BIOPROSPECTING AS A POSSIBLE DEVELOPMENT MECHANISM FOR COLOMBIA

Bioprospección como posible mecanismo de desarrollo para Colombia

LUZ MARINA MELGAREJO. Dr. Sci. Química.
Departamento de Biología, Facultad de Ciencias, Universidad Nacional de Colombia, sede Bogotá. lmmelgarejom@unal.edu.co

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ABSTRACT

Bioprospecting has been on the agenda for discussion by the government, the academic community, businesses and other pertinent actors for many years now; it is an integral topic representing a potential approach to exploit biodiversity to the fullest. This document presents some definitions of what bioprospecting is (some restrictive, others with a broader perspective, depending on different approaches, actors, target markets and countries) in the context of a mechanism for development and cooperation concerning the construction of capacities, advantages and disadvantages. It was found that bioprospecting in Colombia has been developing from a broad perspective (systematic study of biological-genetic resources, transformation into a product which has led to strengthening some value chains, small- and/or large-scale marketing and some advances in intellectual property rights and the distribution of benefits) in order to provide greater benefits for the nation.

Keywords: prospecting biological diversity, technical capacity.

RESUMEN

La bioprospección ha sido durante varios años tema de discusión por los gobiernos, la comunidad académica, las empresas, y otros actores que se integran en el proceso, como potencial de acercamiento y uso de la diversidad biológica. A través del presente documento se presentan algunas definiciones de lo que es la bioprospección (algunas restrictivas otras de perspectiva amplia, dependientes de diferentes aproximaciones, actores, blanco de mercado, contexto del país, entre otros), la bioprospección como mecanismo de desarrollo y cooperación para la construcción de capacidades, ventajas y desventajas. Se encuentra que en Colombia se ha venido desarrollando bioprospección desde la perspectiva amplia (estudio sistemático del recurso biológico-genético, transformación en un producto lo que ha permitido el fortalecimiento de algunas cadenas de valor, comercialización a pequeña o gran escala y algunos avances en temas de propiedad intelectual y distribución de beneficios) lo cual puede brindar mayores beneficios para la nación.

Palabras clave: capacidades técnicas, prospección de la diversidad biológica.

Colombia has a lot of biodiversity, being one of the ten megadiverse countries of the world; and possesses diversity in the terrestrial and marine ecosystems and a unique geostrategic position, with transport routes to the markets of Latin America, the United States, the Caribbean, Europe, China, Japan, and India, among others. The diversity of the biological and genetic resources of Colombia has competitive advantages at the national and international levels. The Convention on Biological Diversity CBD (which came into force in December of 1993, approved by Law 165 of 1994) set the following objectives: a) conservation of biological diversity; b) sustainable use of its components, and c) fair and equitable sharing of benefits arising from its use.

The national biodiversity policy requires action such as education, public participation, legislative and institutional development, and economic valuation, among others. In accordance with the commitments undertaken by signing the CBD, the member countries of the Cartagena Agreement or Andean Pact, adopted a legal regime for access to genetic resources, Decision 391 of 1996. It is worth noting that the indigenous, black and farming communities living in close dependence with biological and genetic resources have contributed to their preservation and should share in the benefits derived from their economic and social development (Melgarejo *et al.*, 2002a; Melgarejo *et al.*, 2002b).

In 2010, the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from the use of biodiversity was adopted. The Protocol promotes the third objective of the Convention, creating legal elements for both providers and users of genetic resources (Secretaría del Convenio sobre la Diversidad Biológica, 2011). Strategies have been developed to access, understand and use biological-genetic resources. Humans, throughout history, have sought to understand the resources in their environment and use or apply them for food, health, and cosmetics, among others; developing industries such as those for food, pharmaceuticals, medical botany, crop protection, etc. These developments involve bioprospecting.

