Proposal for Reform of Brazil's Bioprospecting and Genetic Resources Regulations
18 November 2013

Introduction

The Biotechnology Industry Organization (BIO) welcomes the opportunity to provide the views of its members on facilitating access to genetic resources and traditional knowledge and the sharing of benefits from their use. BIO commends the Brazilian Government for its efforts to revisit its policies with the goal of developing a legal framework that stimulates research and development based on Brazil's rich genetic heritage. Given that technological advances and the innovation that spurs it are the primary drivers of economic growth in the modern era, it is critical that intellectual property laws and practices properly motivate and reward innovation. BIO and its members believe a successful access and benefit-sharing (ABS) regime can create an environment that promotes collaboration and innovation in Brazil. A key element of this environment, however, must be a transparent and robust set of intellectual property laws and practices, separate from a legal framework seeking to protect access to genetic resources.

About BIO and the Biotechnology Industry

BIO is a global not-for-profit trade association representing more than 1,100 companies, universities, research institutions, investors and other entities in the field of biotechnology in more than 32 countries throughout the world. The members of BIO are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. Our members are collectively driving advancements in the biotechnology industry and have spurred the creation of more than one million direct jobs and millions of related jobs in countries all over the world.

The biotechnology industry is a highly intensive research-based industry in which billions of dollars in research and development are spent per year. One of the key drivers of heavy research and development investments is the expectation that new innovations will be protected by intellectual property rights. Indeed, the expectation of these rights is even more important to small- and medium-sized enterprises, which comprise the vast majority of biotechnology companies globally. Because these companies do not have products on the market, their intellectual property on innovative research and development are their principal assets. As a result, these enterprises are heavily dependent on investment from venture capital and public funding entities, such as the BNDES in Brazil, and other similar sources to launch and continue their expensive research and development activities. However, this funding is predicated on strong intellectual property protection on a global scale. One of BIO's major goals therefore is to ensure that biotechnology companies and other entities that are investing heavily in research and development are able to receive an appropriate return on their investment

and that development-stage companies can continue to finance their operations, with an opportunity for an appropriate return in the future.

Given the importance of intellectual property protection for biotechnology product development and commercialization, a streamlined process for patenting and the appropriate scope and subject matter protections are of great importance. Therefore, changes to the law that affect the patentability of biotechnology inventions are extremely troublesome to our members. In particular, in Brazil, where both the public and private sectors have invested heavily in biotechnology, research has resulted in numerous promising discoveries particularly in the agricultural, industrial and environmental biotechnology sectors. A patent framework that facilitates the translation of these discoveries to products is of enormous value to the industry and its users. Accordingly, laws and procedures that place obstacles to obtaining robust intellectual property protection jeopardize the research, development, and commercialization of new and innovative products necessary to support a burgeoning biotechnology industry such as that in Brazil.

Brazil has taken several initiatives to participate actively and contribute to the global biotechnology industry. Major investments from the government, as well as local and foreign companies that are members of BIO, have helped to grow the local biotechnology industry and to generate an entrepreneurial spirit that has resulted in innovations in a number of sectors. As a country with an immense amount of biological diversity, investment in biotechnology and a growing entrepreneurial spirit, Brazil is destined to continue to provide meaningful contributions to the biotechnology industry and the global economy as a whole. For these reasons, among many others, BIO is very attentive to legal and regulatory developments in Brazil that affect the biotechnology industry. BIO therefore appreciates at the outset the opportunity to engage with Brazilian policymakers and share the concerns of its members to ensure that decisions are made that continue to strengthen the biotechnology sector in Brazil for years to come.

Biodiversity in Brazil and the Convention on Biological Diversity

Most, if not all, South American countries see themselves as providers of genetic resources and associated traditional knowledge. Brazil, in particular, is a country that boasts a rich biodiversity and benefits from a long history of traditional knowledge amongst the significant number of local and indigenous communities spread throughout the vast country. It is well known that Brazil is a diverse country that is home to a wide variety of plant and animal species. It is also widely known that the exuberant biodiversity in Brazil may hold a wealth of valuable substances, with potential

applications in a number of different burgeoning biotechnology sectors, including the pharmaceutical, cosmetic, and agrochemical industries.[1]

The identification, extrapolation and modification of substances contained in the Brazilian genetic heritage may undoubtedly lead to products that provide enormous value to mankind and may help improve the quality of life for all. That being said, there is a very long path from identifying key substances of interest to providing a marketable product that has undergone extensive safety and efficacy testing and is able to be scaled up to meet the demands of the market. This latter step requires a significant amount of ingenuity, research and development. This ingenuity and the heavy investments made towards research and development is what is sought to be protected through intellectual property rights.

It follows that the ideal scenario is an environment that is favorable to investment and fosters the collaboration and conservation of genetic heritage and associated traditional knowledge belonging to indigenous communities. Such an environment would be one that encourages collaboration and investment among entrepreneurs, the country, and indigenous communities with the goal of improving the quality of lives for all through innovation.

Considering the importance of Brazil as a country rich in biodiversity and traditional knowledge, it is no surprise that the first international agreement aimed at protecting diversity was signed in Rio de Janeiro in 1992. The Convention on Biological Diversity (CBD), which now has over 190 signatories and includes Brazil, goes beyond previous international initiatives, in that it broadly recognizes that the conservation of biological diversity is a common concern of humankind and that nations are responsible for conserving their biological diversity and for using their biological resources in a sustainable manner.

Obligations in the CBD and the Nagoya Protocol

As much of the discussion of access to genetic resources, traditional knowledge, and benefit sharing arises in connection with the CBD, BIO would like to take this opportunity to provide an overview of the access and benefit-sharing provisions of the CBD and the Nagoya Protocol. The *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity* is a supplementary agreement to the CBD.[2] Brazil is a signatory to the Nagoya Protocol.

The objectives of the CBD, as set forth in Article 1, are threefold: (1) the conservation of biological diversity; (2) the sustainable use of its components; and (3)

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[1] Walter Reid et al, *A New Lease on Life,* Biodiversity Prospecting: Using Genetic Resources for Sustainable Development, World Resources Institute, Washington, D.C.,1993.

[2] The Protocol was adopted on 29 October 2010 in Nagoya, Aichi Province, Japan, and will enter into force 90 days after the fiftieth instrument of ratification.

the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. According to Article 1 of the CBD, the third objective specifically relates to appropriate access to genetic resources and appropriate transfer of related technologies, taking into account all rights over those resources and technologies.

According to the principles set forth in Article 3, the CBD recognizes every state's sovereignty over its own biological resources and affirms that the conservation of biological diversity is a common concern of mankind. The confirmation of the state's sovereignty creates a legal regime, being a precondition for the introduction of bilateral market-like contracts between the holder and user of biodiversity.

A. Access to Genetic Resources

Pursuant to Article 15 of the CBD, the authority to determine access to genetic resources rests with national governments and is subject to national legislation. While states have the sovereign right to exploit their own resources pursuant to their own environmental policies, the principle of national sovereignty is balanced by the obligation of Contracting Parties under Article 15(2) of the CBD to endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other Parties, and not to impose restrictions that run counter to the Convention's objectives. Thus, the right of states to control access to genetic resources is not an absolute right.

