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# Bioprospecting

## Facilitate and regulate bioprospecting

Biodiversity prospecting or bioprospecting is the systematic search for biochemical and genetic information in nature in order to develop commercially-valuable products for pharmaceutical, agricultural, cosmetic and other applications.

**Key words:** ABS; technology transfer; Nagoya Protocol; Biodiversity

## How does it work?

Biodiversity prospecting or bioprospecting is the systematic search for biochemical and genetic information in nature in order to develop commercially-valuable products for pharmaceutical, agricultural, cosmetic and other applications. Bioprospecting activities must comply with the definition of utilization of genetic resources of the Nagoya Protocol or as stated in the national law or policy. The Nagoya Protocol applies to the utilization of genetic resources and their derivatives.

The rationale is to extract the maximum commercial value from genetic resources and indigenous knowledge, while creating a fair compensation system that can benefit all. The phases of bioprospecting start with sample collection, isolation, characterization and move to product development and commercialization. Bioprospecting is possible both in terrestrial and marine environments. Many molecules, such as trabectedin (an antitumor agent) and eribulin (used to treat breast cancer), were discovered from marine organisms.

Bioprospecting, when properly regulated, generates revenues that can be directly linked to the conservation of biodiversity and to the benefit of local communities. Benefits can be monetary and non-monetary. Non-monetary benefits include sharing of the results of research and development; training through research exchanges and collaborative research; joint ownership of intellectual property rights; technology transfer; and the provision of equipment and improvement of infrastructure. Monetary benefits include license fees, up-front payments, payments per sample, milestone payments, and royalties generated from the commercialization of products derived from genetic resources.

The national legislation typically requires the signing of a contract between users (i.e. investors, private or public manufacturers, research entities) and providers (i.e. local communities, landowners and government entities) of genetic resources. The contract often involves a company and a Government counterpart, either the authority responsible for facilitating access to the country's genetic resources or another mandated agency. Representatives from local communities are also involved, but their legal status and rights vary greatly depending on the national legislation and the ratification of the Nagoya Protocol. A number of countries hosting large pharmaceutical multinationals in Europe and North America may not have signed the protocol yet, but all national and multinational enterprises are required to comply with the relevant national legislation. In parallel, the WIPO has established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore to draft an international legal instrument to protect traditional knowledge, traditional cultural expressions and genetic resources.

Depending on the national ABS law or policy, access to the genetic resources might be granted through a basic research permit, which will be later transformed into a benefit-sharing contract if the product has commercial applications. The contract might also grant the right to protect (e.g. exclusive use) the results of bioprospecting activities. Products or processes derived from genetic resources that fulfil the statutory requirements can be protected by intellectual property rights such as patents and plant breeders' rights.

In developing countries, development partners and/or Non-Government Organizations (NGOs) frequently act as brokers, intermediaries and financiers in support of local communities and Government counterparts. Grants are often provided to conduct feasibility studies, environmental and social assessments as well as to strengthen negotiation capacities in the source country.

Two example--from Costa Rica and Colombia--illustrate the promise and challenge of bioprospecting. The agreement between Costa Rica's National Institute of Biodiversity (INBio) and the US pharmaceutical company Merck granted the former the right to receive royalties (3 per cent of sales) from any commercial product identified through bioprospecting. Half of the royalties were to be allocated to national parks. INBio was awarded a two year research and sampling contract. The contribution from Merck of about US\$ 2.6 million was channelled to the Ministry of Environment and

## Summary

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### Bioprospecting

[English \(821.0 kB\)](#)

## Our Perspectives

[Project: Implementing the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing in Bhutan](#)

[Project: Developing and implementing a national access and benefit sharing framework in Malaysia](#)

## Financial Results



## Instruments Used



[Market](#)



[Fiscal](#)

Energy, universities, and other partners. In exchange, Merck obtained [access](#) to “chemical extracts from wild plants, insects, and micro-organisms”. No royalty payment was derived from this agreement. However, INBio has received payments from [other bioprospecting contracts](#) in the last 20 years. [Access](#) to genetic resources in Colombia is regulated by the [Decision 391 on ABS](#) and supported by a national policy for the commercial use of biodiversity resources. This [policy](#) facilitated the creation of a company for bioprospecting to link up with the commercial sector backed by US\$14 million in public funds. As a [result](#), bioprospecting has increased both in the number of research groups (30 per cent) and of registered projects (eight times).

#### Stakeholders

- **Regulatory entity:** government authority (ies) mandated by the law to regulate [access](#) to genetic resources and benefit-sharing.
- **The investor:** private companies and universities that sponsor and finance bioprospecting.
- **The manufacturer/seller:** the company that will manufacture and sell the commercial product. It might or might not be different from the investor.
- **The broker:** NGOs and development partners play a support role by financing on grant or concessional terms or by training Governments and local communities.
- **Local community:** the community living in the area where bioprospecting takes place and which may be involved in the [ABS](#) value chain needed for the development of the final product.

