WILMERHALE

Freedom to Utilize Genetic Resources? The Nagoya Protocol Two Years Later

OCTOBER 12, 2016

Two years ago today, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits from their Utilization to the Convention on Biological Diversity ("Protocol") entered into international force. To date, 87 countries have ratified or acceded to the agreement, and that number is expected to reach 100 by the end of this year. With its entry into force, the Protocol is ushering in a new international system to govern research, development and intellectual property rights surrounding a potentially vast array of products derived from non-human genetic resources. Those products include, among others, pharmaceuticals, products of synthetic biology and biotechnology, seeds, biocides, horticultural and microbiome products, nutritionals, supplements, cosmetics, perfumes, fragrances and industrial enzymes.

In December 2016, the Parties to the Protocol will meet in Mexico for their second biennial meeting to further implement the agreement. As the Protocol's requirements take hold and various nations more vigorously enforce these provisions, any company or research organization that utilizes genetic resources (or genetic information derived from such materials) for research and development should take measures to ensure full compliance. Indeed, proactive compliance measures will be key to reducing the risk of legal liability and reputational harm stemming from alleged violations of the Protocol. Such measures are also needed to ensure the freedom to operate and secure protection of intellectual property rights for a product or process involving the use of genetic material or genetic information accessed from another country.

The Nagoya Protocol

The Nagoya Protocol seeks to create a transparent international legal framework to govern access to and utilization of non-human genetic resources, derivatives thereof and associated traditional knowledge. Each Party must ensure that access to its genetic resources is subject to prior informed consent in a clear and transparent manner and pursuant to fair and non-arbitrary rules. In exchange for allowing such access, the country with sovereignty over the genetic resources may require fair and equitable sharing of any monetary and non-monetary benefits arising from utilization of such resources. This access and benefit-sharing ("ABS") *quid pro quo* is typically achieved through an agreement spelling out detailed contractual terms between the provider country and the user

company or research entity.

To establish an effective international ABS legal system, the Protocol calls upon each Party to adopt domestic-level provider measures and user measures that govern access to and utilization of genetic resources. “Provider measures” require those seeking to access genetic resources to do so only with prior informed consent of the country (and local indigenous community) and in accordance with mutually agreed terms for benefit-sharing. “User measures” must ensure that any genetic resources utilized in a country for research or development were accessed in accordance with provider measures of the country from which the genetic resources were originally obtained. User measures may include, among other requirements, mandatory due diligence reporting requirements and compliance checkpoints.

During the past two years, as various nations have adopted new provider and user measures, the Protocol's legal framework has begun to coalesce into an international regulatory scheme governing access to and use of genetic resources for research and development. To be sure, many Parties have not yet adopted laws to implement the Protocol, and others are relying on existing laws to implement the Protocol. Nevertheless, some of the leading Parties—both on the provider side and user side—have adopted new measures to bring this international system into force. These measures signal the direction forward and serve as important precedents for other countries as they too adopt measures to implement the Protocol. A brief summary of several of these provider and user measures follows below.

Provider Measures

Brazil: On November 17, 2015, Brazil's new Biodiversity Law (Federal Law 13.123) entered into force. It seeks to simplify the process for scientific research and to facilitate commercial development by mandating development and implementation of an electronic registration system for users. The Biodiversity Law also created a mechanism for regularization and reduction of penalties and sanctions of up to 90% for violations of the country's earlier ABS requirements. This regularization scheme, however, expires one year from the date on which Brazil's electronic registration becomes available.

India: In November 2014, India's National Biodiversity Authority issued new “Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations.” The guidelines outline financial obligations of users for particular types of activities that must be in ABS agreements and indicate how benefits are to be shared with the government and communities. Under India's ABS provisions, any party that applies for any intellectual property right relating to use of genetic resources within or outside of India must first obtain permission. The failure to do so is punishable by imprisonment for up to five years.

South Africa: In May 2015, the Department of Environmental Affairs issued revised ABS regulations requiring a “bioprospecting permit” and an executed benefit-sharing agreement for commercialization of the country's “indigenous biological resources.” The revisions are designed to harmonize international and domestic permitting requirements, and provide for more transparent provisions to govern the discovery phase of non-commercial research and administration of the

country's Bioprospecting Trust Fund. The new regulations set forth penalties for any person convicted of a violation and they provide for imprisonment for up to 10 years.