Paragraphs four and five of Article 15 of the CBD contain general conditions for which access to genetic resources may be made dependent. By conditioning access on mutually agreed terms, Article 15(4) implies the expectation of a negotiation between the Party granting access and the company or institution seeking access. Under Article 15(5), access to genetic resources may be subjected to prior informed consent of the Party providing such resources. The specific language employed reveals that imposing this requirement is an option rather than an obligation. Thus, it is a matter for the national legislation to decide in what instances prior consent will apply, and also to specify general requirements of such consent.

Two further principles related to research and utilization of genetic resources, in Articles 15(6) and 15(7), are also worth mentioning. Article 15(6) provides a general obligation of each Party to endeavor to develop and carry out scientific research based on genetic resources provided by other Parties with full participation of, and whenever possible, within the provider country. On the other hand, Article 15(7) sets out that Parties shall adopt a legal framework aimed at sharing in a fair and equitable way the results of research and developments and the benefits arising from the commercial use of genetic resources upon mutually agreed terms. Thus, only legislation that takes into account the interests of the potential users, as well as the providers of genetic resources, in a balanced way will stimulate the environmentally sound use of biodiversity and secure adequate benefits from their exploitation.

B. Access to and Transfer of Technology

In Article 16, Parties have an obligation to provide and/or facilitate access to and transfer of certain technologies to other Parties. The obligation is limited to technologies directly linked to either the conservation or sustainable use of genetic resources or their exploitation, which also includes genetic engineering and other modern biotechnology techniques.

Article 16(2) clarifies this obligation further by stating that the access and transfer must be provided and/or facilitated under fair and most favorable terms. According to paragraph two, in the case of technology subject to intellectual property rights, such access and transfer shall be provided on terms that recognize and are consistent with adequate and effective protection of those rights. This establishes a link to the international regime of intellectual property rights and in particular its standards, as set forth in the TRIPS Agreement. Furthermore, Contracting Parties under Article 16(5) are required to cooperate in the area of intellectual property in order to ensure that such rights support and do not run counter to the objectives of the Convention.

C. The Nagoya Protocol

The Nagoya Protocol contains a series of obligations that are designed to more effectively promote and enforce benefit-sharing obligations relating to use of genetic resources. Importantly, the benefit-sharing obligations specified in the Protocol remain anchored on the principle of "mutually agreed terms." This principle, which is reflected in the original CBD provisions, means that both the existence and nature of benefit-sharing obligations arising from use of a genetic resource is to be defined by an agreement between the provider and user of the resource. Thus, terms found in a contract or material transfer agreement are to give rise to the obligation to share benefits, and to define the nature of these obligations.

The Protocol also establishes a number of additional obligations on Parties to the CBD and the Protocol that are designed to make operational global enforcement of benefit-sharing obligations, and to address perceived lapses in the regulation of the collection of genetic resources. For example, the Protocol establishes measures that require countries to ensure that genetic resources used within their territories were accessed in accordance with laws and regulations governing prior informed consent and benefit sharing found in the country providing access to the resource. More specifically, the Protocol obliges countries to establish "checkpoints" to better document and regulate the physical transfer and movement of genetic resources. In addition, the Protocol establishes an "internationally recognized certificate" that is designed to serve as evidence that a company or researcher complied with prior informed consent and benefit sharing-obligations imposed incidental to collection of a genetic resource. The certificate will be issued by the provider country at the time of access, when prior informed consent is given and a material transfer agreement or other mutually agreed terms is established. Finally, to ensure success, the Protocol envisions the creation of national

focal points and competent national authorities to serve as contact points for information, access or cooperation on issues of compliance.

Examination of Brazil's Legal Framework for Access and Benefit Sharing

Prior to examining the CBD and its specific implementation in Brazil, BIO acknowledges that the Brazilian Federal Constitution of 1988 underscores the importance of regulating the country's vast genetic heritage. Section 1 of Article 225 of the Constitution compels the federal government to preserve the diversity and integrity of the genetic heritage of Brazil and to control entities engaged in research and manipulation of such genetic material. Moreover, Section 4 of the same Article recognizes that areas deemed a national heritage, i.e., the Brazilian Amazon Rain Forest, the Atlantic Rain Forest, the Serra do Mar, the Pantanal Mato-Grossense, and the Coastal zones, shall be used only under conditions that ensure the preservation of their environments, including natural resources in such environments.

A. Legal Background—Executive Order, Decrees, and Resolutions

Grounded largely in the Federal Constitution and the provisions of the CBD highlighted above, the Executive Branch of the Brazilian Federal Government issued Executive Order nº 2.186-16 aimed at protecting Brazil's genetic heritage by regulating access to its natural resources. In practical terms, one of the most significant outcomes of the Executive Order is the creation of the Genetic Heritage Management Council (CGEN)—a government entity led by a representative of the Ministry of Environment. The foremost activities of CGEN are (i) to grant authorization for access to genetic heritage and shipment of samples of components of the genetic heritage and (ii) to grant access certificates to associated traditional knowledge. There are two pathways to obtain authorization from CGEN to access genetic resources in Brazil: (i) a non-commercial use pathway and (ii) a commercial-use pathway.

When there is no potential of commercial use, authorization for access of components of genetic heritage and associated traditional knowledge may be granted by the Brazilian Institute of Environment and Natural Renewable Resources (IBAMA) or by the National Council for Scientific and Technological Development (CNPq). In these cases, authorizations are granted only after prior consent of the holders of the genetic resources and of the associated traditional knowledge, e.g., local indigenous communities.

When access is requested for commercial purposes, CGEN mandates that only duly registered Brazilian institutions may obtain access to traditional knowledge and genetic resources. While local Brazilian institutions may have a partnership with a foreign entity, the local entity must be the party responsible for the collection of any genetic resources and associated traditional knowledge. In these situations, the Brazilian institution may only access genetic resources after the execution and acceptance of a contract referred to as the "Contract for the Use of Genetic Heritage and

Benefit Sharing." The Executive Order specifically provides that access contracts will only enter into force upon the consent of CGEN.

Setting aside the principal Executive Order, there are a number of Decrees that implement and regulate the Executive Order, which provide for more specific rules and regulations regarding access and commercialization of products derived from genetic heritage. For example, Decree 3945/2001 creates the composition of the Board of Management of CGEN, which includes over 19 members of the Federal Government, and outlines additional rules for accessing and using genetic resources. Decree 4946/2003 provides yet even more rules and regulations for companies seeking to obtain access to genetic heritage and Decree 5459/2005 provides for disciplinary sanctions for failing to abide by the regulations concerning access to genetic resources.

