

Nagoya Protocol on Bioprospecting Moves Closer to International Acceptance

Countries Take Steps to Regulate Access and Commercialization of an Array of Products

Many companies and universities obtain samples of plants, microbes and animals from biologically rich countries for research, investigation and development of new products. That research, referred to as “bioprospecting,” will be subject to much greater scrutiny under the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization*. Indeed, this new international agreement may impact research and commercialization of a broad array of products, including pharmaceuticals, biotech products, nutritionals, supplements, cosmetics, perfumes and fragrances, enzymes, and industrial chemicals.

Adopted in October 2010 under the auspices of the United Nations Convention on Biological Diversity (“CBD”), the Nagoya Protocol seeks to further implement that Convention’s provisions governing access to genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such resources. To that end, the Protocol calls upon each nation to establish clear rules and procedures requiring companies to obtain prior informed consent before accessing a country’s genetic resources. The Protocol also reinforces the authority of each country to require companies to enter into benefit-sharing agreements, based on mutually agreeable terms, stemming from the use of such resources. And, each nation must strengthen its efforts to enforce such agreements and ensure compliance by cooperating with other signatories of the Protocol.

Following a special meeting at the United Nation on September 20, 2011, 54 countries have now signed the agreement. More countries are expected to sign the Protocol later this week. The Protocol will enter into international force after it has been ratified by 50 countries. With increasing acceptance by the international community, the Protocol is expected to enter into force by October 2012. Various nations are not waiting until then, however. Some have already moved towards taking unilateral steps to regulate research and commercialization of bioactive compounds, natural products and their derivatives.

The consequences of failing to comply with a country’s domestic access requirements, the Nagoya Protocol and CBD may be draconian. In addition to being branded in the international media as a “biopirate,” those who fail to comply may be subject to litigation challenging the right to commercialize a product. Moreover, patent applications may not be granted, or may be subject to invalidity claims, due to “disclosure of origin” provisions within certain patent laws. A lack of clarity surrounding each country’s laws, and absence of understanding of such requirements among local collectors despite contrary representations, exacerbates the situation and increases the likelihood of negative consequences.

Any company or university which accesses another country’s biological resources for commercial research should understand the access and benefit-sharing provisions of the source country, Nagoya Protocol and CBD. At the same time, it will be critical for firms to determine that their ongoing activities are consistent with these agreements and each nation’s domestic implementation of legislation and rules. That assessment should confirm that access to biological samples either by the company, or its subcontractors, is being properly obtained from the country. An assessment should also evaluate the need for benefit-sharing agreements and the extent to which any intellectual property may be challenged under the Nagoya Protocol, CBD or foreign patent laws.

Ropes & Gray has conducted biodiversity compliance assessments for clients and, through its international network of law firms in more than 100 countries, is well-positioned to assist on international and national patent and biodiversity issues. For additional information, please contact Bruce Manheim at Ropes & Gray, 202-508-4696, bmanheim@ropesgray.com