

Restrictions Governing International Trade in Genetic Resources Move Closer to Adoption

SEPTEMBER 26, 2013

The European Parliament has approved a new Regulation to implement the "Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits from their Utilization" ("Nagoya Protocol" or "Protocol"). This Regulation is meant to govern a practice known as "bioprospecting"—the discovery and commercialization of products based on biological resources and associated traditional knowledge. If the Regulation is approved by the European Council, it will affect companies and organizations that access and utilize biological materials (including both genetic material and any naturally occurring derivative biochemical compound) occurring in the European Union ("EU"). The Regulation may impact both the development of, and intellectual property rights ("IPR") surrounding, an array of products, including pharmaceuticals, biotech products, agricultural products, nutritionals, supplements, cosmetics, perfumes and fragrances, industrial enzymes, and even raw biomass for renewable energy.

Any company or organization that either itself or through third parties utilizes genetic resources or naturally occurring biochemical derivatives should be aware of the following:

1. The Regulation applies to genetic resources over which EU States exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after entry into force of the Nagoya Protocol for the EU. All users will need to exercise due diligence to ensure that such resources have only been accessed with prior consent from the relevant government authority. The Regulation also applies to the benefits arising from the utilization of such genetic resources and to traditional knowledge associated with genetic resources. The Regulation would not apply to commodity trade in general.
2. Negotiations between the European Parliament and European Council are expected to be finalized in mid- to late November. If the Regulation is approved by the Council, EU Member States and the EU itself will be in a position to ratify the Nagoya Protocol. Those ratifications could bring the Protocol into force or move it much closer to becoming effective, which under any circumstance is expected no later than the fall of 2014. The Regulation, in turn, will become effective when the Protocol enters into force. Although the United States has not signed or ratified the Nagoya Protocol, US firms may be subject to the requirements of the EU Regulation and other nations' provisions implementing the

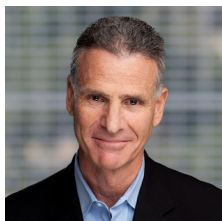
Protocol.

3. As the Protocol moves closer to entry into force, a number of countries and non-governmental organizations have stepped up pressure to amend the World Trade Organization's ("WTO") Agreement on Trade-related Aspects of Intellectual Property Rights ("TRIPS") so as to require disclosure of the origin of genetic resources and/or associated traditional knowledge in patent applications. Similar initiatives are being pursued within the World Intellectual Property Organization ("WIPO"). Some countries have already enacted domestic disclosure rules, although questions remain as to their consistency with TRIPS.
4. Other international regimes and domestic requirements governing particular types of genetic resources or specific geographic areas have been adopted or are being negotiated. This has made an already difficult compliance environment even more challenging, with companies being accused of engaging in "biopiracy" and subjected to criminal sanctions and monetary penalties. Stakeholders should understand these emerging international and domestic requirements, and take steps to reduce the risk of legal liability and reputational damage that may flow from an alleged violation of such regulatory regimes.

Download the full PDF of this alert for a broader description of the Nagoya Protocol, EU Regulation, and other regional and national efforts to implement the Protocol.

Read [Restrictions Governing International Trade in Genetic Resources Move Closer to Adoption](#).

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