Mexico: In October 2014, Mexico declared that the Nagoya Protocol constitutes legally binding law in the nation. Since issuance of this decree, government authorities within the Secretariat of Environment and Natural Resources ("SEMARNAT") have been working on new legislation and regulations to implement the Protocol. Until these measures are adopted, Mexico will operate under both the Protocol and earlier legislative measures establishing ABS requirements. Those measures include the Ecological and Environmental Protection General Act, which authorizes SEMARNAT to require consent and benefit-sharing before users may access biological resources.

User Measures

European Union: On April 16, 2014, the European Union adopted Regulation No. 511/2014. It requires all users in the EU to exercise "due diligence" to ensure that genetic resources have been accessed in accordance with the ABS requirements of the provider country. Moreover, any user who receives research funding or seeks to market a product derived from genetic resources must make a compliance declaration to the relevant authorities. Each EU Member State must establish checkpoints to verify compliance, and adopt penalties for non-compliance. On October 13, 2015, the European Commission issued detailed rules to implement Regulation 511/2014.

United Kingdom: In March 2015, the United Kingdom adopted the "Nagoya Protocol (Compliance) Regulations 2015" (Statutory Instrument 2015 No. 821) to implement EU Regulation No. 511/2014. The UK Regulations empower an inspector to enforce the EU Regulation, and they establish civil sanctions for non-compliance with the EU Regulation's provisions governing due diligence, record-keeping, and a declaration of due diligence and compliance. Any person guilty of such an offense may, on conviction on indictment, be subject to a fine or a term of imprisonment not exceeding two years, or both.

Germany: Germany became a Party to the Protocol on July 20, 2016. In support of its ratification of the Protocol and to comply with EU Regulation 511/2014, the German parliament enacted DS 18.5219 on October 15, 2015. The new law empowers the Federal Ministry for Nature Conservation to impose fines for intentional or negligent violations of the EU Regulation, which may reach EUR 50,000 for each regulatory offense. The legislation also amended the German Patent Act to require any patent application involving an invention that is based on, or involves the use of, biological material to include information on the geographical origin of that biological material.

Switzerland: In December 2015, the Federal Council adopted the "Nagoya Ordinance" to further implement user measures in the country. These measures require users to establish, through due diligence, that access to genetic resources was in accordance with a provider country's ABS regulatory requirements. Users must also notify the Federal Office of Environment of their compliance with this due diligence requirement when a product developed from genetic resources is commercialized or receives market authorization. Users who violate these provisions are subject to fines of up to 100,000 Swiss Francs and their products may not be authorized.

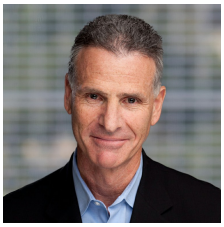
Compliance Is Critical

With the emergence of an international ABS system, any company, university, or research organization that accesses and utilizes non-human genetic resources for research and development should take actions to ensure full compliance. Indeed, the consequences of not fully complying may be draconian and should not be underestimated. In addition to being tarred in the international media as “biopirates,” those who have allegedly failed to comply with ABS requirements have been subject to civil and criminal enforcement actions brought by foreign government authorities. In July 2012, for example, Brazil reportedly fined 35 companies (including US companies) a total of $44 million based on claims that they violated the country's ABS requirements.

Government authorities and non-governmental organizations have also sought to invalidate patents arising from collection activities alleged to violate ABS provisions. To that end, a number of countries have adopted disclosure of origin requirements governing intellectual property rights to strengthen compliance with ABS requirements. At the same time, certain countries have been working within the World Intellectual Property Organization for many years to establish a new international agreement that would require, among other things, all patent applicants to disclose the origin of any genetic resources used in development of an invention and to provide evidence of compliance with the provider country's ABS requirements.

Although the United States has not signed or ratified the Nagoya Protocol, US companies and research organizations seeking to access and utilize genetic resources from other countries are subject to both provider and user measures adopted by the Parties to the Protocol. Accordingly, any company or research entity utilizing genetic resources should fully understand the ABS legal system and the extent to which it may impact their freedom to operate when researching, commercializing, and seeking protection of intellectual property rights for a product or process. And they should implement proactive compliance programs that adhere to a number of key operating principles to ensure compliance with the rapidly emerging global ABS regulatory system.

Authors



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