Biological Diversity</th>
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<tbody>
<tr>
<td><strong>Preamble</strong></td>
</tr>
<tr>
<td>“... desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components...”</td>
</tr>
<tr>
<td><strong>Art. 1</strong></td>
</tr>
<tr>
<td>“... the objectives of this Convention are... 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...”</td>
</tr>
<tr>
<td><strong>Art. 8.j</strong></td>
</tr>
<tr>
<td>“... respect, preserve and maintain the knowledge, innovations and practices of indigenous and local communities ... promote their wider application with their holders’ approval and involvement ... and encourage the equitable sharing of the benefits arising from their utilization...”</td>
</tr>
<tr>
<td><strong>Art. 15.6</strong></td>
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<tr>
<td>“... full participation of provider in scientific research based on genetic resources provided...”</td>
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<tr>
<td><strong>Art. 15.7</strong></td>
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<tr>
<td>“... measures with the aim of sharing fairly and equitably the results of research and development...”</td>
</tr>
<tr>
<td><strong>Art. 15.8</strong></td>
</tr>
<tr>
<td>“... and benefits arising from the commercial or other utilization of genetic resources...”</td>
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<tr>
<td><strong>Art. 16.3</strong></td>
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<tr>
<td>“... access to and transfer of technology using genetic resources to countries providing them...”</td>
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<tr>
<td><strong>Art. 19.1</strong></td>
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<tr>
<td>“... effective participation by providers of genetic resources in biotechnological research on the genetic resources...”</td>
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<tr>
<td><strong>Art. 19.2</strong></td>
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<tr>
<td>“... priority access to the results and benefits from biotechnologies based on genetic resources provided...”</td>
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</tbody>
</table>

Finally, the COP in its decision III/5 (7) instructed the Secretariat of the CBD and the Global Environment Facility (GEF) to prepare a proposal on the means to address the fair and equitable sharing of the benefits arising out of genetic resources including assistance to developing country Parties for consideration by the COP at its fourth meeting in May 1998.

Despite these directions, the lack of definitions and of explicit benefit-sharing requirements, and the use of language that softens any obligations⁶, continue to leave considerable discretion for Parties as to the circumstances in which, the extent to which, and how, they will share benefits. The obligations are between contracting parties, when it is ‘stakeholders’ such as universities, companies and local and indigenous communities, rather than governments, who are mainly involved in and affected by relevant activities. Benefit-sharing is complex and can only achieve its objectives if sufficient flexibility is granted in order to take into account the unique circumstances of each case.

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⁶ See, for example, ‘subject to its national legislation’ (Art. 8(j)), ‘as appropriate’ and ‘with the aim of sharing . . .’ (Art. 15(7)).
CHAPTER 2. RELATIONSHIPS BETWEEN KEY CONCEPTS OF BENEFIT-SHARING

Article 1 of the Convention\(^7\) provides a common thread that links the other, more detailed provisions on benefit-sharing together, stating that benefit-sharing can include access to genetic resources, technology transfer and funding and referring to the need to take into consideration all rights over the resources and technologies.

**Access to genetic resources**

The issue of access to genetic resources is closely linked to the issue of property rights over genetic resources. Consequently, Article 15 on access to genetic resources begins with recognising the ‘sovereign rights of States over their natural resources’ and that the ‘authority to determine access to genetic resources rests with the national governments.’ Article 15 also requires applicants to obtain the informed consent\(^8\) of the national authorities prior to access to genetic resources. It sets out that various forms of benefit-sharing may be mutually agreed by the applicant for access and the national authority in each case. These include sharing the results of research and development conducted on the genetic resources accessed, and sharing the benefits arising from the commercial and other utilisation of genetic resources.

In practice, national access legislation and commitments in contracts concerning access to genetic resources have interpreted ‘results of research and development’ as data, knowledge, new innovations and products. The benefits of commercialisation are similarly interpreted as a mixture of monetary benefits, typically royalties on sales of the final product, and non-monetary benefits, such as technology, training or information. Article 15 (6) explicitly requires each Party ‘to endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties’. This provision is mirrored in Article 19, in the specific case of biotechnological research, and highlights the emphasis the Convention places on enabling Parties to be involved in research on the genetic resources to which they provide access. Both the benefit-sharing provisions of the Convention and national access measures encourage the involvement of provider countries in the value-adding activities that take place following access to genetic resources.

**Technology transfer**

Technology transfer is explicitly presented as a form of benefit-sharing in Article 1, and is raised again in Article 16. Article 16(3) requires parties to ‘take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries,

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\(^7\) ‘The objectives of this Convention, to be pursued in accordance with its relevant provisions, 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’.

\(^8\) Article 15(5). See section 3 of this paper.
which provide genetic resources are provided access to and transfer of technology which makes use of those resources’. It is clear that technology transfer is both a form of benefit-sharing, linked to access to genetic resources, and also an independent obligation on Parties.

**Funding**

Article 15(7) provides that, where necessary, the financial mechanism established by Articles 20 and 21 can be used by Contracting Parties to support them in taking the legislative, administrative or policy measures required to encourage benefit-sharing. Since this provision is also ‘in accordance with Articles 16 and 19’ it is not clear whether the Article envisages support from the Financial Mechanism for countries developing access measures to promote benefit-sharing, or financial support for concessional technology transfer, or both.

The latter interpretation is supported by another clause concerning funding, namely Article 16(2). This clause requires access to and transfer of technology to developing countries ‘to be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21’. These specific references to aspects of benefit-sharing are endorsed by the general obligations to provide financial support and incentives to achieve the objectives of this Convention (Article 20) and for developed country Parties to provide new and additional financial resources to enable developing country Parties to meet the agreed full incremental costs to them of implementing measures to fulfil the obligations of the Convention and to benefit from its provisions (Article 21).

**Property rights**

The Convention addresses national sovereignty, and the rights of States over natural and genetic resources. It also contains provisions concerning two kinds of private rights, which, according to Article 1, are to be considered in the context of benefit-sharing. The first is the need for the approval and involvement of indigenous and local communities embodying traditional lifestyles when their knowledge, innovations and practices are applied (8j). The second concerns intellectual property rights over technologies. Article 16(2) states that access and transfer to technology ‘shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights’, although Article 16(5) requires Parties to co-operate to ensure that such rights ‘are supportive of and do not run counter to’ benefit-sharing and the other objectives of the Convention. Intellectual property rights are also addressed in other international agreements such as the TRIPS-agreement under the GATT/WTO which accords protection to certain categories of commercially valuable intellectual property rights.

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9 Articles 3 and 15(1).
10 Article 8 (j) states that each Contracting Party shall, ‘... subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices; ...’
Prior informed consent

According to the Convention, access to genetic resources requires the prior informed consent of the Contracting Party providing the resources (Article 15(5)\(^{11}\)). Application of the knowledge, innovations and practices of indigenous and local communities should be with the approval and involvement of the holders of such knowledge (Article 8 (j)). Some national measures introduce benefit-sharing obligations not only for access to genetic resources, but also for associated knowledge. For example, the Andean Pact Common System on Access to Genetic Resources (Comisión del Acuerdo Cartagena: 1996) defines access\(^{12}\) to include an ‘intangible component’, which means ‘any knowledge, innovation or individual or collective practice of actual or potential value associated with the genetic resource, its derivatives or the biological resource containing them, whether or not it is protected by intellectual property systems’.

