

New Restrictions On Int'l Trade In Genetic Resources

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On Oct. 12, 2014, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits from their Utilization entered into international force. The protocol establishes a new legal framework to govern access to and utilization of genetic resources, including genetic material and any naturally occurring derivative compound.

With entry into force of the protocol, a number of countries have adopted new laws and regulations that will impact the development of, and intellectual property rights surrounding, an array of products. Such products include pharmaceuticals, biotech products, agricultural products, nutritionals, supplements, cosmetics, perfumes and fragrances, and industrial enzymes. Although the United States has not signed or ratified the Nagoya Protocol, U.S. companies and universities that utilize genetic resources from other countries for scientific research or commercial purposes will be subjected to these new requirements and restrictions.



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Indeed, companies and universities utilizing genetic resources from plants, animals, bacteria and other organisms must be especially mindful of these new and emerging international and domestic requirements. The same is true for scientific and commercial activities relating to the use of traditional knowledge held by indigenous and local communities.

With many countries already vigorously enforcing such restrictions, the consequences of not fully complying may be draconian. In addition to being tarred in the international media as a "biopirate," those who allegedly fail to comply may be subject to enforcement actions brought by a government authority challenging the right to study and commercialize a product. Governmental authorities may also threaten criminal prosecutions. And, in certain countries, patent applications that noncomplying researchers and companies file for products derived from genetic resources or traditional knowledge may be jeopardized if they do not comply with applicable "disclosure of origin" provisions.

Background — The Biodiversity Convention

The Convention on Biological Diversity (CBD) was opened for signature during the Earth Summit in 1992. To date, the treaty has been ratified by 194 countries. The CBD marked a dramatic shift in the way that genetic resources are treated from a legal perspective. Previously, such resources were considered the "common heritage of mankind" and, therefore, available for everyone's access, use and benefit. The CBD, however, established that each nation maintains sovereign rights over genetic resources occurring within its geopolitical borders.

And, with that sovereignty, each party was authorized to control access to and share in any benefits arising out of the utilization and commercialization of its genetic resources—a term that is broadly defined to include any genetic material of actual or potential value.[1] These access and benefit sharing, or ABS, provisions broke new ground in international law, and fundamentally altered the manner in which countries regulate access to and utilization of their genetic resources by companies and researchers.

Following adoption of the CBD, the parties struggled with implementation and enforcement of the agreement's ABS provisions. In 2002, the parties adopted voluntary guidelines to assist with the development of legislative, administrative or policy measures on ABS and negotiation of contractual arrangements with users. While these guidelines were an important first step, they fell short of spurring implementation of the CBD's ABS provisions. Accordingly, in 2004, the parties agreed to elaborate and negotiate an international regime on access to genetic resources and benefit sharing with the aim of effectively implementing the ABS provisions of the CBD.

Six years of intense negotiations later, that regime — the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits from their Utilization — was adopted. To date, the protocol has been signed by 92 countries and 54 nations have ratified or acceded to the agreement.

The Nagoya Protocol

The Nagoya Protocol reaffirms the fundamental principle from the CBD that each state maintains sovereign rights over its genetic resources. In exercising that authority, each country must adhere to the following core obligations under the protocol:

Access Obligations

Each party must take measures to ensure that access to its genetic resources is subject to its prior informed consent (PIC). To that end, parties must establish fair and nonarbitrary rules and procedures that establish legal certainty, clarity and transparency. Those procedures must indicate how to apply for prior informed consent and they must provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time. When access is granted, these procedures must provide for the issuance of a permit or the equivalent thereof.

Benefit-Sharing Obligations

Each party must adopt measures requiring that the benefits arising from utilization of its genetic resources are shared in a fair and equitable manner and on the basis of mutually agreed terms. Utilization is broadly defined to include research and development involving the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology. Biotechnology is, in turn, defined to mean any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Compliance Obligations

Each party is obligated to support compliance with its domestic legislation and the regulatory requirements of other parties that provide genetic resources. To that end, parties must, among other things, cooperate in cases of alleged violations of another party's requirements. They must also take measures to monitor the utilization of genetic resources after they leave the country by, for example, designating effective checkpoints at any stage of the value-chain: research, development, innovation, pre-commercialization or commercialization.

Institutional Obligations

Each party is required to designate a national focal point (NFP) and competent national authority (CNA) to serve as a contact for information, grant access or cooperate on issues of compliance. At the same time, each party must make certain information available to an ABS clearinghouse established by the protocol. Such information includes legislative, administrative and policy measures on ABS, information on the NFP and CNAs, and permits that have been issued allowing access to genetic resources.

The protocol also calls on each party to take measures, in accordance with domestic law, to ensure that traditional knowledge associated with genetic resources held by indigenous and local communities is only accessed with the prior approval and involvement of such communities and that such access is based on mutually agreed terms. To these ends, the access, benefit-sharing and compliance obligations set forth above also apply to utilization of traditional knowledge. While the protocol does not itself define the term "traditional knowledge," the CBD refers to traditional knowledge as the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.