#### Potential in monetary terms

Only a low volume of bioprospecting transactions is recorded, despite the potential for revenue generation. The value of bioprospecting contracts is estimated to be below US\$100 million a year, compared with research and development investment by pharmaceutical companies of US\$ 50 billion a year. Bioprospecting research contracts rarely surpass US\$1 million in value, while royalties<sup>34</sup> theoretically with a potential of generating billions<sup>34</sup> have rarely materialized. For example, in the agreement signed between the Union of Zapoteco Chinanteca Communities in Mexico and the Swiss firm, Novartis, [Novartis](#) agreed to pay between US\$1 and US\$2 million for each active compound. GlaxoSmith Kline and the biotechnology company Extracta in Brazil [transacted](#) made an agreement worth US\$ 3.2 million for the collection of 30,000 samples.

Although the market value of drugs derived from plants originally used by indigenous peoples is [estimated](#) at US\$43 billion, the lack of legislative provisions and of their enforcement have impeded the collection of royalties from bioprospecting. Given that the largest pharmaceutical and cosmetic companies are housed in developed countries, the indirect economic benefit through profit and sales taxation has been also minimal in developing countries. The situation is one in which both the potential for income generation and the risk of not accruing actual revenues are high.

The potential of bioprospecting can be assessed by referring to the [profits](#) accrued from the exploitation of natural genetic resources as the tax base for a royalty: Pravachol (cholesterol) generated US\$1.5 billion in profit to Bristol-Myers Squibb while Zocor (cholesterol) and Mevacor (cholesterol) generated respectively US\$3.6 billion and US\$1.1 billion to Merck. A 3 per cent profit-sharing agreement over the above-mentioned drugs could have generated revenues of about US\$200 million.

While largely theoretical, other approaches exist. The contribution of an area of land to drug discovery can be [estimated](#): based on stated assumptions, the value per hectare varies from US\$21 to US\$9,177. Another approach uses industry figures to calculate the net present value of an extract in a screening programme, which was [estimated](#) at US\$487 on average.

The relative share of royalties (long term revenue) and up-front fees (short term revenue) is determined by the [ABS](#) legal framework and the outcome of the negotiation between the local institutions and multinational companies.

## When is it feasible?

Bioprospecting can only be carried out in countries that have a national law or policy to regulate access to [genetic resources](#) and [ABS](#), which may or may not be compliant with the [Nagoya Protocol](#). The strength, quality and likelihood of enforcement of the legal framework need to be assessed before any actions. These [ABS](#) frameworks should clarify [access](#) procedures, including Prior Informed Consent, Mutually Agreed Terms, the ownership of [genetic resources](#), and the scope of [access](#). Many developing countries are still in the process of completing and institutionalizing these national [ABS](#) frameworks.

Being a spatial activity, the assessment of economic feasibility for bioprospecting is contextual. Pre-feasibility requirements can include qualitative assessments of the use of animals, microbes and native plants in traditional medicine and/or various ways of accounting genetic resources.

#### Minimum investment required and running costs

## Sources of Finance



## Related SDG



## Related Sector



If there is no national [ABS](#) law or policy, an investment by the Government or development partners in the range of US\$200,000–700,000 might be required to establish the necessary regulatory capacity. The management costs related to the collection of royalties by Government entities are almost nil, even if provisions connected to legal risks should be made.

The investment cost paid by private investors for bioprospecting are minor if compared with the research and development budgets of large multinationals, but beyond the reach of small and medium enterprises. They can vary based on sector, geography and the availability of qualified personal, but often in the range of US\$100,000- US\$5,000,000 for one or two years. These costs do not include the testing, production and commercialization of products derived from bioprospecting research. The registration of an international [patent](#) can cost over US\$1 million.

#### Use in appropriate time and context

- Wealth of genetic diversity, including high numbers of endemic plants is a distinctive success factor for bioprospecting;
- When the legal framework protects host communities' rights, thus lowering the risk of conflict and guaranteeing a fair distribution of benefits;
- The presence of research departments in local universities able to conduct bioprospecting assignments;
- The level of sophistication of the private sector (host country) and its capacity to integrate into regional and global value chains will determine the amount of local value addition in successful discoveries.

## What are the main risks and challenges?

#### Pros

- It creates an incentive to monitor and preserve biodiversity in order to avoid the risk of losing economic opportunities from competitors or extinction;
- It promotes technology and knowledge transfer among countries (North-South and South-South) along with foreign direct investment;
- Local populations will become increasingly aware of the potential economic value of natural habitats, providing incentives to the domestic population for biodiversity conservation;
- It promotes innovation, helping countries to develop new pharmaceutical products. It also favours employment opportunities related to natural products;
- It helps to preserve traditional culture and habits by rediscovering ancient native practices.

#### Cons

- Bioprospecting is time-consuming and high risk in terms of expected returns;
- Even the most advanced legal frameworks often fail to offer sufficient protection to traditional knowledge;
- The [Nagoya Protocol](#) coverage is still limited, increasing the risks of [biopiracy](#) from non-signature countries.