Although the CBD refers to securing prior informed consent from Contracting Parties, national access measures, such as those in the Philippines and Andean Pact and proposed in Brazil, require the agreement of stakeholders such as local communities, indigenous cultural communities and peoples, protected area management boards, and owners, holders and administrators of land\(^{13}\). This provides an opportunity for such groups to consent to access only on condition of benefit-sharing. In some national measures, benefit-sharing with such groups is explicitly required. For example, the Philippines legislation stipulates that ‘benefit-sharing arrangements must ensure that benefits and results received must accrue to the benefit of the Local Communities/Indigenous Peoples/Protected Areas concerned’.

Other relevant provisions

Several other provisions of the Convention are relevant to benefit-sharing. Among these are Article 10(e), which encourages cooperation between governmental authorities and the private sector in developing methods for sustainable use of biological resources and Article 11, requiring Parties to adopt economically and socially sound measures as incentives for the conservation and sustainable use of components of biological diversity. Incentive measures for benefit-sharing could result in the promotion of conservation and the sustainable use of biodiversity.

Research and training, the exchange of information, and technical and scientific cooperation can all be important components of benefit-sharing, and are the subject of measures that Parties must take as set out in Articles 12, 17, and 18 respectively. A particularly important role in this context is played by the Clearing-House Mechanism ‘to promote and facilitate technical and scientific cooperation’ (Article 18(3)), which includes the exchange of certain information about genetic resources between Parties. The Clearing-House Mechanism is fully operational and can be accessed through the website of the Secretariat of the Convention (http://www.biodiv.org). All of the above-mentioned Articles together build through cross-referencing a tight web of references that establishes the fair and equitable sharing of benefits as a central issue in all aspects of the Convention.

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\(^{11}\) ‘Unless otherwise determined’ might suggest, on the one hand, that if access measures are not in place, PIC is not required or, on the other, that access remains restricted and PIC is required until a Party legally determines otherwise. See UNEP/CBD/COP/3/20.

\(^{12}\) ‘Access’ means the acquisition and use of genetic resources conserved in ex-situ and in-situ conditions and of their derivatives or, as applicable, intangible components, for purposes of research, biological prospecting, conservation, industrial application or commercial use, among others.’

\(^{13}\) See UNEP/CBD/COP/3/20.
CHAPTER 3. PRIVATE BENEFITS AND PUBLIC POLICY OBJECTIVES -- THE MONETARY AND NON-MONETARY BENEFITS OF UTILISING GENETIC RESOURCES

Genetic resources are valuable. They have value as the basis for actual or potential products and also as a contribution to the maintenance of species and ecosystems. This value provides benefits to those owning genetic resources or controlling access to them. The Convention on Biological Diversity reaffirms that national governments have the authority to determine access to genetic resources, since States have sovereign rights over their natural resources. However, the full value of genetic resources is only realised in combination with a series of other activities, resources and players. This gives different parties claims to at least a share of the total benefits resulting from uses involving genetic resources.

Before approaching the key problem of how these benefits can be divided between different claimants, it is helpful to examine the different uses that are made of genetic resources. The great difficulty in assessing the different uses of genetic resources stems from the fact that they combine to different degrees private benefits and public benefits. Private benefits are benefits that result from commercial activities pursued in markets whose benefits accrue to identifiable individuals or companies. These private benefits can, in principle, be measured in monetary terms, even if royalties may arise twenty or even more years after the original access to genetic resources and only a tiny proportion of individual access transactions give rise to royalties.

Public benefits relate to policy issues such as improvement of public health, economic development, international trade and technology transfer, environmental protection and the conservation of biological diversity for which the genetic resources and their use have important implications. The utilisation of genetic resources can also provide a public benefit by leading to an improved understanding of the ecosystem functions of biodiversity, and thus a greater appreciation of the importance of its conservation and sustainable use. The utilisation of genetic resources and the sharing of the resulting benefits inevitably displays aspects that relate to private as well as to public benefits.

This dual nature of the benefits from different uses of genetic resources or biodiversity in general, to which genetic resources are unavoidably linked, provides difficulties and opportunities. The difficulties relate to the conceptual discussion of benefit sharing and the task of finding a common language for all the stakeholders involved. The opportunities relate to the design of policies that aim to realise the maximum amount of commercial benefits while at the same time aiming at compatibility with public goods such as development and conservation. In fact, the concept of sustainable is defined by such a combination in which privately profitable activities are compatible with wider public policy objectives.

3.1 The distribution of private benefits from the utilisation of genetic resources

The division of monetary (private) and non-monetary (public) benefits proceeds according to different rules. This sub-chapter examines the distribution of monetary benefits, introduces the concept of economic rent, discusses how stakeholders bargain over its distribution, and shows the importance of establishing property rights in this connection. The following sub-chapter will review the possibilities to link this process with wider policy objectives such as economic development and the conservation of biological diversity.
The creation of ‘rent’

The primary reason for the commercial interest in genetic resources results from the fact that they possess value in connection with the possible commercialisation of, e.g., pharmaceutical products derived from natural genetic resources. The commercial value of the products derived on the basis of natural genetic resources is clearly not equivalent to the commercial value of those resources themselves. The final product value is only realised in combination with a series of activities that contribute value to the final product. Other than the genetic resource itself, a successful product will involve successive steps such as extraction, sampling, testing, refinement, processing and marketing to mention the most important ones. Thus the original genetic resource contributes to the commercial value of the final product; it is, however, very difficult to determine exactly how much that contribution is worth, once the other contributing factors are taken into account.

While the commercial (private) value of genetic resources as an input into the production of commercial products is difficult to assess due to its combination with other factors, it remains larger than the costs of accessing these genetic resources. This surplus, i.e., the value of the genetic resource used as an input minus the cost to access it, is called a *rent*. Examples for other resources yielding rents are valuable minerals (after extraction costs have been deducted), land (after maintenance cost have been deducted), or a position as a monopolist (after the costs of achieving that position have been deducted).

In the simplest case, the commercial benefit from the utilisation of genetic resources (its rent) has to be divided between two providers, for instance, a pharmaceutical company and the country in which the genetic resource is found. Both are owners of one necessary input needed in order to realise a marketable product: that is, the raw genetic material and the research and development that converts them into a final product. Both will also stake a claim to at least a share of the rent. The shares of the rent that each party will receive will depend on the relative scarcity of their contributions and on the outcome of the bargaining process they will engage in.

The issue of bargaining

One can imagine different scenarios for negotiations over the distribution of rent. If, for example, a genetic resource is gained from a plant that grows in several countries but that can be exploited only by a few highly sophisticated companies, then the share of the rent going to the provider countries will be low. On the other hand, if many (similarly efficient) companies are all interested in one particular resource that is available only from one specific country, then the share of the rent accruing to that country will be high.

Thus the division of rent would be relatively straightforward in circumstances where the genetic resource in question is either very scarce or very abundant. But most cases of the utilisation of genetic resources will fall somewhere in between those two boundary cases. More than one country will offer a certain resource of interest and more than one company will be interested in it. In those cases, bargaining between the partners decides the outcome.

Bargaining power, however, is greatly affected by factors such as knowledge of markets, access to information, the possibility to hire lawyers and accountants, or the access to legal protection and enforcement. One could add that it can also depend on the sheer bargaining skill of a professional
negotiator. Where these factors differ between claimants, the bargaining process will favour the party with more of these bargaining-relevant attributes at its disposal.