There are various definitions of bioprospecting, depending on the different approaches (researchers, communities, businesses, governments), the country and its context, the market, and the level of technological development (technology leading countries *vs.* non-technology leading ones that are rich in biodiversity) (Melgarejo, 2003; Duarte *et al.*, 2006; Duarte and Velho, 2008; Duarte and Velho, 2009). Some are restrictive to activities such as systematically searching for genes, chemical compounds, proteins and other metabolites that may have potential economic value; others have a broad perspective and include traditional knowledge, the systematic search for and characterization of biological-genetic resources (genes, primary and secondary metabolites); to determine and evaluate the biological action of the active elements, to develop products, to market them, and to protect them with intellectual property rights and the participation of actors at different stages of the process, among others.

Some definitions are mentioned by Melgarejo *et al.*, 2002a and Melgarejo *et al.*, 2002b, others are presented below:

— Searching for information in biological species for later use in the production processes of various sectors. An example of which is the information contained in the genetic material of all living beings (genetic prospecting), in the chemical compounds they produce (chemical prospecting) or in traditional knowledge (Alatorre, 1995).

— A way to compensate countries for the use of their genetic resources which have natural components by mainly the chemical and pharmaceutical industries (Brush, 1999).
— A process that involves three stages: understanding and characterizing the biological-genetic resources, converting it into a product (for use in medicine, food, agriculture or other) and marketing it (Melgarejo, 2003).
— An activity of nature exploration, non-destructive, which, through scientific research, aims to obtain useful information derived from the collection of small quantities of biological material for application in medicine, agriculture and industry (Setzer *et al.*, 2003).
— The systematic search of genes, chemical compounds, proteins and other products that have an actual or potential economic value and are the components of biological diversity, to gain a potential for product development (Castree, 2003).
— A process that involves four steps: sample collection; isolation, characterization and culture; screening for pharmaceutical activity; development of product, patenting, trials, sales and marketing (Jabour-Green and Nicol, 2003).
— The characterization of biological material in its various components, along with a projection to protect the interests of intellectual property and develop a marketing process for new products which may include modifying the chemical structure to increase efficiency (Bull, 2004).
— The systematic search for the development of new biological sources which may have commercial value, including all organisms, genes, chemicals, extracts, and other products of nature; and the sustainable use of biological resources through biotechnology and scientific and socioeconomic development of source countries and local communities (Quesada, 2007).

Duarte and Velho (2008) reported that in bioprospecting, "*an interaction can occur between different types of knowledge, especially traditional knowledge held by indigenous and local communities in countries rich in biodiversity and scientific or technological knowledge of academic and research sectors that operate on their own or at the service of transforming companies, primarily those of pharmaceutical and agro-input industries of technology leading countries. This confluence is characterized by divergent motivations and interests between actors with very different powers, resulting in the need to have regulatory frameworks that help regulate this interaction*" (p. 104 -105).
Colombia, through Conpes de Biotecnología 3697 of June 2011, framed the term bioprospecting with a restrictive perspective as the "systematic exploration and sustainability of biodiversity to identify and secure new sources of chemical compounds, genes, proteins, microorganisms and other products that have potential to be commercially exploited". However, Colombia should not focus only on restrictive activities, but, given the global evolution of the definition of bioprospecting from different actors and interests, and the trend of the country to promote bioprospecting, in the Colombian context, bioprospecting should be carried out with a broad perspective to strengthen processes involving scientific, political, politico-economic and socio-environmental-ethical spheres as an alternative for Colombian social welfare. It is of utmost importance to include communities for regional development which is vital for growth with equity, participation of the various actors in the monetary and non-monetary benefits, consolidation of value chains, that could boost the domestic industry and generate

employment through the development and strengthening of sectors such as agribusiness (natural products, bio-products, enzymology), cosmetics, pharmaceuticals and medical botany or others that, though prior country and conditions market research, show profitability; with projected or determined plans for manufacturing, mass production and marketing of the product; the calculated added economic value, the calculated potential royalties and the distribution of benefits to different stakeholders including communities; the protection under intellectual property rights of the characterized components, the obtained products, the new developments or other substances obtained from the basic metabolites or components derived from the biological-genetic resource base; among other elements that can be added with public policy, participatory action of the bioprospecting actors, and interdisciplinary and multidisciplinary analysis; thereby creating bargaining power with technology leading countries.