Perhaps one of the most troublesome new set of rules from the perspective of BIO and its members is laid out in Decree 6159/2007, which altered a number of provisions of Decree 3945/2001. Decree 6159/2007 requires, among other things, that the aforementioned "Contract for the Use of Genetic Heritage and Benefit Sharing" must be approved by CGEN prior to any technological development using the genetic resources *and* prior to the filing of any patent application. Moreover, this Decree places additional conditions and limitations regarding the use of genetic material. For example, if the genetic material is to be sent abroad, a Material Transfer Form must be submitted to CGEN, which expressly states that the party receiving the genetic resource should not (i) transfer the genetic resource to any other third party; (ii) initiate technological development; or (iii) file a patent application without first obtaining a signed contract and corresponding authorization from CGEN. In other words, approval from CGEN must be obtained in order to transfer the genetic material, to begin research and development, and ultimately to file a patent application.

With the adoption of Decree 6159/2007, the issuance of patents covering products or processes derived from samples of genetic heritage is conditioned on compliance with numerous rules and regulations. To comply with the aforementioned Decrees, the National Intellectual Property Institute (INPI) passed a number of Resolutions. The most recently enacted Resolution 69/2013, which follows Resolutions 207/2009 and 134/2006, requires applicants to inform INPI of the origin of the genetic material and of any associated traditional knowledge, as well as the Genetic Heritage Access Authorization number obtained from CGEN. If the patent application is not based on the use of any genetic material or traditional knowledge, a separate form must be submitted to INPI confirming this information. Hence, prior to any substantive examination, the patent applicant must affirm that all requirements of the Executive Order and accompanying Decrees have been satisfied.

B. A Closer Analysis of the Legal Framework

1. Access Authorization from CGEN

The entire legal process from obtaining access to genetic material to filing patent applications on technologies and ultimately to commercializing products derived from genetic material obtained in Brazil is so complex and cumbersome that it is practically impossible to navigate. An overarching concern therefore is that the rules for complying with the aforementioned Decrees and Resolutions are so complicated and convoluted that it is difficult to comply with all of the legal requirements in a timely manner that is conducive to realizing and executing research and development (R&D) projects.

With respect to obtaining access, there are several uncertainties as to how to go about obtaining proper authorization. As a preliminary matter, when an indigenous community is involved, access to land of indigenous communities must first be approved by the National Indian Foundation (Fundação Nacional do Indio - FUNAI). When the access goes beyond mere collecting of samples and involves scientific analysis of the samples, technological development, and access to traditional knowledge, approval from CGEN must be obtained.

This approval process has many steps and lacks order and coordination. For example, requests to CGEN for authorization require a full project report highlighting the activities and proposed research. In addition, a CGEN-approved Depositary Institution must be selected that will be responsible for safeguarding the genetic resources. Furthermore, an agreement must be obtained in which the leadership of the indigenous or local community agrees to cooperate with the organization seeking access to genetic resources and traditional knowledge. In most cases, an independent anthropological report will also be needed in order to obtain access. Finally, a multilateral contract agreement will be required in which the project is again described in detail and the terms for benefit sharing are clearly stipulated.

In addition to being quite burdensome, a closer examination of the requirements illustrates the complexities of the application process. For instance, the rules do not specify the information that must be contained in the proposed research and anthropological reports. As for the Depositary Institution, it is not clear whether a non-CGEN approved institution can be used, and, if so, there is little guidance as to which institutions are approved by CGEN. Finally, regarding the benefit-sharing agreement, it is not apparent who will be the parties to the agreement. These questions are very difficult to answer as it appears that CGEN has different criteria depending on the particularities of each case.

Finally, the complex rules and procedures governing access to and use of genetic material and traditional knowledge creates significant barriers to innovation due in large part to CGEN's delay in approving R&D projects. Our experiences to date illustrate that it takes two to three years for biotechnology companies to receive the necessary approvals from CGEN. This delay clearly stunts and discourages research and development,

particularly in a field in which enterprises must be nimble and react quickly to a changing marketplace and to new scientific information and developments.

2. Implications of CGEN Authorization on IP

CGEN's role in providing approval prior to filing a patent application in Brazil presents significant impediments to patent protection. The requirement that CGEN approve a technological development project as a necessary requirement prior to the filing of a patent application amounts to an effective new requirement for patentability that is not foreseen in the Brazilian IP Law 9279/1996.

Under the present system, in order to obtain a patent, an applicant must obtain the approval of CGEN and provide this prior approval to INPI before the Office engages in a substantive examination of the patent application. Conceptually, an invention could meet the requirements of patentability, i.e., the invention could be new, involve an inventive step, be industrially applicable, and be fully disclosed, but denied patentability on the basis that prior approval from CGEN was not obtained. As a result, mandatory approvals from CGEN may, on these grounds, further hinder innovation and investment by potentially foreclosing the patenting of many important products and processes.

Notwithstanding, determining whether one needs CGEN's approval prior to filing a patent application is highly questionable given that in many instances it is difficult, and arguably impossible, to know the exact origin of a genetic resource that may have been used or described in a patent application. Furthermore, appropriate guidance as to the circumstances for compliance is lacking, i.e., the relevance of the genetic material or traditional knowledge to the claimed invention. This lack of clarity generates a substantial amount of uncertainty regarding the scope and applicability of the relevant rules and regulations.

Besides creating additional patentability criteria, any requirement that mandates prior approval from CGEN unduly prolongs the patent examination process and adds to the exceedingly large backlog of the INPI. It is not uncommon for biotechnology companies to have patent applications pending before INPI for 10 years. Any additional prerequisites to filing or additional approvals, outside the patent office, will result in significant further patent delays, which have serious economic effects in terms of immediate losses and in potential future investment.

3. Practical Implications of Current Framework

The complexities and uncertainties arising from the Executive Order and its accompanying Decrees have made it extremely challenging to access and use the genetic heritage of Brazil. The unfortunate result is that there have been very few authorizations to access genetic heritage approved by CGEN over the last decade. Even more troublesome is that a disproportionately larger number of fines have been levied against companies engaged in biotechnology research and development.

The entity responsible for imposing fines, IBAMA, has handed out fines in the range of US $250,000 per case to multiple companies, including many Brazilian companies, under a new program called Operação Novos Rumos (New Paths). It is very disturbing to hear that IBAMA fined companies without any evidence of a violation of the Executive Order or Decrees, but rather used generic and unsubstantiated claims with respect to perceived access to genetic resources. Another troublesome concern is that IBAMA has imposed fines on companies, including Brazilian companies, for using genetic heritage that is not indigenous to Brazil and, thus, that falls outside the scope of the Executive Order and Decrees. Besides creating disincentives to innovation in Brazil, these fines also threaten collaboration and conservation efforts between local indigenous communities and industry that arise from initiatives based upon the sharing of knowledge and expertise from trained scientists and local communities.

In addition to the concerns about fines imposed by IBAMA, BIO would also like to point out that CGEN's interpretation of what constitutes bioprospecting exceeds the definition of genetic heritage as provided for in the Executive Order and the CDB. More specifically, CGEN's Technical Orientation provides that the scope of bioprospecting includes access to "biological material," which is broader in scope than the definitions of genetic heritage provided for in the Executive Order and the CBD. In reaction to the excessive extrapolation by CGEN in defining bio-prospecting, the biotechnology community is further left in a position of juridical insecurity as to whether the Executive Order and the administrative acts of IBAMA and CGEN are legally authorized.