Consequently, the building of intellectual, administrative and legal capacity is an important and often decisive, consideration. Only when parties possess similar bargaining power, can it be reasonably expected that the rent from the utilisation of genetic resources will be distributed in a manner that corresponds roughly to their relative contributions to the final product. To the extent that policy-makers and the public are interested in a ‘fair and equitable sharing of benefits’, relative bargaining power and consequently capacity building is an issue.

The issue of property rights

In this context the establishment of property rights is crucial and closely linked to capacity building. Only with the clear definition, knowledge and enforcement of property rights can a fair share of rents be secured. Otherwise, the rent will be partly dissipated and partly captured by the first user of the valuable resource, who is not necessarily the most efficient one. The establishment of property rights is also the basis for the optimisation of rent. With secure and tradeable property rights the exploitation of the resource will eventually go to the company that can make most effective use of it and thus can offer the greatest amount of benefits to be shared.

While property rights exist for some natural resources, their definition and firmness varies from case to case. Not all resources are protected in the same way. Partly this is due to the fact that it is easier to protect some resources; partly this is due to the fact that historically certain areas have been subjected to legal codification prior to other areas. The Convention on Biological Diversity affirms that national governments have the authority to determine access to genetic resources. This provides a de facto property right for the purposes of establishing a firm basis for the bargaining over rent.

Similarly, the scientific knowledge and the production processes of commercial companies are well protected by international patents and intellectual property rights regimes. Two examples, however, illustrate the difficulties to define straightforward property rights in all cases and the complexities of rent sharing this implies: the determination of the degree of derivation of a product from the original genetic resource and the absence of clear property rights of indigenous people over their knowledge, traditions and practices.

The distribution of the rents resulting from commercial products is complicated where genetic resources have been used as the basis for an initial study of a certain molecular process rather than as a material input into a commercial product. The utilisation of genetic resources in this manner raises difficult questions concerning the public nature of such information. Similarly, demarcation and protection of rights associated with the knowledge, innovations and practices of indigenous people is often lacking. This absence of codified property rights makes it more difficult to ensure that all stakeholders can participate adequately in the bargaining processes over the sharing of rents.

In this situation, the safe-guarding and the documentation of indigenous knowledge and practices, possibly with the involvement of the partners interested in the sharing of benefits is an important first step of taking its value into account and can constitute, in some cases, an element of benefit sharing in itself. Case-by-case solutions between the partners in a benefit-sharing arrangement have to be developed in order to take account of the particular circumstances of each individual case.
It should be emphasised that the creation of adequate capacity to engage in benefit sharing is not only a distributional issue, but also contains a dynamic win-win element. The creation of adequate intellectual, administrative and legal capacity can reduce mistrust that leads to purely defensive strategies which ultimately raise costs for all involved.\textsuperscript{14} Paying attention to the determinants of the bargaining process such as property rights, the institutional structures to enforce them and the capacity to use them effectively is ultimately more important than defining any ‘desirable’ outcomes in advance.

3.2 Public benefits from the utilisation of genetic resources

The preceding chapter has highlighted issues that pertain to the commercial, private benefits from the utilisation of genetic resources. But despite the fact that the utilisation of genetic resources and the sharing of the resulting benefits will heavily involve the private sector it is also crucially linked to wider policy considerations pertaining to public goods such as economic development and the conservation of biodiversity. The key question for policy makers is now how to organise that link in a manner such that commercial activities of private, profit-oriented companies yield maximum benefits for the achievement of these wider policy objectives.

While in reality circumstances differ in different countries, the popular discussion tends to associate these two broad policy interests, economic development and the conservation of biodiversity, with certain country groups and their role in the process of the utilisation of genetic resources: developing countries are seen as the providers of genetic resources with an interest in furthering their economic development, while industrialised countries are seen as having an interest in the conservation of biodiversity, as well as providing a base for companies capable of transforming genetic resources into commercial products. However broad-brushed such a distinction might appear in practice, it helps to organise a first discussion around the main issues.

In such a perspective, developing countries would like to employ the utilisation of genetic resources to realise the rent of genetic resources and to contribute through capacity building and technology transfer to their own economic and social development. Industrialised countries instead would like to secure access to genetic resource as well as to assure the conservation of biodiversity. One could argue that this should lead to an international bargaining process in which ‘the industrialised countries’ provide assistance and technology in return for commitments to provide access and preserve nature in ‘the developing countries’.

The conceptual difficulty in this process is, that this trade-off of interests has to be effectuated with the help of the private sector. While the process of transformation of genetic resources to commercial products also involves public and semi-public institutions such as universities, sample collections and data-banks, it crucially depends at key points on private companies. For instance, the vital issue of technology transfer cannot be fully addressed without the involvement of the private sector because of the critical role of industry in the research and commercialisation process.

\textsuperscript{14} Amongst the unco-operative games studied by game theory the best known is probably the ‘prisoners’ dilemma’. In this game both partners behave unco-operatively and thus destroy the ‘rent’ that could be gained from co-operation. Their behaviour is induced by the fact that they have no possibility to secure a share of the rent that would be gained through their co-operation. Looked at it the other way round -- the ability to secure a fair share of the rent is a precondition for co-operative behaviour. More complicated versions of the ‘prisoners’ dilemma’ allow for communication and repetition (i.e., learning and the building of trust) and, in fact, do achieve rents for both participants to be shared.
The involvement of the private sector has to take the complicating factor into account that the contribution to public policy objectives such as development and nature conservation is not costless for the private sector. The cost difference may not be huge and there may exist private benefits from engaging in a sustainable use, such as positive publicity in the case of the wide advertising of benefit sharing agreements. In general, however, the difference between privately and publicly optimal behaviour has to be overcome through appropriate incentives. These can be either positive incentives, such as industry-government partnerships, subsidies (or tax breaks) for companies that conform to certain forms of bioprospecting and benefit sharing, or negative incentives such as fines for companies that do not.

Such considerations are not new. Subsidies for environmentally friendly technologies or technical standards aim at achieving much the same harmonisation of private activities with public policy objectives. The difference in connection with the utilisation of genetic resources is that it involves as a third party, i.e., the governments of developing countries with their own policy objectives. Thus public benefits of industrialised countries, private benefits of industry and the public benefits of developing countries have to be combined with the appropriate incentives. Figure 2. portrays one model for the flow of incentives and benefits.

In practice, several types of relationships among these partners are conceivable and many different incentives, as well as many different forms of the transfer of benefits are possible and not all answers would distribute the costs of achieving public policy objectives in the same manner. However, in order to arrive at politically sustainable solutions, the considerations of all stakeholders have to be addressed. This involves two main points: first, capacity building and the establishment of widely applicable property rights regimes have to be pursued in order to allow a fair sharing of the private
benefits from the utilisation of genetic resources. Second, the utilisation of genetic resources has to be integrated with public policy objectives such as economic development and the conservation of biodiversity. The objective is thus to realise the double nature of the value of genetic resources, their value as an input for commercial products that yield monetary benefits and their value as part of ecosystems and as elements of development strategies that yield non-monetary public benefits.
CHAPTER 4. BENEFITS, BENEFIT-SHARING PROFILES AND POSSIBLE INCENTIVES FOR BENEFIT-SHARING

4.1 Overview of possible benefits from the utilisation of genetic resources

The private and public benefits associated with access to genetic resources and alluded to in a general manner in the preceding chapter are complex. Many parameters shape what could be part of a fair and equitable sharing of benefits in any given case. The following list provides an overview of the possible benefits of the private and the public kind. Since an exhaustive definition of potential benefits is impossible, the following overview contains indicative examples of benefits shared in the past.