It is considered as potentially harmful for the country to establish a national bioprospecting company engaged only in activities stated by the restrictive definition of Conpes 3697 of June 2011 without compulsory generation of value added products, that could be used and/or marketed in various regions of the country or abroad, technology transfer and other benefits for the nation that have been mentioned above when working with a broad perspective. Additionally, it is necessary to note that in other countries where bioprospecting has been done with a restrictive view, the monetary and nonmonetary benefits that were expected have not been generated, and that Colombia confers some resources in concessions which could lead to the detriment of the property of the nation and the communities in general.

Duarte *et al.* (2006), in a review of Bioprospecting as a cooperation mechanism for endogenous capacity building in science and technology and analysis of the capabilities of Colombia to advance bioprospecting processes, reported that the main motivations and interests of biodiversity-rich countries are: 1) The possibility of the participating research groups and the domestic product involved in the process gaining worldwide recognition, 2) Strengthening research infrastructure (equipment, laboratories), 3) The potential for human resource training, 4) Strengthening negotiating skills; 5) Access to knowledge, specialized software and complementary techniques, through technology transfer processes; 6) In the case of achieving product marketing , economic benefits are expected through the payment of royalties; 7) The ability to generate new employment opportunities through the commercialization of products resulting from the process. While the principal motivations of the leading countries in technology are related to: 1) Increased sales of value added products, 2) The diversification of raw materials, which will supply the company with a competitive advantage, 3) Access to different and suitable agroecosystems of the tropic zones; 4) The possibility of intellectual property rights for the obtained products. The authors mention that the majority of motivations of countries rich in biodiversity are related to access and strengthening different kinds of knowledge and skills; while the motivations of the leading countries in technology are commercial. The authors consider bioprospecting as a formal cooperation mechanism among leading countries in technology and technology dependent countries rich in biodiversity with the objective of strengthening national endogenous capacities in science and technology (p. 5-6). However, Duarte *et al.* (2006) concluded that after more than a decade with the CBD, it has yet to produce the expected economic benefits

for biodiversity-rich countries to strengthen their capacities in science and technology. This is likely due to the limited capacity of negotiation by diversity rich countries because, in many of these countries, the priority for researchers is to form alliances with international technology leaders and joint publications in recognized journals, rather than the development of products that could be protected by patents and lead to monetary profit.

Literature reports indicate that the current scientific and technological capacity of Colombia to address bioprospecting processes is represented by several research groups, which means that this capacity must be strengthened (Melgarejo *et al.*, 2002a; Duarte *et al.*, 2006), both regionally and nationally, with a strategy of specific measures of science and technology policy. Up to 2002, there were mainly collections, taxonomic studies for biodiversity inventories and chemical characterizations of some molecules; afterwards, as part of the advances in bioprospecting, these activities continued, but with the determination of biological activities without taking into account their commercial potential. Today, in addition to determining the biological activities, the potential has to be seen in order to be exploited commercially and produce some products on a pilot scale, but aspects of intellectual property have barely been touched. Several groups have developed capabilities mainly in genomics and bioinformatics, followed by metabolomics, transcriptomics and some for proteomics; furthermore, some capabilities in product development with potential for different industries have been observed.

In this vein, funding has been given by centers of excellence: 1) in 2004, "Comprehensive study of promising tropical aromatic and medicinal species for the development of competitive and sustainable agribusiness essences, extracts and natural derivatives in Colombia" by the Centro Nacional de Investigaciones para la Agroindustrialización de Especies Vegetales Aromáticas y Medicinales Tropicales, CENIVAM. 2) in 2007, "Formation of a metagenomic and bioinformatic platform for characterization and utilization of genetic resources of extreme environments", by the Centro Colombiano de Genómica y Bioinformática de Ambientes Extremos, GeBiX. Similarly, funding for knowledge networks has been generated, in 2012: 1) Bioprospecting and development of natural ingredients for cosmetic, pharmaceutical and hygiene products, based on Colombian biodiversity. 2) Red Nacional para la Bioprospección de Frutas Tropicales RIFRUTBIO, where partnerships are made primarily for national groups and also international groups.

