SIDLEY

The Nagoya Protocol's Impact on Research and Development

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Summary

The life sciences industry's relationship with biodiversity is longstanding, and plants are a major source for medicinal products of natural origin.

The United Nations' Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (**Nagoya Protocol**) is a supplementary agreement to the Convention on Biological Diversity (**CBD**). The Nagoya Protocol aims to promote a transparent and effective sharing of the benefits arising from the use of genetic resources. It applies to companies that conduct research and development (**R&D**) on biological materials of non-human origin, i.e., any material of plant, animal, microbial, or other biological origin (so-called **genetic resources**) and regulates the access and utilization of such resources.

Within the life sciences industry, aspects of vaccines, compounds, diagnostic materials, research tools, and production processes may all fall under the scope of the Nagoya Protocol. The Nagoya Protocol could for example apply to the development of a vaccine against a pathogen originating in a contracting party, using that pathogen.

The Nagoya Protocol entered into force on 12 October 2014. It has now 127 Parties, including the EU, the EU Member States, the United Kingdom, and Switzerland.

Access and Benefit Sharing

The objective of the Nagoya Protocol is to implement the CBD's third objective, which is the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. To fulfil this objective, the Nagoya Protocol sets out core obligations for the Parties to implement measures in relation to the three following pillars:

1. **Access to genetic resources**: Parties *may* regulate access to genetic resources originating from their territories. In that case, access to genetic resources will be subject to the prior informed consent of the host Party providing such resources (the **provider**).

2. **Benefit-sharing of genetic resources**: Parties providing genetic resources *may* also require that benefits arising from the utilization of the genetic resources, as well as subsequent applications and commercialization, are fairly and equitably shared by the users. Such sharing must be upon mutually agreed terms. Benefits may be monetary (e.g., royalties) or nonmonetary (e.g., sharing of research results).

3. **Compliance**: Parties *must* monitor the use of genetic resources on their territory to ensure that companies comply with the access and benefit-sharing (**ABS**) rules where the genetic resources originated. For example, the EU has adopted such rules whereby companies based in the EU must prove that they comply with the ABS rules of the provider country. To that purpose, these companies must file a declaration stating compliance with applicable ABS rules before submitting an application for a marketing authorization to the European Medicines Agency (see Regulation 511/2014, Article 7). Switzerland has issued a Nagoya Ordinance which came into force on 1 February 2016. Its rules are similar to those in the EU but differ insofar as the declaration stating compliance doesn't have to be available before the application for a marketing authorization is submitted to Swissmedic but can be can filed until the end of the procedure. However, Swissmedic is to withhold its decision about a requested marketing authorization until the declaration of compliance is submitted in due form (Article 11 Nagoya Ordinance).

Fragmented Implementation

The Nagoya Protocol requires effective implementation at the national level. Since the adoption of the Nagoya Protocol, the volume of national implementing rules has proliferated. The determination of the applicable ABS rules therefore becomes increasingly complex, in particular if several national regimes are involved.

In view of the increasing number of national implementing rules, companies may wish to:

- Adopt standard operating procedures establishing processes to determine whether ABS rules apply in countries where they are accessing or using genetic resources, and, if so, applicable compliance mechanisms.
- Develop procedures for vetting partners to ensure they comply with applicable ABS requirements. For instance, working with trusted partners in countries that have adopted ABS rules is key to ensure compliance with internal procedures and regulatory requirements.
- Provide appropriate training to relevant employees and partners.
- Put in place an internal system to keep track of the genetic resources accessed by the company.

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The Nagoya Protocol calls for the establishment of mechanisms and processes which are likely to drive the costs incurred by life sciences companies during the R&D phase. Life sciences companies may therefore want to verify whether any ABS obligations apply to their business each time they conduct R&D involving nonhuman genetic resources.