Direct monetary benefits
- collecting fee (small down-payment for permit, fee per sample, milestone payments);
- research budget to conduct agreed work, up-front or in instalments;
- royalties, stake in equity or share in profit of company developing product from genetic resources;
- salaries for collection services, for work at R&D and production facilities; stipends to shaman or apprentice to continue to work in ethno-medicine;
- local employment of guides, parataxonomists, collectors, scientists; employment in manufacturing and/or plantation facilities established for long-term supply and production in country of origin.

Humanitarian aid
- medical assistance: e.g., medical kits, medical and dental visits for remote communities, distribution of drugs at cost or free;
- setting up an integrated health care clinic;
- food supplies;
- transport: building of airstrip; purchasing vehicles; financing travel to meetings, conferences;
- licenses for the manufacture and sale of commercial products within the country;

Information and knowledge transfer
- information on biodiversity, such as, for instance, on the distribution, habitat and taxonomic identification of a country’s flora;
- sharing of research results, such as results of screens, uses to which the provider’s genetic resources and knowledge have been put, clinical data on the standardisation of traditional medicine;
- scientific and technical literature, translated as appropriate; educational materials;
- focus research on host-country concerns, e.g., tropical or other orphan diseases;
- traditional medicinal handbooks in local language;
- collections, such as national collections of genetic resources by duplicate specimens.
**Technology transfer**

- field, laboratory and office equipment for collection and research such as lights, nets, mobile refrigerators, cameras, global positioning systems (GPS); milling machines, freeze-dryers, chemicals, containers, automated screens, high-performance liquid chromatography (HPLCs), etc.; inventory equipment such as plant presses, mounting boxes, cabinets, solvents, computers, software (e.g., compound and collection databases), collection management tools;
- building a laboratory to manufacture local remedies.

**Training and capacity building**

- science capacity: collecting techniques and preparation of specimens, systematics, biochemistry, molecular and microbiology, ecology, ethnobotany, micro-propagation and plant breeding;
- resource management capacity: in situ and ex situ conservation techniques, protected area management, environmental & social impact assessment, etc.;
- information management: biodiversity inventories, logging material transfers and use of ethnobotanical information, for example, on herbarium specimens, developing GIS systems, etc.;
- know-how: how to set up and operate screens; how to use and adapt equipment, software, etc.
- legal, administrative and management capacity: administration of conservation and sustainable use of biodiversity, how to use intellectual property rights, negotiate agreements, plan benefit-sharing, manage participatory processes, etc.

**Joint research and development, institutional capacity building**

- collaboration in training and research programmes, participation in product development, joint ventures, travel to conferences, co-authorship of publications.
- development of partnerships, identification of institutional channels for the sharing of benefits, building networks of research institutions, etc.;
- institutional development through the involvement of community groups, botanic gardens, university departments, small businesses and the creation of national focal points for access.

**4.2 Benefit-sharing profile for the development of a new drug by a major pharmaceutical company**

Different combinations of benefits at different stages of drug development can be illustrated with the help of a so-called benefit-sharing profile. The concept of benefit-sharing profiles was developed to display these as compactly and simply as possible (see CBD Secretariat, 1996). Table 2. is a schematic illustration of the ‘benefit-sharing profile’ of the development of a new drug by a major pharmaceutical company. It displays the length, expense and probabilities of success at different stages in the development of a pharmaceutical, and shows the range of monetary benefits that arise throughout the process. The process itself may last for thirty or more years, and certain benefits will arise and can be shared irrespective of whether a product finally succeeds on the market.
<table>
<thead>
<tr>
<th>Stage</th>
<th>Process or product</th>
<th>Monetary benefits</th>
<th>Non-monetary benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead Discovery</td>
<td>- Collection&lt;br&gt;- Extraction&lt;br&gt;- Primary screening of, e.g., 5 million compounds of which are potentially interesting ca. 1000 ‘hits’&lt;br&gt;- Structural elucidation&lt;br&gt;- Dereplication&lt;br&gt;- Secondary screening for possibly 10 serious leads&lt;br&gt;- Patent filing</td>
<td>May include, singly or in combination:&lt;br&gt;- Collection fee&lt;br&gt;- Research grant&lt;br&gt;- Consulting fee&lt;br&gt;- Annual payment for supply</td>
<td>- Collection fee&lt;br&gt;- Research grant&lt;br&gt;- Consulting fee&lt;br&gt;- Annual payment for supply:&lt;br&gt;- May include, singly or in combination:</td>
</tr>
<tr>
<td>Lead Discovery and Optimisation</td>
<td>- Analogue synthesis&lt;br&gt;- Improve yield, potency &amp; bioavailability&lt;br&gt;- Reduce steps in synthesis&lt;br&gt;- Patent registration for ca. 5 drug candidates.</td>
<td>- Milestone payment</td>
<td>- Exchange of staff and joint research on lead optimisation.</td>
</tr>
<tr>
<td>Development and Registration</td>
<td>- Biological studies&lt;br&gt;- Scaling-up of production&lt;br&gt;- Pre-registration&lt;br&gt;- Phase I clinical trials: tests on 10s of people; ca. 2 yrs; ca. 5 candidate drugs&lt;br&gt;- Phase II trials: tests on 100s of people; 2-3 yrs; ca. 5 candidate drugs&lt;br&gt;- Phase III trials: tests on 1000s of people; ca. 5 yrs ca. 2 candidate drugs;</td>
<td>- Milestone payment</td>
<td>- Share results of biological studies;&lt;br&gt;- Employment of local population for the re-collection of larger quantities of genetic resource;&lt;br&gt;- Joint research and/or joint ventures with local institutions on product development;</td>
</tr>
<tr>
<td>Marketing and sales</td>
<td>- Filing of drug application&lt;br&gt;- Approval of drug&lt;br&gt;- Marketing&lt;br&gt;- Sales</td>
<td>- Periodic royalty payments until patent expires, payment over fixed period or lumpsum payment.</td>
<td>- Granting of license to manufacture product to provider country.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Continuing supplies of bulk, cultivated raw materials, or value-added, processed materials from provider country, where possible.</td>
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</tbody>
</table>
The research and development strategies and budgets even of comparable companies differ considerably. Smaller pharmaceutical and biotechnology companies would have different benefit-sharing profiles. Within a certain economic sector, benefit-sharing profiles may be variations on a theme, but will likely be different in kind for other uses, for example in sectors such as agriculture and horticulture. In cases where genetic resources are used for scientific, non-commercial purposes only, for example in the case of access for taxonomic research by a herbarium, the benefit-sharing profile will continue to comprise the non-monetary components that it has traditionally been able to provide: exchange of information, training, and some relevant technology. Benefits arise in the commercial field whether or not a product reaches the market. Similarly, the benefits of academic research go well beyond the broad benefits to scholarship of additions to specialist literature once research is completed.

Benefits arise from the planning stage of research, since activities can be directed to meeting the sustainable development needs of countries, institutions and communities. As other Conventions such as CITES have found, drawing a distinction between commercial and non-commercial use is difficult. For instance, taxonomy can focus on economically or culturally important local plants, or those endangered by overuse. Propagation and cultivation skills can be transferred, promoting conservation of wild genetic resources, and joint research on national resources can support the work of local researchers and enable them to focus on national priorities. Much conservation-related research can support practical conservation measures in situ and ex situ. Both pure and applied research can promote sustainable uses of biodiversity and the development of sustainable livelihoods. Research can also attract financial support from research councils and other donors, and part of these sums can support activities by local counterparts.