Achieving Access and Benefit Sharing

BIO has long supported the access and benefit-sharing goals of the CBD. Moreover, BIO strongly opposes any wrongful removal of genetic resources from their rightful owners. For reasons articulated below, BIO believes that the most effective way to achieve the shared objectives of the CBD is through national laws, passed by a federal legislative body and independent of the patent system, that can more directly and more efficiently regulate access and control over genetic resources and traditional knowledge. BIO also firmly believes that regulating access to genetic resources and traditional knowledge should focus on promoting research, economic development, and sharing of benefits.

A. Clear, practical and well-defined access and benefit-sharing regimes promote R&D and stimulate development and conservation efforts.

In order to provide examples of how to further the goals of the CBD and achieve a successful access and benefit-sharing regime that promotes R&D, BIO appreciates the opportunity to share the experiences of the United States, a non-CBD member, and Costa Rica, as both of these countries have sought to develop successful contract-based systems to ensure appropriate access and benefit sharing. A brief overview of access and benefit-sharing regimes in these countries will illustrate how a clear and well-defined contract-based regime can facilitate the research, development, and

commercialization of biotechnological innovations, particularly when this regime is independent of the patent system.

1. United States

In the United States, property and contract law, *inter alia*, govern access to genetic resources and benefit sharing from the use of such resources. In general, the owner of land owns the genetic resources found on or in that land. The United States federal government, state and local governments, tribes, corporations, individuals and non-United States nationals can and do own land. In the case of federal National Parks, under the jurisdiction of the U.S. Department of the Interior, for example, the National Parks Omnibus Management Act of 1998 (Act of 1988) encourages use of parks for science and publication of the results of research conducted in parks, and requires that research conducted in parks be consistent with park laws and management policies. This law also requires that research be conducted in a manner that poses no threat to park resources or public enjoyment.

Of key significance, the Act of 1998 expressly authorizes negotiations with the research community and private industry for equitable, efficient benefit-sharing arrangements in connection with research conducted in national parks. The Act also mandates increased scientific research in the national parks and the use of scientific analysis in park management decisions. The law further encourages the national parks to be places for scientific study by public as well as private sector researchers, and mandates long-term inventory and monitoring programs that provide baseline information.

The National Park Service (NPS), a bureau of the U.S. Department of the Interior, manages national parks and related areas in accordance with federal laws and regulations. In accordance with the Act of 1998, the NPS has established its own set of rules and regulations to ensure appropriate access and benefit sharing. Specifically, the NPS has separate requirements for collecting materials from national parks, depending on the type of intended use. For collections that are solely for scientific and educational purposes, the national park has the authority to issue a Scientific Research and Collecting Permit.[3] Specimen collections for scientific research will be authorized only if the collection is necessary for the stated scientific purposes included in the research request.[4] Thus, the permit used by the NPS specifies the terms and conditions by which a party will be permitted to collect materials from the park and the purposes for which such specimens may be used.

Any party that submits an application for a Scientific Research and Collecting Permit proposing to use the results of research for commercial or revenue-generating

[3] See 36 C.F.R. 1.6 ("Permits"). See http://www.gpo.gov/fdsys/granule/CFR-2012-title36-vol1/CFR-2012-title36-vol1-sec1-6/content-detail.html

[4] See 36 C.F.R. 1.6 ("Permits) and 2.5 ("Research Specimens"). See http://www.gpo.gov/fdsys/granule/CFR-2011-title36-vol1/CFR-2011-title36-vol1-sec2-5/content-detail.html

purposes must enter into a Cooperative Research and Development Agreement (CRADA), or other approved benefit-sharing agreement with NPS.[5] Typically, under the terms of a CRADA, a party may make commercial or other revenue-generating use of the results of its research with benefit sharing to the NPS. A CRADA would also identify the allocation of ownership in any inventions made, and the other rights and obligations of the parties, including reporting requirements and the manner in which disputes may be handled. Reporting requirements may include notification of the development of any invention based upon research using specimens collected in the parks and identification of any patent application claiming an invention developed as a result of the research on collected specimens or other collected materials.

An excellent example of a partnership that involved sharing of benefits of both a monetary and non-monetary kind is the CRADA negotiated between Diversa Corporation and Yellowstone National Park. In return for access to the genetic resources in the unique habitat of Yellowstone, Diversa agreed to provide Yellowstone with an up-front payment of US $100,000, payable in five annual installments, to be offset against any future royalty payments received by Yellowstone.[6] The CRADA also contained provisions for the payment to Yellowstone of royalties in the event that a product derived from Yellowstone genetic resources yields a profit.[7]

In addition to the monetary benefits under the agreement, the partnership involved a component of donation of equipment to Yellowstone, and training of its staff. Diversa has given the park staff equipment, such as DNA extraction kits and DNA "primers" needed to start the polymerase chain reaction to detect target DNA.[8] Diversa scientists have also helped train Yellowstone staff in molecular biology techniques.[9]

2. Costa Rica

Costa Rica is generally viewed as a leader for developing a successful strategy regarding access and benefit sharing of genetic resources. This is largely due to the fact that Costa Rica has one of the more advanced and transparent regimes. The regulations in Costa Rica for obtaining access to genetic resources are clear and well defined and as a result of the clarity in the guidelines and collaborative relationship with the government, there are a significant number of contracts with companies in the life

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[5] The Federal Technology Act of 1986 was enacted by the US Congress with the intention of encouraging cooperative research and technology transfer between the federal government and the private sector. A CRADA is defined as a contract under which a private company contributes resources, i.e., funds, facilities, services, or personnel, to a federal laboratory or facility that performs research. See 15 USC 3710a, http://www.gpo.gov/fdsys/granule/USCODE-2011-title15/USCODE-2011-title15-chap63-sec3710a/content-detail.html.

[6] *Benefit-Sharing Case Study: Yellowstone National Park and Diversa Corporation*, Submission to the Executive Secretary of the Convention on Biological Diversity by the Royal Botanic Gardens, Kew, April 22, 1998, page 19.

[7] Id.

[8] Id. at page 20.

[9] Id.

sciences industry.[10] In addition, due to the growing number of contracts, there are substantial benefits flowing back into Costa Rican development and conservation efforts. For example, even before the adoption of the CBD in 1992, Costa Rica and INBio negotiated bioprospecting contracts with numerous companies.[11] Successful partnerships with local enterprises in the agro-industrial area developed through Costa Rica's bioprospecting program have created jobs and benefited the local population through the development of new products for the local market.[12]

In addition, INBio's cooperation with international companies has become a pre-requisite for the realization of many projects. For example, through funds from the Inter-American Development Bank, small local enterprises, using biological material as production inputs, are able to initiate low-cost projects for the local market, requiring simple technologies and limited time of development. These smaller projects are contributing value in the form of profit, employment, and agricultural innovations.[13]

This type of bioprospecting agreement is best exemplified by the 1991 collaborative research agreement between Merck & Company, one of the largest pharmaceutical companies, and INBio. Merck agreed to pay INBio a sum of US $1 million for all of the plant, insect, and soil samples the institute could collect in addition to a percentage of the royalties from any drugs that Merck developed from samples provided by INBio.[14] In addition to the money received from Merck, INBio has benefited from technology transfer in the form of equipment donations worth US $135,000 to carry out chemical extraction processes.[15] Merck also supplied INBio with two natural products chemists to set up extraction laboratories and to train scientists to discover and extract valuable substances.[16]

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[10] Although Costa Rica's biodiversity law of 1988 requires evidence of access and prior informed consent prior to the grant of industrial property rights on innovations that involve genetic heritage, Costa Rica's contract-based approach was extremely successful in achieving ABS for years prior to the enactment of their biodiversity law. This is a testament to the fact that new patentability requirements relating to the source or origin of genetic materials are not necessary to further the ABS objectives of the CBD. Moreover, while Article 80 of Costa Rica's biodiversity law requires patent-granting authorities to consult with the competent body in Costa Rica that grants access to the genetic resources before granting industrial property rights, it is our understanding that no patents have been identified that have made use of national genetic resources. Thus, in reality, the evidentiary requirements imposed by Costa Rica's biodiversity laws lack any practical effect.