#### Risks

- The returns from bioprospecting are uncertain; bioprospecting success rates have been low;
- Unequal capacities of host country stakeholders lead to unfair negotiation outcomes over benefit sharing. The negotiation of bioprospecting contracts can be difficult, including the determination of a fair price for exploration and commercialization;
- The enforcement of the legal framework, including [biopiracy](#) and intellectual property theft linked to low capacity in enforcing laws and international treaties;
- Legal risks, including of litigation in multiple jurisdictions; conflicts of jurisdiction (e.g. [Antarctica](#)) are more frequent in marine environments;
- Unsustainable harvesting of resources and other negative environmental impacts;
- Social tension in local communities that might perceive being unfairly treated.

## How can the design be ameliorated to improve the impact?

The impact of bioprospecting on social cohesion and the environment depends on the actual discovery and potential use of [genetic resources](#), the amount of revenues generated, their use and benefit sharing clauses, the participation of host country in the product's value chain and the minimization of negative impacts. Given the limited number of contracts signed, the evidence of the direct benefits accrued through bioprospecting activities is limited and based on estimates of future benefits and income. However, it is known that nature has historically played a critical role in drug discovery and in human health and other sciences: it is [estimated](#), for example, that between 25 and 50 per cent of marketed drugs

owe their origins to natural products and that between 1983 and 2003 about two thirds of anti-cancer agents being investigated as drug candidates were derived from natural products. Bioprospecting has and will continue to spur innovation in medical sciences, agriculture and other fields. The positive impact of bioprospecting can be maximized by:

- Stronger (national/international) legal and enforcement measures against [biopiracy](#). [Biopiracy](#) and weak [ABS](#) frameworks have reduced the impact of bioprospecting, but prospects are improving with more and more countries updating their legislation and adhering to the [Nagoya Protocol](#). The emergence of best practices and greater focus on Corporate Social Responsibility and [ESG](#) are important enablers.
- More environmental friendly bioprospecting operations. Learning by doing and the adoption of non-invasive innovations in bioprospecting are success factors, but they require scale, investment and research. The potential negative impacts on the environment from bioprospecting activities% destruction of habitats, extinction of species, worsening of vulnerability or fragility in the structure or function of ecosystems% need to be minimized. Best practices in collecting samples in accordance with sustainable management protocols in monitoring social and environmental impacts should be promoted. Collection practices must be planned, supervised, and monitored to prevent over-exploitation of genetic resources.
- More effective use of resources and stronger negotiation capacities in the source country (to increase revenues). Revenues generated by bioprospecting can be reinvested in the local community and in habitat conservation. While extraction and screening create opportunities for the economic empowerment of local communities, product development and commercialization is usually done abroad. Further research and sample processing can increase the value-added of samples shipped abroad, thus increasing the benefit for the host country.
- Greater investment in research and productive capacities in the source country to allow local companies and universities to participate in the whole value chain. Research and development in the source country can create quality jobs and reduce poverty and should be promoted via incentives and legislation.
- More robust [ABS](#) frameworks to protect the culture and interests of local communities. All bioprospecting agreements should respect the customs, traditions, values and customary practices of indigenous and local communities from which [genetic resources](#) have been obtained. Bioprospecting can harm society by marginalizing local communities and generating conflicts and damage human health or essential elements of the cultural identity of the people. Mitigation measures include best practices in managing community protocols and obtaining prior informed consent from local communities. Local communities should also obtain non-monetary benefits, e.g. training and local infrastructure. InBio in Costa Rica is improving bio-literacy, using high quality publications and educational games.

Because bioprospecting requires expertise from different disciplines, bringing together government, academia, the business sector, and indigenous people, cooperation and dialogue is necessary. Given the gap in capacities, additional provisions for technical assistance--including via the [Nagoya Protocol Implementation Fund](#)--should be provided.

## Guidelines and Case Studies

### Guidance

- [Conservation Finance Alliance Finance Guide](#)
- [Convention on Biological Diversity: Codes of conduct, guidelines and best practices and/or standards](#)
- [Nagoya protocol on ABS from their utilization to the Convention on Biological Diversity](#)
- [Biotechnology industry organization: Guidelines for BIO Members Engaging in Bioprospecting](#)
- [Deal Making in Bioprospecting](#)
- [The Legal and Scientific Implications of Bioprospecting Contracts](#)

### Case studies

- [Suriname: ICBG Project](#)
- [South Africa: Regulatory framework](#)
- [South Africa/Lesotho: Pelargonium sidoides](#)
- [Mexico: UZACHI and Novartis](#)

### Our work

[International Guidebook of Environmental Finance Tools](#)

### Sustainable Development Goals

### Environmental finance

### Our Perspective



**09 Jul 2015**

We should reach a consensus on the fact that macroeconomic policies in low-income economies need to also jettison the conventional wisdom of undue restrictiveness.