Caraballo (2010) conducted an assessment of the benefits of bioprospecting activities undertaken by centers of excellence and a research institute, concluding that: 1) none of the cases included indigenous, local, or black communities, 2) the need to establish more partnerships to develop bioprospecting activities and generate greater benefits is notable, 3) benefits are mainly non-monetary (human resource training, infrastructure and strengthening technology platforms), social benefits are at still very limited. This indicates that, although bioprospecting is an alternative for growth and development for the country; the government, the decision makers in science and technology policies, the different sectors of society, the centers of excellence, the research centers, the universities and the knowledge networks, among others, must advance participatory technology development mechanisms directed towards sectors of society that are not favored.

Although bioprospecting can be a high risk investment, since not necessarily everything produced by bioprospecting will succeed in the market (sometimes after five, ten or 20 years, only 1 % is successful), it is quite possible that if there is success, there will be a return of the investment to the country's economic benefit. In the short and medium term, non-monetary benefits are obtained, such as the strengthening of the science and technology of the country (technical, scientific, infrastructure, knowledge networks, strengthening of production or value chains, partnerships between national and regional research groups, alliances with international groups, human resources training, regional strengthening, education systems focused on science, engineering and social studies, expertise in mechanisms of intellectual property law, negotiation skills, etc.).

In regards to research and use of biodiversity in Andean Community countries, Roca (2004) reported that plant, animal and micro-organism bioprospecting is being impacted by modern biotechnology and chemistry in the search for new sources of components for the development of more effective biopharmaceuticals (e.g., second generation vaccines: attenuated viruses, and third generation vaccines: viral proteins), for the production of proteins of therapeutic interest (insulin, interferons, etc.), for developing cosmetics, for the production of more effective methods in the diagnosis of diseases for better productivity and management of agricultural crops and finally for the use of genomic information in the implementation of individualized molecular medicine. Furthermore, the author indicated that bioprospecting is the meeting point between biotechnology and biodiversity, and so constitutes the principal focus of action of modern biotechnology (Roca, 2004).

In Colombia, to advance bioprospecting activities, teamwork is needed that takes into account the participatory elements of public policy from all sectors of society. Since the government is vital to making an adequate legal regulatory framework (intellectual property rights, access to biological-genetic resources, bargaining power), economic (economic valuation, negotiation skills), social (involving communities, fair and equitable sharing of benefits derived from biodiversity, associativity), environmental (ecosystem conservation, cost-benefit), and educational (educational system geared for the sciences and engineering, attracting people with initiative, creativity and innovation, and support to integrate research centers, Colombian companies, and universities; continuous human resources training).

The biodiversity of Colombia has been in the crosshairs; Duarte and Velho (2008) reported that some foreign companies sought to take advantage of the regulations issued early in 1997, in order to try to obtain the relevant permits for advance bio-prospecting practices throughout Colombia, offering in return, some non-monetary incentives represented by equipped laboratories, shared publications and training of technical personnel in Colombia, which did not correspond to the potential value of the biodiversity to which they would have had access.

Restrictions for collecting permits, research permits and access to genetic resources have impeded Colombian bioprospecting contracts with foreign companies, and even for Colombian researchers. However, although the restrictions on access to biological-genetic resources have created disadvantages for the country, at the same time, they have enabled Colombian groups to be the ones who study the biodiversity and prospects, thus creating technical capabilities and advantages for future negotiations with

technology leading countries. By the same token, it does not serve the national interest to change the restrictive regime of Decision 391 of 1996 for one widely permissive and governed by freedom of contracts and private autonomy, making the biological resources the sovereign property of the States (CBD), which must be placed at the service of the country.