[11] See Richerzhagen and Holm-Mueller, *The Effectiveness of Access and Benefit Sharing in Costa Rica: Implications for National and International Regimes*, Ecological Economics, 53 (2005) page 452. In 1989, the National Institute for Biodiversity (INBio) was created as a private, but non-profit institute to coordinate the different activities of universities, private organizations, and government and to become a national focal point in the field of biodiversity. The institute's mission is to raise awareness of the value of biodiversity and thereby promote the conservation and economic development in Costa Rica.

[12] Id. at 453.

[13] Id.

[14] Blum, E., *Making Biodiversity Profitable: A Case Study of the Merck/INBio Agreement*, Environment 35 (4), 1993 available at http://www.ciesin.org/docs/002-270/002-270.html at page 4.

[15] Id.

[16] Id.

Under the agreement, Merck would receive exclusive rights, called "right of first refusal," to evaluate the approximately 10,000 samples that INBio agreed to supply to Merck.[17] Moreover, if Merck discovered any active ingredients from which it developed commercial products, the company would retain all patent rights to the developed product.[18] The prospect of royalties from commercially developed products could have a dramatic positive effect on Costa Rica's economy. According to the World Resources Institute, if INBio received two percent of the royalties from the sale of 20 products based on its samples, INBio would have received more money than Costa Rica did from the sale of coffee and bananas-- two prime exports.[19] This source of revenue, if realized, could be used to build a Costa Rican biotechnology industry and to strengthen Costa Rica's economy.

BIO believes that the aforementioned access and benefit-sharing regimes are easily adapted to other legal regimes and can provide countries with the flexibility to protect their genetic resources and associated traditional knowledge with little or no connection to a country's separate intellectual property regime. In BIO's view, these contract-based access and benefit-sharing arrangements represent a win-win situation: they protect the proprietary rights of the industry and provide countries with the ability to use their natural resources in a sustainable way, while at the same time strengthening their economy.

B. The patent system is not the appropriate vehicle for regulating access and benefit sharing.

Disclosure requirements in the patent law that mandate applicants to provide the source or origin of genetic resources/associated traditional knowledge, evidence of prior-informed consent, and evidence of benefit sharing have been used without evident success by countries as a means to comply with or monitor compliance with the ABS obligations in the CBD.[20] It is our view, based on analyses of such laws, that the most effective means for achieving the stated objectives of the CBD is through national laws specifically designed to regulate access and benefit sharing. The introduction of additional patent disclosure requirements that are unrelated to the patentability of a claimed invention will not achieve the objectives of the CBD and, instead, will have a detrimental impact on innovation.

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[17] Id.
[18] Id.
[19] Id. at pages 4-5.
[20] "Disclosure requirements" refer collectively to disclosure requirements in the patent law regarding source or origin of genetic resources/traditional knowledge, evidence of prior-informed consent, and evidence of equitable benefit sharing.

1. *Patent disclosure and prior-informed consent requirements will not achieve the objectives of the CBD.*

While our members believe that access to genetic resources should be authorized and that benefits arising from the use of such resources should be shared equitably with the providers of those resources, our support for the goals of the CBD does not translate to support for special disclosure requirements in a country's patent laws. BIO believes that patent systems are not efficient tools for enforcing the access and benefit-sharing obligations in the CBD. Requiring as a condition of patentability the disclosure of genetic resources and evidence of prior-informed consent and benefit sharing will do nothing to ensure that prior-informed consent or benefit sharing actually occurs. Indeed, no country that has implemented special patent disclosure requirements or proof of prior-informed consent has been able to demonstrate that such requirements have led to benefit sharing.

First, patent disclosure requirements will not guarantee that prior-informed consent was obtained. It bears emphasis that it is the relevant prior consent agreement itself, usually in the form a contract, and not a disclosure in a patent application or a response to an office action that manifests prior informed consent. A researcher needs to know where to go, whom to contact, and who is authorized to grant approval to collect specimens or materials. Thus, if a country views these goals as necessary, it must establish a completely separate and transparent mechanism to regulate access to its genetic resources, independent of additional patent disclosure requirements.

In a similar vein, disclosure requirements in the patent system or requirements to demonstrate proof of prior-informed consent will not ensure that benefits are equitably shared with the provider of the genetic resources or traditional knowledge. Patent disclosure requirements cannot transfer benefits, as such requirements would merely convey information, but would have no mechanism to transfer any benefits between parties. A mechanism to transfer benefits would still need to be established to ensure that the custodians of the relevant genetic resource receive appropriate benefits.

Moreover, when a patent is not granted, inventions are not commercialized, no sharing of benefits occurs, and the consumer and the holder of the genetic resources do not gain anything. Further, patent disclosure requirements fail to address benefit sharing resulting from commercialization that occurs outside the patent system. These disclosure requirements will be meaningless when products derived from or based on genetic resources or traditional knowledge are commercialized, but not patented. There are many different ways of protecting ideas that lead to commercialization, including trade secret and unfair competition laws. In these situations, provider countries that rely on patent disclosure laws and rules requiring that an applicant provide proof of prior-informed consent would likely realize no benefits.

Finally, if proof of prior-informed consent is indeed a necessary requirement for obtaining patent protection, the patent system would be frustrated by the delay in

obtaining such consent, which is approximately two to three years in Brazil. This is further aggravated by the difficulties in interpreting the scope and applicability of many of Brazil's rules on this subject matter. The same rules also suggest that foreign entities must obtain the consent of CGEN prior to filing a patent application that uses or is based on Brazilian genetic heritage. Together, these rules not only frustrate the existing patent laws, but also act as a considerable barrier to conducting research and development in Brazil.

For these reasons, regulation of access and benefit sharing through the patent system would do little to deter unauthorized access and would not ensure equitable benefits would be distributed to most providers of resources, even when access has been authorized. Our members firmly believe a more direct path for fulfilling the goals of the CBD is through the facilitation of contractual agreements between the holders and users of genetic resources, outside of the patent system. Contractual systems to regulate access and benefit sharing now exist that ensure that benefit sharing occurs in the event of any commercialization of products, regardless of whether those products are the subject of patents. (See aforementioned section on successful access and benefit-sharing regimes.)