4.3 Creating possible incentives for benefit-sharing

As illustrated in the benefit-sharing profile in Table 2., benefits arise from the initial moment of access, through the creation of research results, to the final use of the material. Without deciding a priori what would be a ‘fair and equitable’ manner of sharing these benefits the following overview in Table 3. proposes for consideration a series of measures that could provide appropriate incentives to share benefits at various stages in this process.

The incentive measures proposed for consideration also highlight the problematic nature of the distinction between economic and legal or regulatory incentive measures. Any economic incentive such as, for instance, a tax depends on an accompanying legal process in order to enact it. Similarly, many of the legal measures proposed below have immediate consequences for prices, the structure of markets and the distribution of gains. In practice, it is more important to consider the economic consequences of a measure rather than its a priori classification.
Table 3. Some examples of possible incentives to stimulate benefit-sharing

<table>
<thead>
<tr>
<th>Step of process</th>
<th>Incentive measure</th>
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</table>
| 1. Project planning or initiation     | - User country government institutions, multi-lateral organisations or foundations collaborate with private sector in research that includes a benefit-sharing regime;  
- User country governments, multi-lateral organisations or foundations offer grants to research partnerships with benefit-sharing regimes. |
| 2. Initial access, user obtains material | - Provider access legislation requires access contract stipulating benefit-sharing;  
- Users adopt voluntary code of conduct for collection and enter into access contract. |
| 3. Material exported from provider country | - Provider access legislation and/or export permits stipulate benefit-sharing;  
- User-end import requirements require importer to honour benefit-sharing commitments; positive incentives (e.g., tax breaks) for benefit-sharing commitments. |
| 4. Lead discovered, useful trait identified | - Provider access legislation and access contracts require sharing of research results and other benefits as they arise. |
| 5. User seeks more material           | - Provider access legislation requires more detailed benefit-sharing contract to be negotiated. |
| 6. Product development                | - Provider access legislation requires user to notify/seek consent of provider country authorities for commercial use |
| 7. User files for intellectual property rights | - Provider access legislation requires user to notify provider and/or seek further prior informed consent;  
- Administration in user country requires disclosure of country of origin and/or proof of prior informed consent before granting patent. |
| 8. User files for product approval     | - Administration in user country requires disclosure of country of origin and/or proof of prior informed consent before granting product license. |
| 9. Product generates sales            | - Provider access legislation and contracts stipulate return of share of financial benefits;  
- Tax rebates for profits from products whose benefits are shared according to certain criteria. |

15 Adapted from ten Kate, 1997. The following measures have been suggested at various times in international fora and academic publications. The OECD or its Member countries do not endorse any of these policy measures specifically, or the list generally.
CHAPTER 5. CASE STUDY: SHARING OF BENEFITS BETWEEN AUSTRALIA AND THE UNITED STATES FROM THE UTILISATION OF GENETIC MATERIAL STEMMING FROM THE SMOKEBUSH

The complicated nature of the sharing of benefits stemming from the utilisation of genetic resources becomes most evident if studied in detail in practice. Each single case has, of course, features that are peculiarly its own. Nevertheless, the inclusion of a case study can help to explain the sheer complexity of the issue, the importance of timing, the importance of institutional frameworks and rules, as well as the importance of building trust and knowledge. The following case study was chosen as it regards benefit-sharing between two OECD countries. While in the case of benefit-sharing that involves non-OECD countries many additional issues may come into play, the following case study allows to develop a first intuition for the challenges facing the institutionalisation of benefit-sharing.

Initial collection

The Department of Conservation and Land Management (CALM) in Western Australia is responsible for granting permits to collect and conduct research on Western Australian flora. In 1981, a U.S. Department of Agriculture botanist collected around 1200 plant specimens in Western Australia. These were processed by the Western Australian Herbarium and sent by the botanist to the U.S. National Institutes of Health for screening. During the 1960s, the U.S. National Cancer Institute (NCI) of the Institutes of Health instituted a huge plant collection programme with the aim of discovering new medicines to treat cancer. Since the emergence of the threat of AIDS in the late 1980s, NCI has been re-testing its global collection, now consisting of over 90 000 samples, against HIV cell-lines. Four plant extracts have shown promising activity, from Samoa, Sarawak and Cameroon, and a species of smokebush (genus Conospermum) from Western Australia. The NCI obtained a patent on conocurvone, the active compound of the smokebush. At the same time, research by scientists in Western Australia also revealed the potential anti-HIV activity of the smokebush.

December 1993: the first CALM-AMRAD agreement

CALM wished to ensure that Western Australia would receive the maximum benefit from the use of its own biological resources. Not content with simply receiving royalties on production of any drug from the smokebush plant, CALM was determined that the development and production of any potential drug should be based and co-ordinated in Western Australia. CALM entered into negotiations with AMRAD, an Australian pharmaceutical company. A subsequent amendment to the Conservation and Land Management Act allowed CALM to grant exclusive rights to one company for the commercial development of a product derived from Western Australian flora. CALM agreed to grant AMRAD access to the smokebush and permission to develop it commercially; in return, AMRAD agreed to provide Aus$1.15m to CALM, a share in royalties, and the right of first refusal for CALM to conduct any research on the active compound. In addition, AMRAD provided Aus$ 500 000 for further research by a consortium of 26 Western Australian scientists, in collaboration with the NCI, on some 8 smokebush patents lodged by CALM. The research would explore the chemical structure of conocurvone and the synthesis and development of analogues. The CALM-AMRAD agreement also supported conservation and benefit-sharing.
Concerning the support for conservation, CALM was responsible under the agreement for ensuring the sustainable collection of the raw material. CALM used the funds received from the AMRAD agreement to support the conservation infrastructure in Western Australia. Aus$ 600 000 from the AMRAD agreement was put directly into conservation projects in WA:
- Aus$ 300 000 for the conservation of rare and endangered WA flora and fauna;
- Aus$ 300 000 for other conservation activities, including information technology (geographical information systems, data capture and management to study population dynamics, etc.)

Benefit-sharing took two forms: research funding covering joint research and technology acquisition, and a share in royalties:

Research funding

- **Joint research:** The consortium of Western Australian scientists (ecologists, geographers, botanists, chemists, pharmacologists and immunologists) received Aus$ 150 000 to cover research conducted prior to the agreement that had led to several WA patents on conocurvone. Over the year following the agreement, the consortium received an additional Aus$ 500 000 for its further research.
- **Technology acquisition:** government and university laboratories of consortium members were equipped with technology such as HPLC machines.
- **WABEL:** The remaining funds were used by CALM to establish the Western Australian Biotic Extract Library (WABEL), a library of biotic extracts for drug discovery.

Royalties

- CALM was to receive royalties from sales by AMRAD of any products derived from the smokebush project.

**March 1994: the first AMRAD-NCI agreement**

United States law concerning research and development agreements with public bodies constrains the ability of an institution such as NCI to enter into benefit-sharing commitments with a country of origin when these would have to be honoured by a licensee of an NCI patent. At the time the material is obtained from the provider country, the ultimate licensee of any potential future product is unknown, and exploitation of NCI patents must be tendered for competition. Consequently, NCI was originally not in a position to enter into agreements with Western Australia containing terms that would impose benefit-sharing obligations on any company that NCI might subsequently license to exploit conocurvone. Since CALM, however, had already agreed to provide access to the smokebush exclusively to AMRAD and since AMRAD was the only company capable of guaranteeing the supply of the material in the quantity and of the quality needed to exploit the patent, NCI eventually awarded AMRAD an exclusive production and marketing licence.