Internationally, bioprospecting is primarily related to secondary metabolites at all organismic levels (plants, animals, microorganisms) and ecosystems (marine and terrestrial), due to the economic impact generated by the pharmaceutical industry, but also involves the characterization of genomes and biological components for different bioprospecting industries, using omic tools (genomics, transcriptomics, metabolomics, proteomics, etc.), the integration of human resources in science and engineering for such studies, the use of biotechnology and technology for required research processes, product development and marketing, and the contribution of capital by companies.

The literature has documented some international bioprospecting models (Carrizosa, 2002) as a benchmark for Colombia. Carrizosa (2002) conducted an analysis and concluded that bioprospecting projects are not sharing the benefits derived from biodiversity fairly and equitably. Also, the objectives of conservation and sustainable use of biodiversity of these projects are not very significant. In the analysis of the models of the University of Lausanne (Switzerland) in Zimbabwe, CGIB of Chile, Argentina and Mexico, GCIB Suriname, the author stated that the actors in the biodiversity-rich countries are not treated as true bioprospecting partners by industrialized countries or leaders in technology, and the bioprospecting activities taking place in countries rich in biodiversity are limited to ensure that there is a constant source of samples, while activities that add value to the product and provide a significant capital investment in research are performed in leading biotech countries which would not be beneficial to countries like Colombia because they have no chance of developing a strong technology platform or negotiation skills, among others.

In regards to the Project of the National Institute of Cancer in Sarawak (Malaysia) and INBio and multinational pharmaceutical and biotechnology companies in Costa Rica, it was stated that "part of the capital investment and construction of local capacity can take place in biodiversity-rich countries if they have the appropriate financial incentives to establish strategic alliances with bioprospectors. INBio is a classic example of how an organization can gain relatively important benefits for the conservation of biodiversity, without the need to enlist the help of laws regulating access to genetic resources. In countries with laws regulating access to genetic resources such as the Philippines, it is seen that investment in constructing local capacity is available through partnership contracts. This model symbolizes the sovereignty that the Philippine access laws give biodiversity-rich countries and the opportunity to lead these negotiation processes and the fair and equitable sharing of benefits at the local perspective. However, the reality is, that despite local initiatives for capacity construction that may have been inspired by organizations like the INBio and promoted by laws regulating access to genetic resources, in any model of bioprospecting executed so far in biodiversity-rich countries, the most significant capital investment and marketing of products has been carried out in the laboratories of industries located in countries that are technology leaders (Carrizosa, 2002).

Given the above, and although there are advantages and disadvantages, it is important for Colombia to continue working on building local capacity in relation to intellectual property and the development of trading strategies to produce "close the gap" technology that still separates countries that are rich in biodiversity from technology leading countries.

To build and strengthen local capacity in Colombia, it is necessary to make a current and motivated review for change, with the aim of making suggestions for the advancement and development of the country. Considering the submissions made by a group of international researchers who participated in the first meeting of bioprospecting for the development of the Colombian agricultural sector, coordinated by Corpoica, held between 15 and 16 December of 2011 in Corpoica Tibaitatá-Colombia. The author suggests that there are several elements that could be considered for implementing or strengthening sectors such as agriculture, health and environment. Since the process of bioprospecting involves various aspects (educational-social-economic-political-environmental-ethical), the possibility of carrying out this process depends on political-governmental decisions, organization, financing, and the active participation of a large number of citizens (not just experts) who represent actors, with multi - and interdisciplinary approaches to the construction of guidelines and implementation of different activities. Among the elements, there are: 1) Establish socially relevant programs with defined goals, emphasizing and rewarding innovation; not pushing for publication fees is often counterproductive if innovation and patents are desired; maintaining the interface between research institutions, the intellectual property legal authorities, entrepreneurs and investors, businesses, and government regulations, educators and business schools, and communities in the regions; with focus on one goal and commitment of all stakeholders, identifying capabilities and uniqueness of projects, products and people; additionally, be realistic and carry out activities with the available budget and time, and have commitment to the short, medium and long term returns on investment and improve competitiveness in global markets. 2) Conduct national projects that include these issues while promoting a culture of innovation, more Research and Development, funding by companies or the state, use of research results for different industries, strengthening of technology transfer from academia to industry and promoting collaboration between different sectors by encouraging cooperation and national industrial participation. 3) Organized and systematic studies using classic and current techniques and basic and applied sciences, which can be used to obtain a great number of useful results for different industries and therefore business opportunities, which must have a technology platform with national and international cooperation for various analyzes. The scope may be large initially and then taper in the viability and function of detection assays. 4) Development and improvement of products. In universities and research centers, there should be an office of technology transfer which takes inventory of developed innovations, taking into account issues of intellectual property (patents, etc.) and contacts with industry for marketing, thus, creating part of the investment return. 5) Development of national infrastructure and economic development for sustainability and minimal impact on the environment, with governance to attract foreign investment, promotion of entrepreneurship and business creation, investment in education and manufacturing better technology. 6) Recognition of a short-term product,