2. Patents should not be used as a vehicle for monitoring CBD compliance.

Patent disclosure requirements to address issues related to access and benefit sharing introduce into the patent system a precedent for its use as an enforcement tool rather than as a tool to encourage innovation. BIO strongly believes that the attempt to use the patent system to implement obligations in the CBD is something that should be resisted. Moreover, BIO advocates that a comprehensive and transparent contract-based approach to achieving access and benefit sharing can be adequately monitored and enforced without resorting to the patent law.

Patent law was not designed to regulate or enforce misconduct issues, such as misappropriation of genetic resources or associated traditional knowledge, but rather to promote the development and commercialization of new ideas and discoveries. Patent rights permit an inventor to exclude others from engaging in certain infringing activities, e.g., those enumerated in Article 28 of the TRIPS Agreement, but they do not permit an inventor to use the invention without restriction. Several restrictions are often placed on the use of certain inventions to ensure safety and efficacy (regulations governing pharmaceutical products) or to protect the environment (regulations governing vehicular emissions). These restrictions, however, are enforced outside the patent system by separate regulatory mechanisms. Similarly, BIO urges that the patent system should not be used to enforce compliance with contract-based access and benefit-sharing regimes.

3. Patent disclosure requirements create new uncertainties.

Disclosure of origin requirements, along with evidentiary requirements of prior-informed consent and benefit sharing, would weaken the patent system by creating additional uncertainty for patent holders. It is difficult to establish exactly the relationship between the invention and the biogenetic resources and/or associated traditional knowledge for disclosure of origin to apply. In many cases, knowledge and material relevant to an invention may be manifold. Accordingly, it is extremely challenging to create a uniformly consistent standard as to when sources of knowledge and material are relevant to the invention. Thus, numerous patent applications would be subject to attack for not disclosing the correct or sufficiently complete information about the genetic resource, making patent certainty precarious. For granted patents, these additional patent requirements would create a cloud of uncertainty by opening a new avenue of review for litigation. These uncertainties undermine the role of the patent system in promoting innovation and technological development.

A recent decision handed down by a federal court in Brazil is illustrative of the uncertainty that plagues the biotechnology sector with respect to this issue. The decision involves Brazilian companies that developed an oil-containing soap obtained from the seed of a palm tree called "murumuru." Alleging that some rules established by the Executive Order No. 2,186-16 were violated, a public civil lawsuit was initiated against certain companies claiming improper use of murumuru and traditional knowledge from the Ashaninka, a tribe located in the State of Acre, bordering Peru and Bolivia.

The federal court confirmed that there was no illegal access to genetic resources or traditional knowledge because: (i) the information/properties of the murumuru were obtained from scientific documents published during the 1940s; (ii) one of the companies obtained an authorization for accessing murumuru from another region, namely the State of Amazonas; and (iii) another company obtained murumuru oil from a manufacturer, which obtained such oil from the Ashaninka. While the court held that a company does not need access authorization if it simply explores features/properties of genetic resources that were disclosed beforehand in the scientific literature, there is still a substantial lack of clarity involving the scope of applicability of the various rules and regulations in Brazil involving access to genetic resources. Interposing these uncertainties into the patent system does little to resolve any of the lingering questions as to how the biotechnology sector needs to operate in order to continue carrying out innovative research in Brazil.

C. Recommendations

In view of the concerns expressed above, BIO and its members sincerely believe that access to and use of genetic resources and associated traditional knowledge may be better regulated by providing clearer guidance and greater certainty with respect to obtaining approval to access and negotiating with local communities on access to genetic

resources and associated traditional knowledge. Likewise, BIO and its members strongly encourage the Brazilian legislature and CGEN to keep separate the intellectual property laws from legislation regarding access to and use of genetic resources. BIO believes there are adequate regulatory pathways that can guarantee a sustainable approach to regulating access to genetic resources without undermining innovation incentives within the biotechnology industry, particularly the burgeoning Brazilian biotechnology sector and the subsequent research and development of new products that seek to improve the lives of humankind. In this regard, BIO would like to offer the following recommendations:

Recommendation #1

Brazil should adopt simple, straightforward, and flexible processes for accessing and utilizing genetic resources.

BIO believes that a practical and workable ABS system will benefit both the owner and the user of genetic resources and help countries to utilize their resources to develop their economies. A system that engenders innovation through a robust, clear and practical legal framework will not only attract outside investment, but will also foster local entrepreneurial activity. Conversely, unclear, convoluted and burdensome requirements and bureaucracy, such as those described in the section outlining Brazil's legal framework, will diminish the likelihood that companies will invest in the research and development of genetic resources and, consequently, that local indigenous communities will receive any subsequent funding that may be applied to conservation efforts, education, and local research and development.

Complex and rigid regulatory frameworks often require time-consuming processes that seldom meet conservation and development objectives, often halting research altogether. Most companies consider it beyond their expertise to navigate Brazil's complex terrain of seeking prior-informed consent and complying with all the legal requirements. Smaller companies that do not have the bandwidth to deal with convoluted procedures will shy away from collecting genetic resources that require a permit. Moreover, expediency is very important to discovery and development. Because it takes a long period of time to obtain authorization from CGEN, companies are likely to lose interest and funding.

The experiences of the United States and Costa Rica are proof that actual and potential benefits accruing from bio-prospecting agreements will aid countries like Brazil in developing its biotechnology industry so that all levels of research can take place entirely within Brazil's boundaries. It is important that as Brazil considers amendments to its national regulations, the newly proposed regulations must not be overly restrictive or burdensome, as researchers will be discouraged from undertaking projects or collaborations in Brazil, and instead, will simply seek access to genetic resources from countries with more reasonable laws and clearer regulatory guidelines, such as Costa Rica or the United States.

For these reasons, BIO strongly encourages that CGEN provide clarifications on it requirements and procedures, and commit to working with members of the biotechnology industry so that applications for access to genetic resources can be approved quickly so that new research and development may be carried out in Brazil in reasonably acceptable timelines.

Recommendation #2

Brazil's approach to monitoring its genetic heritage should be implemented though the development of laws and regulations outside the patent system.

In BIO's view, the best way to implement the obligations in the CBD is by a system that permits parties seeking access to genetic resources to enter into contracts with the sovereign entity or private party responsible for granting access, somewhat similar to the contractual framework currently provided for by the aforementioned Executive Order. Laws and regulations, unlike those in place in Brazil, should clearly identify points of contact, such as governments or indigenous parties, who are authorized to provide access to the materials. To achieve effective implementation, BIO recommends that such contracts could provide, in detail, the terms and conditions under which access is granted, including requirements for joint research and development or for transfer of technology developed from or using the genetic resources or traditional knowledge. In addition, questions involving choice-of-law and breach of contract can be spelled out and provisions regarding investments in conservation and education efforts may also be proscribed on a case-by-case basis so as to provide for flexibility in a given research and development project taking into account the unique considerations and circumstances of each particular case.