The awarding of the exclusive production and marketing licence to AMRAD by NCI took place in the context of an ongoing effort of the NCI to conclude agreements concerning the collection of natural compounds. NCI’s ‘Letter of Intent’ (later ‘Letter of Collection’) programme had been in operation for several years. Furthermore, when NCI published the notice of intent to license the compound in August 1993, it also contained the requirement that the licensee must negotiate agreements for benefit-sharing with the government of Australia. The final outcome was the result of both, access legislation and institutional processes.
May 1995: the second CALM-AMRAD agreement

As a result of the further work of the Western Australian consortium, CALM had developed 86 analogues of conospermum. AMRAD then provided a further research grant to CALM. The company now has a product derived from the smokebush in Phase I Clinical trials. A final agreement with CALM was concluded that regulates the sharing of eventual royalties from the sales of any product that succeeds through these trials to the market.

Replicability and lessons learned

To what extent could this model be repeated in other settings? This case study has a number of notable features:

Consortium to conduct value-added work: In common with many developing countries, Western Australia does not have a well-developed drug development industry, but does have expertise in many relevant disciplines within academia. CALM created a research consortium capable of conducting value-added scientific studies in Western Australia.

Provider country authorities exercise sovereignty and negotiate benefits: Access legislation and bioprospecting agreements are only of value where the sovereign authorities of provider countries are prepared to monitor and enforce them.

Good will: In the absence of national legislation and authorities to regulate access to genetic resources, the good will of the user institution and/or the user government has been and continues to be important in achieving appropriate benefit-sharing arrangements. In the present example, the three parties, NCI, CALM and AMRAD, were prepared to negotiate around issues such as sovereignty, intellectual property rights, and where and by whom the research in discovery and development would be conducted.

Distinction between scientific and commercial use of genetic resources: The case study highlights the importance to negotiate the sharing of benefits as and when these arise for all collectors, whether nationals or foreigners, whether collecting initially for scientific purposes or ostensibly for commercial development. While it is fairly obvious that, if a sample is collected with drug discovery in mind, a commercial product might emerge, the line between commercial and basic research can be difficult to identify in some fields at the moment of an initial collection. Many commercial products derive from ‘purely scientific’ research. The many years of both academic and commercial research involving numerous parties that are involved before a natural resource yields a commercial product can further blur the distinction.

Benefits dedicated to conservation: Benefits will only accrue to conservation if they are deliberately designed into the partnership. While the Australian government had an interest in conservation, this might not be necessarily the case in other countries. In those cases and under the condition that third parties might have an interest in conservation, international mechanisms to balance costs and interests have to be found.
Resupply essential: More raw materials, particularly with plant sources, are generally needed after the initial collection for structure determination and/or follow-up studies. In this case, NCI’s co-operation with CALM ensured that a benefit-sharing agreement would be developed between Australian authorities and a licensee. However, this may not be the case with all natural products. In the absence of such policies, the necessity of recollection can be an important incentive for the development of appropriate agreements. In some cases, the initial collection, even of tiny quantities is sufficient to elucidate the structure of the active compound. In cases where the active compound derived from a plant can be synthesised cost-effectively, the collector may never need to return, removing one of the most obvious incentives for negotiation of benefit-sharing and mechanisms for alerting providers to the prospect of commercialisation of resources collected for scientific purposes. Micro-organisms, for instance, can generally be cultured in sufficient quantities to remove the need for recollection altogether.

Endemic species - stronger bargaining power: The entire genus Conospermum is found only in Australia, with the majority of the resources in Western Australia itself. This offered CALM a strong bargaining tool, even once NCI had a patent on conocurvone. Few provider countries will find themselves in such a position. In the vast majority of cases collectors could obtain the same species from several different countries, and could use this to ‘bargain down’ the benefits they would offer. However, the capacity to offer reliable taxonomic determination and resupply of genetic resources can improve the competitiveness of a provider even of genetic resources that are found in many countries.

AIDS indication - fast track product approval: Finally, compounds with activity against AIDS enjoy the benefit of fast-track development, with a similar development cycle to anti-cancer drugs and correspondingly less expensive FDA trials. Such compounds are attractive for licensees and may provide financial benefits sooner to the providers of leads or raw materials.

Despite these unusually favourable circumstances, the case study offers a number of general lessons. First, the endemic distribution of the smokebush and the need for recollection enabled an Australian company, AMRAD, to win the license for commercialisation from the patent holder, NCI. Leverage to negotiate a benefit-sharing agreement between AMRAD and CALM was provided both by the endemic nature of the plant (corresponding to CALM’s authority over natural resources) and the policies of the NCI which required that the licensee negotiate with the state authorities. This highlights the importance of access legislation that requires all collectors, whether national or foreign, to negotiate the sharing of benefits as and when these arise. Second, it demonstrates the importance of appropriate institutional policies in the user country and co-operation with those institutions. Third, it reveals the importance of local capacity in research and development in obtaining a share of the more valuable benefits, such as joint research. Finally, benefits will only accrue to conservation if they are deliberately designed into the partnership.
CHAPTER 6. ESTIMATES OF MONETARY BENEFITS FROM THE UTILISATION OF GENETIC RESOURCES

Quantification of the value of access to genetic resources and the various ‘benefits’ exchanged is complicated for a number of reasons. First, quantification entails refining methodologies for assessing the economic value of biodiversity. Second, it involves quantifying the share of the market price contributed by the ‘raw’ biological resources themselves, by stakeholders providing access to them and knowledge concerning them, and the value added through the formal research and development process. This is particularly complicated since the end product is frequently so far removed from the original material as to be all but unrecognisable.

Pharmaceuticals, for example, occasionally use genetic resources directly. More often, the resources themselves are the ‘building block’ for the production of semi-synthetic drugs. At one level further removed, the genetic resource may provide the template or blueprint serving as the model for a new synthetic compound, and finally, a drug can be designed to emulate the mode of action of a natural product that interacts with the body. Many drugs in this category were developed without ever needing access to the genetic resources whose activity inspired their development. Depending on which of the four categories of derivation one is prepared to include in the definition of ‘natural product’, Box 1. could suggest that either 3 per cent, 17 per cent, 21 per cent or 37 per cent of the sales of pharmaceuticals stem from ‘natural products’.

<table>
<thead>
<tr>
<th>Box 1.</th>
<th>The top 25 drugs in the UK in 1993: a breakdown of natural and synthetic products</th>
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<tbody>
<tr>
<td>Of the 25 drugs with greatest sales in the UK in 1993 (totalling £18.3 billion), fifteen were purely synthetic products, with sales of £11.6 billion (63% of total sales). Of the 10 products in some way derived from or inspired by natural sources (37%) none is derived from a plant, 5 are from fungi (17%), 2 from micro-organisms (7%), and 3 from animals (two from snake venom and one from horse urine)(13%). Of the naturally derived medicines, one uses the purified natural product (the horse urine - 3%), 3 are semi-synthetic (14%), 1 is derived from a natural template (4%), and 4 were designed following inspiration from the mode of action studied in a natural source (17%).</td>
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</table>

Third, markets often fail to integrate environmental and social costs into economic decisions, and constantly do not offer mechanisms to capture benefits. Until ‘externalities’ such as the costs of conservation enter into cost calculations, benefits will generally not reflect the full value of genetic resources, in particular the services of communities conserving them. This stresses the importance of further work on complementary issues such as full cost pricing, access legislation and other policy.