National Implementation of the Protocol's ABS Requirements

Many nations and jurisdictions have adopted new regulatory measures or taken other steps to implement the foregoing provisions of the Nagoya Protocol.[2] For example, in April 2014, the European Parliament and the Council of the European Union adopted a new regulation (Regulation No 511/2014) to regulate access to and utilization of genetic resources. It obliges all users to exercise due diligence to ascertain that genetic resources and associated traditional knowledge have been accessed in accordance with all applicable legal requirements, and that any benefits are fairly and equitably shared in accordance with mutually agreed terms.

The regulation applies to genetic resources over which states exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol. The EU regulation became effective with entry into force of the protocol, but several key provisions will enter into force a year later.

Elsewhere, India and Brazil have moved to implement the protocol by supplementing existing legislation. Those efforts are being watched closely by other biologically rich nations as they too consider measures to ratify the protocol. India ratified the protocol in 2012 on the basis of its National Biodiversity Act. Under that act, failure to gain approval from the country's National Biodiversity Authority for the use or transfer of genetic resources may result in imprisonment for up to five years, fines, benefit-sharing fees, and royalties.

Although Brazil has not yet ratified the protocol, it is relying on a provisional measure (MP 2.186-16) and other authorities to govern access to its genetic resources. Failure to comply with this MP may result in fines, confiscation of samples and products, suspension of the sale of products, closing down establishments, and suspension or cancellation of the registry, patent, license or authorization. Revisions of Brazil's ABS legislation are reportedly underway.

Still other nations have adopted regulations that broadly construe the scope of genetic resources subject to ABS requirements. For example, under its National Environmental Management Biodiversity Act, South Africa regulates all "indigenous biological resources," which are defined to include any chemical compounds and products obtained through the use of biotechnology that have been altered with genetic material or chemical compounds found in indigenous species."

Moreover, some countries and nongovernmental organizations are taking the position that the protocol's ABS obligations apply to the utilization of genetic resources and biological materials that were collected long before the protocol was adopted or entered into force. This has become a key issue because many genetic resources from source countries have already been collected and are currently housed *ex situ* in collections around the world.

Enforcement of ABS Requirements

With the adoption of these laws, many countries are vigorously enforcing their PIC and ABS requirements. In July 2012, for example, Brazil reportedly fined 35 companies a total of \$44 million based on claims that they violated the country's ABS requirements. India's National Biodiversity Authority and nongovernmental groups have repeatedly alleged that a large U.S. company violated that country's ABS laws. Still other nongovernmental organizations have alleged that a large nutritional products company improperly sought patents on South African plants without first obtaining consent from that government. Elsewhere, indigenous groups along with several organizations have sought to invalidate patents involving a drug product, claiming that the applications were based on illegal misappropriation of traditional knowledge involving the use of two plant species.

Another way in which parties are enforcing ABS requirements is through their patent laws. Indeed, certain countries have amended their laws to forbid the issuance of patents for inventions relying on illegally acquired genetic resources or associated traditional knowledge. China's patent law, for example, requires an applicant to disclose "the direct source and the original source of the genetic resources." If the applicant cannot document that such resources were accessed properly, the patent may not be granted. Similarly, South Africa's patent law provides that patents will not be issued unless the patent applicant "furnishes proof" of title or authority to make use of indigenous biological resources or traditional knowledge. Similar disclosure requirements can be found in the laws of other countries, including Brazil and India.

At the same time, a number of these countries are pressing for an amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights that would establish an international requirement compelling the disclosure of the origin of genetic resources and/or associated traditional knowledge in patent applications.

This initiative is also being pursued within the World Intellectual Property Organization, where negotiations are underway to develop a new international instrument establishing a disclosure of origin requirement for all parties. A draft of the

agreement would require each party to require patent applicants to disclose the source and country of origin of the claimed genetic resource and traditional knowledge and to provide relevant information regarding compliance with ABS and PIC requirements of the source country. In the event that an applicant fails to do so, its application may not be further processed or may be declined.

Conclusion

With entry into force of the Nagoya Protocol, companies and researchers utilizing genetic resources occurring in foreign countries are subject to new requirements governing access and benefit-sharing. These restrictions raise an array of legal questions cutting across several distinct areas, including compliance, international trade, international litigation, transactional and licensing arrangements, and protection of intellectual property rights.

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[1] The term “genetic resources” used in the CBD does not include human genetic material.

[2] To date, the following countries have ratified or acceded to the Nagoya Protocol: Albania, Belarus, Benin, Bhutan, Botswana, Burkina Faso, Burundi, Comoros, Cote D’Ivoire, Denmark, Egypt, Ethiopia, European Union, Fiji, Gabon, Gambia, Guatemala, Guinea, Guinea Bissau, Guyana, Honduras, Hungary, India, Indonesia, Jordan, Kenya, Lao People’s Democratic Republic, Madagascar, Malawi, Mauritius, Mexico, the Federated States of Micronesia, Mongolia, Mozambique, Myanmar, Namibia, Niger, Norway, Panama, Peru, Rwanda, Samoa, Seychelles, South Africa, Spain, Sudan, Switzerland, Syrian Arab Republic, Tajikistan, Uganda, United Arab Emirates, Uruguay, Vanuatu, and Vietnam.