BIO therefore also believes that a contract-based approach can be used effectively to control the collection of resources and ensure the sharing of benefits from their use. Contracts can provide a great deal of flexibility in determining benefit sharing, including monetary and non-monetary benefits and, unlike in the current regulatory framework in Brazil, could stipulate precisely how benefits are to be applied by and within local indigenous communities. For example, such contracts can require researchers to report regularly on the progress of their research, including any commercialization utilizing the underlying genetic resources or traditional knowledge, whether patented or not. In many cases, companies or research institutions that sign such "bio-prospecting" contracts with provider countries can receive property rights for the purchased material in exchange for fees and up-front payments. In case of successful development, the companies receive intellectual property rights for innovative and valued products and consequently further payments and benefits may pass down to indigenous communities to increase conservation efforts, education and local research and development.

In addition, the Nagoya Protocol is also instructive as to how a country can best monitor its genetic resources. The Nagoya Protocol was designed to create uniformity for monitoring and compliance issues so that users in a particular jurisdiction comply

with ABS legislation and mutually agreed terms. For example, Article 17 of the Nagoya Protocol articulates a number of measures to monitor and enhance transparency about the utilization of genetic resources, while Article 18 sets out a framework for compliance with mutually agreed terms. BIO sincerely believes that implementing the provisions of the Nagoya Protocol will be extremely effective in monitoring compliance with Brazil's ABS requirements.

While BIO recognizes the importance of monitoring the utilization of a country's genetic resources, BIO strongly opposes the introduction of additional patent disclosure requirements that are unrelated to the patentability of a claimed invention. Because the patent system has always been a highly effective tool for technological and economic development, BIO cautions against upsetting a balanced patent system, especially when it is doubtful that changes will achieve their purported goals. As discussed earlier, BIO does not believe that additional patent disclosure requirements, along with other evidentiary requirements of prior-informed consent or benefit sharing, will accomplish the goals of ensuring access and equitable benefit sharing. Moreover, BIO is very concerned that such requirements will have significant negative consequences by inserting new burdens and uncertainties into the patent system. We know from experience that these significant risks will discourage capital investment in biotechnology research conducted by our members. Without this capital investment, our members cannot undertake vital research on better foods, alternative sources of energy, and medicines. As a result, the owners of genetic resources and Brazilian society as a whole will stand to lose from this lack of investment.

For these reasons, BIO urges the Brazilian government to eliminate provisions in its laws and regulations that use the patent system as a tool for monitoring compliance with ABS provisions. In particular, BIO recommends that in keeping separate the intellectual property laws from legislation regarding access to and use of genetic resources, additional patent disclosure requirements and restrictions regarding filing patent applications or obtaining patent protection, such as those currently in place in Brazil that require approval from CGEN prior to filing, should be abolished.

Furthermore, as a proponent of the utilization of model guidelines, model Material Transfer Agreements, and contractual agreements for ABS after a country has implemented the CBD through national legislation, BIO recommends the adoption of comparable guidelines. This would address perceptions of misappropriation while preserving certainty in the patent system. BIO's *Guidelines for Members Engaged in Bioprospecting, (http://www.bio.org/ip/international/200507memo.asp* and *http://www.bio.org/ip/international/200507guide.asp)* make BIO's position on these points clear and provide guidance to its members on these issues. BIO has also developed a model Material Transfer Agreement (MTA), which is available at *http://www.bio.org/sites/default/files/BIO_Model_MTA.pdf*.

Additional Considerations

A. Patenting of Biological Materials

BIO would also like to take this opportunity to express concerns regarding the lack of patent protection in Brazil for isolated biological materials. For example, according to Article 18 of the Brazilian IP law, only transgenic microorganisms are eligible for patent protection. While unmodified products of nature are not patentable subject matter, innovations based on biological substances that are the products of human ingenuity and have a distinctive character and use are eligible for patent protection in many jurisdictions.

In the United States, biological substances can be patented if they are sufficiently "isolated" from their naturally occurring states. The practice of granting patents on products of nature that have been isolated and purified goes back to the late 1800s when a patent was issued to Louis Pasteur on yeast that were free from organic germs of disease. For the last century, United States courts have supported the principle that non-naturally occurring products of nature may be patented.[21]

The most significant ruling on the patentability of biological products was the 1980 decision of *Diamond v. Chakrabarty,* in which the United States Supreme Court upheld the first patent on a newly created living organism, a bacterium for digesting crude oil in oil spills. The Court in *Chakrabarty* noted that this new bacterium had markedly different characteristics from any found in nature as it was capable of breaking down oil spills at a much faster rate and even more importantly, it was not affected by varying environmental conditions.[22] As the Court explained, Chakrabarty's claim was not to an unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter that was the product of human ingenuity having a distinctive character and use.[23]

Since the *Chakrabarty* decision, the United States Patent and Trademark Office has issued thousands of patents to biological material, including isolated microorganisms, seeds, plants, cells, as well as genetic material derived from these sources. Shortly thereafter, the European Patent Office and the Japan Patent Office followed suit by granting patents to similar types of biological material. In 1998, the European Union Directive on Biotechnology harmonized legislation in regards to biological patents by providing for the patenting of natural biological products as long as they are isolated from their natural environment or produced by means of a technical process. In a similar fashion, according to Japan's patent law, if chemical substances

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[21] *See, e.g.*, *Farbenfabriken Co. v. Kuehmsted*, 171 F. 887 (C.C.N.D. Ill. 1909) (holding that *purified* salicylic acid, aspirin, is patentable); *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F.95, 103 (S.D.N.Y. 1911) (holding that *purified* adrenaline obtained from gland tissue is patentable); *In re Bergstrom*, 427 F.2d 1394, 1397 (holding that *purified* prostaglandin hormones obtained from sheep prostate glands are patentable).

[22] *Chakrabarty* at 308.
[23] *Chakrabarty* at 309.

have been isolated artificially from their natural surroundings then those creations are considered to be a statutory invention. Key emerging economies, i.e., Russia and China, also provide patent protection for substances isolated from nature if the substances can be properly characterized by structure or other parameters.

Patents covering isolated biological materials have led to the development of numerous advancements across all sectors in biotechnology. One of the most significant contributions to the growth of the biotechnology industry is attributed to a microorganism, a single bacterium, isolated from the hot springs of Yellowstone National Park. It turns out that the enzymes of these bacteria are very tolerant of heat and are active even at boiling water temperatures. The first such bacterium discovered, and one that has proved of special significance for biotechnology, is called *Thermus aquaticus*.[24] Enzymes from this source, Taq Polymerase, have revolutionized DNA synthesis and sequencing due to their unique thermostable properties.[25]

In order to copy DNA and amplify it using the polymerase chain reaction (PCR), an enzyme is needed which is active at high temperatures. The thermostable Taq polymerase enables running the PCR at high temperatures, making PCR applicable to a large variety of applications involving DNA analysis.[26] During the successive heating cycles of PCR, Taq polymerase is not destroyed, but continues to work. During each successive round of heating, the amount of DNA doubles. Progressive doubling leads to an exponential increase in DNA. From one original molecule, in a single closed tube in a relatively simple machine, millions of copies of DNA can be generated.