16 See, for example, UNEP/CBD/SBSTTA/2/13 and Simpson et al., 1992, forthcoming.
17 ten Kate, 1995a, as modified in ten Kate, 1997.
interventions that can promote fairness and equity in the sharing of benefits. Taking all these factors into consideration, quantification of the economic benefits arising from access to genetic resources from market data is a highly speculative exercise. Some approximate figures for the size of the markets in which potential products in whose production bioprospecting is involved are set out in Table 4.

<table>
<thead>
<tr>
<th>Table 4. Estimates of the size of markets for the products of bioprospecting</th>
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<tbody>
<tr>
<td><strong>Pharmaceuticals</strong></td>
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<tr>
<td>Global pharmaceutical market sales, 1993</td>
</tr>
<tr>
<td>Global market for natural product-based pharmaceuticals, based on estimate of 25% of total</td>
</tr>
<tr>
<td><strong>Phytomedicines</strong></td>
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<tr>
<td>European phyto-therapeutics market turnover in 1993</td>
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<tr>
<td>The 1994 herbal medicine market in the USA in 1994</td>
</tr>
<tr>
<td><strong>Biotechnologies</strong></td>
</tr>
<tr>
<td>European market for products dependent on the application of biotechnology in 1994</td>
</tr>
<tr>
<td>(ECU 4 billion chemicals, ECU 15 billion pharmaceutical and animal health, ECU 1 billion agriculture supply industry, ECU 10 billion food industry, and ECU 8 billion diagnostics and equipment.)</td>
</tr>
<tr>
<td>European market for products dependent on the application of biotechnology other than pharmaceuticals in 1994</td>
</tr>
<tr>
<td><strong>Agrochemicals</strong></td>
</tr>
<tr>
<td>Global sales of agrochemicals for crop protection in 1993</td>
</tr>
<tr>
<td><strong>Cosmetics, toiletries and perfumes</strong></td>
</tr>
<tr>
<td>Total Cosmetics and Toiletries sales in US in 1994</td>
</tr>
<tr>
<td>‘Natural’ C&amp;T sales in US in 1994 based on 2.5% of total global output.</td>
</tr>
</tbody>
</table>

Several efforts have also been made to quantify potential revenues from bioprospecting by economic modelling, for specific geographical areas (usually at the scale of individual protected areas), for certain business sectors (notably pharmaceuticals) and also more generally. The modellers frequently acknowledge the lack of data, and the inevitable limitations of modelling an activity as speculative as bioprospecting.\(^\text{20}\) Working with heroic assumptions their results vary by up to several orders of magnitude. There is no single manner in which decision-makers from government and business will use

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\(^{18}\) See ten Kate, 1997, for detailed information about the sources of the estimates.

\(^{19}\) This percentage varies according to the author and the method of estimation. According to analysis by Cragg et al., 1997, over 60% of the anticancer and anti-infective approved drugs and pre-NDA candidates for the period 1989-1005, other than biologics, ‘are of natural origin’. Grifo et al., 1997, found that 57% of the top 150 brand names prescribed from January to September 1993 ‘contained at least one compound now or once derived or patterned after compounds derived from biological diversity’.

\(^{20}\) See, for instance, Simpson et al., forthcoming.
this information. They may find particular models attractive, or draw the best conclusions that they may from them all. The results are presented below for illustrative purposes only.

Table 5.
Results of different methodologies for valuing bioprospecting for medicines

<table>
<thead>
<tr>
<th>Quantity measured</th>
<th>Author</th>
<th>Methodologies</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual value to the pharmaceutical industry per successful species</td>
<td>Farnsworth &amp; Soejarto (1985)</td>
<td>per successful species</td>
<td>$ 203 m, USA</td>
</tr>
<tr>
<td></td>
<td>Pearce &amp; Moran (1994)</td>
<td>per successful species</td>
<td>$ 390 m, USA</td>
</tr>
<tr>
<td></td>
<td>Principe (1989)</td>
<td>per successful species</td>
<td>$ 200 m, USA;</td>
</tr>
<tr>
<td></td>
<td>Aylward (1993)</td>
<td>using Principe (1989)</td>
<td>$ 600 m, OECD</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$ 37.5 bn, OECD</td>
</tr>
<tr>
<td>Annual value to the pharmaceutical industry - per untested species</td>
<td>Simpson et al (1996)</td>
<td>marginal species</td>
<td>neglbl. to $10 000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- w/ Fwth. (1985)</td>
<td>$ 1.62 m</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- w/ Principe (1989)</td>
<td>$ 23.7 m</td>
</tr>
<tr>
<td></td>
<td></td>
<td>per extract</td>
<td>$ 1 100</td>
</tr>
<tr>
<td>Annual value to the pharmaceutical industry - per biotic sample</td>
<td>Artuso (forthcoming)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Royalty returns per untested species</td>
<td>Aylward (1993)</td>
<td>w/ Reid et al. (1993)</td>
<td>$52.50 to $46 000</td>
</tr>
<tr>
<td>Royalty returns per biotic sample</td>
<td>Aylward (1993)</td>
<td>mean royalty returns</td>
<td>$20 to $2 000</td>
</tr>
<tr>
<td>Value to phct. industry of 'drugs in the forest'</td>
<td>Mendelsohn &amp; Balick (1995)</td>
<td>undiscovered drugs</td>
<td>$ 147 bn</td>
</tr>
<tr>
<td></td>
<td>Mendelsohn &amp; Balick (1995)</td>
<td>‘rights to the forest’</td>
<td>$ 2.8 bn to 4.1 bn</td>
</tr>
<tr>
<td>Sales of medicines derived from natural products</td>
<td>Durning (1994)</td>
<td>forest ingredients</td>
<td>$ 100 bn p.a.</td>
</tr>
<tr>
<td></td>
<td>Principe (1991)</td>
<td>plant cancer cures</td>
<td>$ 34 bn to $300 bn p.a., USA</td>
</tr>
<tr>
<td>Loss to economies from species reduction</td>
<td>Pearce &amp; Moran (1994)</td>
<td>annual loss, market-based</td>
<td>$ 8.8 bn, USA;</td>
</tr>
<tr>
<td></td>
<td>Farnsworth &amp; Soejarto (1985)</td>
<td>drugs lost</td>
<td>$ 180 bn, USA;</td>
</tr>
<tr>
<td></td>
<td>Principe (1989)</td>
<td>drugs lost</td>
<td>$500 bn, OECD</td>
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<td></td>
<td></td>
<td></td>
<td>$ 3.248 bn, USA</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>$ 15 bn, OECD</td>
</tr>
<tr>
<td>Value of land for medicinal plants</td>
<td>Pearce &amp; Moran (1994)</td>
<td>undiscovered drugs</td>
<td>neglbl. to $ 420/ha</td>
</tr>
<tr>
<td></td>
<td>Mendelsohn &amp; Balick (1995)</td>
<td>undiscovered drugs</td>
<td>$ 48/ha</td>
</tr>
<tr>
<td></td>
<td>Mendelsohn &amp; Balick (1995)</td>
<td>allocated revenues</td>
<td>$ 0.9 to $ 1.32/ha</td>
</tr>
<tr>
<td></td>
<td>Simpson et al (1996)</td>
<td>WTP based on Myers</td>
<td>neglbl. to $ 20/ha</td>
</tr>
</tbody>
</table>

21 ten Kate, 1995b.
CHAPTER 7. CONCLUDING REMARKS

7.1 Monetary benefits and the conservation of biodiversity

Market figures do not reveal the economic value of benefits ultimately returned to those actually managing biodiversity (e.g., national parks, local communities). This is because genetic resources are frequently readily available to commercial users without the obligation to share benefits (for example, from ex situ collections), and because those benefits that are shared are often captured by one group in society (for example, one institution supplying genetic resources, or a government that obtains all benefits) to the exclusion of others (such as research institutions, or local communities).