product implementation in small and medium industries, integration with a value chain (see the value, create the value and deliver the value to the product); with focus on the commercial potential and not just research, and business development with an international projection. 7) Development with the networking methodology. Network of infrastructure and knowledge with academic agreements with national and international universities and research centers; network of trade agreements with several national and international companies, network of development capabilities depending on the stage of bioprospecting carried out in collaboration with companies, universities or research centers for technology transfer. Networking and interdisciplinarity between the knowledgeable sectors is necessary in order to reduce the time and costs in product development and marketing and forms of protection of intellectual property rights; additionally allow analysis of natural sources with new technologies to increase the potential for commercial use. 8) Sound legal framework and the decision by the country on the issue of access to genetic resources, which are key to negotiation (non-disclosure agreements, research collaboration agreements and other legal documents containing aspects of intellectual property rights and distribution of benefits, including the communities of origin of the biological-genetic resource and the numbers of patents, trademarks, licenses, etc.), are also vital. The factors of success are related to the networking capabilities and a sound legal structure; however, marketing natural products in a competitive manner is the main risk.

Regarding agricultural bioprospecting in Colombia, it was found to be one of the most developed sectors in the country (Database of GrupLAC-Colciencias), similar to that reported by Chaparro and Vanegas (2010) in the Research on biological and genetic resources in the country: agriculture research centers, in which it is stated that a high percentage of research involving access to genetic resources, is intended to advance the agricultural and livestock production sector, and have developed technical capabilities and processes related to biotechnology. Currently, there is information and literature reports in scientific papers and books, all related to a stage of bioprospecting, made by various entities in partnership with the productive sector, generating products that have economic returns, i.e., value added to the biological-genetic resource, primary products and byproducts, and they have been successful bringing products to market. There are several examples of suitable cultivated species, both introduced and from our diversity (coffee, cacao, fruit, aromatics), however, there are some weaknesses that are in the process, namely: lack of integrated knowledge of the raw material or the biological-genetic organism; insufficient high quality raw material that supplements the bioprospecting process at different stages, lack of developed agribusiness and logistic deficits in marketing and quality control of products, realization of fair and equitable benefits, and quantification of the economic value achieved by the development.

Colombia has some experience and technical expertise in different sectors of agriculture, livestock, health and environment; for their development, it is necessary to continue to implement programs and projects in each of the sectors which can be defined after consultation processes. For example, in the agricultural sector, for greater success, it is better to research and development products (with short, medium and long term results for different bioprospecting industries) from a few crops and then to, after the experience, replicate the model to other crops or products. It is advisable to use cacao, fruit (banana,

cape gooseberry, passion flowers), coffee or any other crop that has wide acceptance and an assured market presence, nationally and internationally, for at least ten years; which requires research and continual innovation to remain competitive. Another example is the development of the industries of natural products and enzymes derived from plants, microorganisms or animals. It is recommended that sectors and a few species be prioritized, where various academic entities, the productive sector, community and government can advance to obtain added value from biological-genetic resources that we possess.

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