In addition to numerous patents on the thermostable polymerases useful in PCR, there are hundreds of patents in the United States alone that claim aspects of PCR. Such patents cover the basic methods, reagents, and applications involving the PCR process.[27] This collection of patents is owned by a wide variety of entities including government agencies, corporations, and universities.[28] From one original discovery, Taq polymerase finds wide use in medical diagnosis and forensics, e.g., DNA fingerprinting, and has become the basis of a multibillion dollar industry.[29]

Other notable examples of patents on biological substances in the healthcare industry include the powerful anti-cancer drug, Taxol, derived from the bark of the Pacific Yew tree.[30] First isolated in 1962 from Pacific yew trees in Washington State, today Taxol, which is used to treat ovarian and breast tumors, lung cancer, and Kaposi's

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[24] See Brock, *Life at High Temperatures, Biotechnology in Yellowstone*, 1994 Yellowstone Association for Natural Science, History & Education available at http://bioinfo.bact.wisc.edu/themicrobialworld/LAHT/b27.html
[25] Id.
[26] Id.
[27] Carroll & Casimir, *PCR Patent Issues, Chapter 2* from Methods in Molecular Biology, Vol 226: 7-14 , 2013 available at http://www.ncbi.nlm.nih.gov/pubmed/12958471
[28] Id.
[29] Id.
[30] US Patent No. 5,425,869

sarcoma, is the best-selling anti-cancer drug with annual sales of US $1.6 billion.[31] Other discoveries include cardiac arrhythmia drugs isolated from the bark the cinchona tree[32] and chemotherapy drugs derived from the *Shortia galacofolia* leaves.[33]

In addition to the healthcare industry, many significant breakthroughs in industrial, energy, and environmental applications are derived from natural resources. In the realm of renewable energy, natural products are being studied to generate alternate energy sources, such as biofuels. For example, scientists continue to study biological substances, such as algae and *E.coli,* in the hopes of increasing reproductive efficiency, producing oil that is easier to extract, and creating more attractive fuel options. Other advances focus on ways to break down cellulosic material. Because of the copious amount of sugar contained in cellulose, cellulosic ethanol technology continues to be pursued by the biotech industry.

A recent example of a promising advancement in the commercialization of biomass-derived fuels involves the utilization of components in certain fungi. In April 2013, the Energy Biosciences Institute, a partnership between the University of California, Berkley and British Petroleum (BP), was awarded a patent for their discovery that components in certain fungi, e.g., *Neurospora crassa,* were found to improve sugar transport necessary for biofuel production.[34] The research leading to this biotechnological discovery was facilitated by BP's investment of US $500 million to create the Institute, which reportedly has at least 50 patents aimed at developing more sustainable, efficient constructions of biofuels.[35]

Global experiences continue to demonstrate the importance of IP protection for biological materials, including non-transgenic or isolated biological resources. All sectors of biotechnological innovation rely on the patenting of isolated biological substances, with a recent focus on patenting microorganisms.

B. Special Considerations for Industrial and Environmental Technologies

BIO would also like to express the concerns of its members regarding the difficulty of bringing certain technology to Brazil due to the lack of patent protection for microorganisms, such as bacteria and yeast, that are used in novel industrial and environmental technology applications such as renewable chemicals, biofuels, and biobased product applications.

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[31] Kilham, *Pacific Yew: A Potent Cancer Fighting Agent*, August 21, 2013 available at http://www.foxnews.com/health/2013/08/21/pacific-yew-potent-cancer-fighting-agent/
[32] US Patent No. 6,844,355
[33] US Patent. No. 7,691,417
[34] US Patent No. 8,431,360
[35] Petrillo, *Energy Biosciences Institute Granted Patent for Biofuels*, The Daily Californian, October 19, 2013 available at http://www.dailycal.org/2013/06/09/energy-biosciences-institute-granted-patent-for-biofuels/

In the Brazilian agricultural sector, intellectual property rights have been strengthened by the Law of Cultivares, 9.456 of April 25, 1997, which affords protection for new plant varieties defined by morphological features that are distinguishable from other known plant varieties. This 15 year term of protection encourages the development of novel varieties of plants and has resulted in significant research and development expenditures, thus boosting Brazil to the status of a global leader in agricultural technology.

In the industrial and environmental technology sectors, on the other hand, there is no such protection for innovations based on isolated microorganisms, such as bacteria and yeast, which may be useful in developing new technologies and products. This lack of protection makes it very difficult to obtain funding necessary for carrying out biotechnological research and development activities in Brazil. The lack of an equivalent Law of Cultivares for these industries is a great deterrent to additional R&D expenditures, which calls into question Brazil's role in helping to bring new technologies to the world, particularly as it pertains to renewable chemicals, biofuels, and biobased products,, where innovations will lead to cleaner and more sustainable technologies for generations to come.

The current IP Law, in Article 18, paragraph III, only affords protection to *transgenic* microorganisms that are novel, non-obvious and industrially applicable. Hence, while genetically modified microorganisms are able to be protected under the current Brazilian IP law, industries are increasingly relying on all microorganisms, transgenic or not, to develop new technologies and products. It is important therefore, for the reasons above, to afford protection to all microorganisms, and not just transgenic microorganisms. This way industries can continue to engage in developments resulting from costly investments in high-technology projects involving isolated microorganisms.

C. Recommendations

BIO's members believe that an amendment to Brazil's IP Law is necessary so that Brazilian industries may become key players in emerging biotechnology industries based on developing cleaner technologies and renewable energy sources. It is BIO's recommendation therefore that Article 18, paragraph III of the IP Law be amended so as to delete the term transgenic from the text, so that the text may read as follows:

Article 18:

The following are not patentable:

…

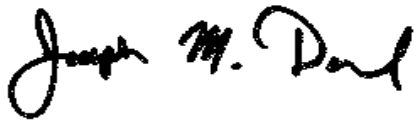
III –living beings, in whole or in part, except for ~~transgenic~~ microorganisms that meet the three patentability requirements – novelty, inventive activity and industrial application – foreseeing in article 8, and which are not mere discoveries.

Conclusion

Biotechnological innovation is a complex and challenging process that requires scientific excellence, commitment of significant resources and, in some cases, access to genetic material. Only through close collaboration will providers of genetic material and the biotechnology industry ensure that benefits are shared equitably. BIO supports fair and equitable benefit sharing on mutually agreed terms embodied in a contract or other agreement that represents a meeting of the minds of the provider and the user of genetic resources. BIO reiterates its opposition to patent disclosure requirements as they will be ineffective in promoting the objectives of the CBD and will introduce uncertainties into the patent system that will inhibit innovation in relevant technologies, thereby decreasing potential benefit sharing from such efforts. BIO urges Brazil to consider adoption of a contract-based system that is separate from a patent system aimed to serve the needs of encouraging research and development.

We applaud your efforts to re-evaluate your existing laws and policies so as to encourage research and development based on Brazil's genetic heritage and the protection of microorganisms used in biotechnology innovations and projects. We look forward to working with you to achieve these very important goals.

Respectfully submitted,



Joseph Damond
Senior Vice President, International Affairs
Biotechnology Industry Organization (BIO)