Even after overcoming the considerable difficulties outlined in the preceding sections, namely identifying beneficiaries and assessing and allocating benefits, it is rare for the benefits to be dedicated to conservation. The Convention does not require but provides considerable support for the notion of dedicating some benefits to conservation. This situation is mirrored in national access measures, which generally introduce criteria for sustainable sourcing, but do not stipulate the dedication of benefits to conservation. Nonetheless, some bioprospecting cases do plough benefits back into conservation.

The application by the Department of Conservation and Land Management in Western Australia of Aus$ 600 000 from AMRAD is explained above. The Costa Rican government has also introduced measures to ensure the dedication of some benefits to conservation. MIRENEM, the Ministry of Natural Resources, Energy and Mines, requires INBio to pay 10 per cent of its research budget and 50 per cent of royalties from sales of natural products derived from Costa Rican biodiversity to a National Park Fund. MIRENEM received US$ 100 000 from INBio for each of its two agreements with Merck. INBio also donates equipment and materials to MIRENEM, provides it with technical advice and makes available to it the information on INBio’s inventory and conservation databases.

It is important to bear in mind that the proceeds from benefit-sharing are unlikely to be sufficient to cover the funds necessary for the conservation of biological diversity. The potential income discussed in Chapter 6 can be compared with the sums estimated by the UNCED Secretariat as the average total annual cost between 1993 and 2000 of implementing the activities of Chapter 15 of Agenda 21 on the conservation of biological diversity. The figure arrived at was US$ 3.5 billion, including about US$ 1.75 billion from the international community on grant or concessional terms.

Of course, such a comparison is of dubious value in the first place. A priori there is no reason why there should be any relationship between the size of the rent from pharmaceutical products based on

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22 The use to which commercial and other benefits arising from access are put is prima facie a matter for national authorities, as part of their determination of access to genetic resources. However, dedication of some benefits to conservation could be one term mutually agreed between the authorities and the user of genetic resources.

23 One of the justifications for benefit-sharing (other than equity) is that it offers an economic incentive for conservation and sustainable use, which would seem to support the dedication of some benefits to conservation. Furthermore, several provisions of the Convention link activities such as access to genetic resources to sustainable use of biodiversity (see, for example, Articles 9a, 14 and 15.2).

24 For example, by setting limits on quantities of material accessed and introducing requirements for environmental impact assessment of access activities.
natural genetic resources and the amount of funds spent on the conservation of biological diversity. The first, relates to the private value of a subset of biological diversity, the second relates to the public value of the whole of biodiversity. The realisation of the public value of biological diversity through conservation, in an ideal economy, would be realised through the full cost pricing (internalisation of externalities) of activities that exert pressure on biodiversity. Such an approach would, however, face insurmountable obstacles of measurement, supervision and enforcement.

One alternative and promising approach is the integration of conservation activities and bioprospecting activities. A share of the proceeds from eventual benefit-sharing would thus contribute as one source of funding to conservation and to sustainable use. At the same time, structures would be set up which could fruitfully employ any additional funds that would be provided for conservation purposes. One working example of this process is the International Cooperative Biodiversity Groups program sponsored by the U.S. National Institutes of Health and the U.S. National Science Foundation. 25

It is worth noting that, while bioprospecting may not make an important contribution to gross national product, the modest revenues it generates can bring about significant environmental, social and economic results, provided the benefits are captured at a local level and some dedicated to conservation. $100 000 dollars in the hands of an NGO, a small business or a local community can go a long way: providing medicines, supporting a nature reserve or an inventory of biodiversity, funding a clinic or processing facilities, and creating employment. These direct benefits can be felt indirectly in other sectors of the economy - for example, in tourism or through providing transferable skills such as in information technology - thus contributing to a country’s broader sustainable development.

7.2 Fairness and equity

The Convention on Biological Diversity stipulates that benefit-sharing should be ‘fair and equitable’. The definition of fairness and equity will necessarily involve value judgements and cannot be decided on analytical grounds. What is fair and equitable 26 will ultimately depend upon the arbiter, as there is no single right answer. The authority of national governments to determine access (Art. 15(1)), their requirement for prior informed consent and the variety of roles they play in negotiating benefit-sharing, as defined in access legislation, suggests that government will play a part in determining what is ‘fair and equitable’. The use of the phrase ‘mutually agreed terms’ in various articles of the Convention allows the specific parties to access and benefit-sharing transactions to reach agreement on the basis of what they consider fair and equitable, and of meeting each others’ needs.

Similarly, the allocation of benefits to their final use is linked to the identification of beneficiaries, as well as the basis for sharing and quantification of benefits. Just as with fairness and equity, there is no correct method for allocation. The desired result is one which fairly reflects the efforts contributed by the different stakeholders in making the genetic resources available (through conservation, provision of access to, provision of information, collection and research). This will be a matter to be decided by national authorities and mutual agreement between parties to specific arrangements. Material transfer agreements frequently clarify the share of royalties between the various parties, and may be an appropriate mechanism for allocating benefits when there are relatively few beneficiaries.

27 15(4); 16(3); 19(2) and as ‘mutual agreement’ in 18(5).
In the case of competing uses, for example when the knowledge on which an invention is based is common throughout a country or a community, or when conservation efforts have been a shared responsibility among farming communities for generations, it may be appropriate to share benefits nationally, as well as allocating some to local institutions and communities that have contributed. For this purpose, a ‘multi-stakeholder’ committee may be helpful to define the application of benefits for public goods on a national or regional level. These are issues to which policy responses should be clarified, in consultation with all relevant stakeholders during the development of national measures to regulate access.

7.3 Institutions and criteria

The complexity of the issues associated with the sharing of benefits, their controversial nature and the current evolution of the debate suggests that the priority for policy-makers, in both provider and user countries, is to create the necessary institutions, the incentives and criteria according to which benefit-sharing shall proceed. Some important considerations in the policy process are ‘prior informed consent’, duties for information exchange, benefit-sharing negotiations, the building of capacity and the setting of priorities for allocating benefits obtained.

Concerning criteria or elements that could be part of benefit-sharing agreements the study has mentioned a series of elements that could contribute to capacity building and sustainable development reaching from active involvement of the local population to donations of equipment and access to botanic information. Each benefit-sharing case will have its own characteristics, challenges and opportunities and benefit-sharing agreements need to be able to reflect the particular circumstances of each case. However, benefit-sharing agreements will only achieve their purpose if they manage to combine private, commercial interests and wider policy objectives and to contribute concretely to both.

While most benefit-sharing ultimately takes place in a market environment, policy makers can contribute to defining the structures of that market in at least two ways: first, by helping to define the issues, and second, by providing incentives that promote not only fair and equitable sharing of the private benefits from the utilisation of genetic resources, but also economic development and the conservation of biodiversity through its sustainable use.

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28 See, for example, Laird and Wynberg, 1996.
29 Some of the technical and quantitative information contained in the present paper is based on an earlier paper prepared for the Secretariat of the Convention on Biological Diversity, namely Fair and Equitable Sharing of Benefits Arising from the Use of Genetic Resources. The permission of the Secretariat of the Convention on Biological Diversity to reproduce that information is gratefully acknowledged.
BIBLIOGRAPHY


