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Client Alert

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Restrictions Governing International Trade in Genetic Resources Move Closer to Adoption

European Parliament Approves a New Regulation to Implement and Ratify the Nagoya Protocol; Other Nations Consider Legislation to Regulate "Bioprospecting" and Ban "Biopiracy"

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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.

A broader description of the Nagoya Protocol, EU Regulation, and other regional and national efforts to implement the Protocol follows below.

The EU Regulation to Implement the Nagoya Protocol

The Nagoya Protocol was adopted in October 2010 to further implement the access and benefit sharing ("ABS") and prior informed consent ("PIC") provisions of the UN Convention on Biological Diversity ("CBD") as they apply to the utilization of a country's genetic resources. Under the CBD and the Protocol, the term "genetic resources" is defined to include genetic material or any naturally occurring derivative biochemical compound. The Protocol follows the adoption of guidelines ("Bonn Guidelines") by the CBD parties in 2002 to implement these provisions. It authorizes each country to require users to obtain permission on mutually agreeable terms ("MAT") from the appropriate government authority before accessing and utilizing a country's genetic resources. The Protocol also reaffirms the authority of each country to require companies to share any benefits stemming from the use or commercialization of such resources and associated traditional knowledge through the adoption of ABS agreements. To date, 92 countries have signed the Nagoya Protocol and 20 have ratified it. The Protocol will enter into force on the 90th day after it has been ratified by 50 countries.

Many nations are currently taking steps to ratify and bring this emerging international legal framework into force. To that end, on September 12, 2013, the European Parliament approved a Regulation ("Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union").[1] If approved by the European Council, the Regulation would establish the following new restrictions and obligations with respect to access and utilization of genetic resources in the EU and associated traditional knowledge:

- It will be unlawful for any person to "utilize" illegally acquired genetic resources. Utilization includes research and development of the genetic or biochemical composition of genetic resources, including through the application of biotechnology. Those who violate this prohibition will be subject to fines, immediate suspension of specific use activities, and confiscation of illegally acquired genetic resources.

- Users will need to ensure that genetic resources are only accessed with prior informed consent from the relevant government authority of the source country and that such access and utilization are based on mutually agreed terms that contemplate fair and equitable sharing of benefits. Users will be required to maintain all information and documents relevant to compliance under the Regulation.

- All users will need to exercise due diligence to confirm that genetic resources were accessed with prior informed consent and on the basis of mutually agreed terms. Each user will also need to declare that it has fulfilled this requirement at various points in the chain of activities, including upon receipt of research funding, applying for intellectual property rights, and seeking market approval. Such information will be summarized by the European Commission and posted on the Internet.

[1] The European Parliament must still adopt the resolution accompanying the legislation before the proposal is passed on to the European Council. The final vote will not affect the content of the Regulation.

- Users will only be permitted to transfer genetic resources to other users in accordance with an internationally recognized certificate of compliance (or prior informed consent) and mutually agreed terms. To the extent that subsequent users intend to use the genetic resources under conditions not included in the prior terms, they will need to renegotiate the terms of such use with the authorities from the source country.

- The Regulation declares that it applies to new acquisitions or new utilizations that take place or commence after entry into force of the Protocol. This is significant because many genetic resources are currently housed in *ex situ* collections in Europe. To the extent that such resources are utilized after the Protocol enters into force, users will still be subject to the Regulation and ABS provisions even though such resources may have been collected or obtained before the Protocol entered into force.

- The Regulation recites the need for a system of EU-registered collections to be set in place. Such collections would only supply samples of genetic resources to third persons with documentation providing evidence of legal acquisition. Member States would verify if a collection meets the requirements for recognition as an EU-registered collection. Users that acquire a genetic resource from an EU collection would be considered to have exercised due diligence in terms of seeking necessary information.

- The Regulation empowers the Commission to establish rules, which would require benefit-sharing to be at least at the level of best practice in the sector concerned and would establish conditions for the sharing of non-monetary benefits. Users are required under the Regulation to keep information relevant to ABS for 20 years after the end of the period of utilization or subsequent commercialization.

- An EU platform will be established. Member States that plan to adopt rules governing access to their genetic resources will need to conduct an impact assessment and submit the results to the EU platform. The platform is meant to streamline access conditions at the EU level by focusing on the design of PIC and ABS regimes established in Member States.

- The Regulation will require the European Commission to work with the European Patent Office and the WIPO to ensure that references to genetic resources and their origins are included in patent registrations. The question of enforcement of the CBD and Nagoya Protocol through the WIPO and TRIPS agreement, as well as the consistency of particular disclosure, procedural and other requirements with TRIPS and IPR regimes, have been the subject of considerable debate during the past few years.

- The Regulation does not apply to genetic resources for which ABS is governed by a specialized international instrument to which the EU is a party. Also, the Regulation does not apply to genetic resources from a country of origin which decides not to adopt domestic access rules in accordance with the requirements of the Protocol in place or to commodity trade in general.

Under Article 294 of the Treaty on the Functioning of the European Union ("TFEU"), the Regulation may become effective in one of two ways. The European Council could approve the Parliament's proposal with no further action required. Under this scenario, approval by the Council is on a "take it or leave it" basis and no changes to the Parliament draft would be made. Alternatively, if the Council does not agree with the Parliament's position, the bill would go into a second reading. With this approach, the Council may suggest changes to the bill, and the Parliament would need to vote on them. If the Parliament fails to act within three months, the bill would be adopted with language corresponding to the Council's proposal. Negotiations between the European Parliament and the Council are expected to begin shortly and to conclude in mid- to late November. When the Regulation does receive final EU-level approval by the European Council, both the EU and its Member States may ratify the Nagoya Protocol itself. The Regulation would then become effective with entry into force of the Nagoya Protocol, which is expected no later than the fall of 2014.

An Emerging International Regulatory Scheme

The EU Regulation is just one example of multilateral efforts to establish a new regulatory scheme for genetic resources that embodies the ABS and PIC principles set forth in the CBD and the Nagoya Protocol. For example, the International Treaty on Plant Genetic Resources for Food and Agriculture (the "Plant Treaty") contains provisions governing access and benefit sharing of genetic resources of certain food crops listed in an annex to the agreement. The parties to the UN Law of the Sea Convention and the Antarctic Treaty are considering similar measures to govern genetic resources occurring within the oceans and Antarctica, respectively. And, beyond the EU, other countries have adopted regional agreements to govern access to and benefit sharing involving genetic resources that cross multiple borders (e.g., Decision 391: Common Regime on Access to Genetic Resources, Andean Pact; Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore within the Framework of the African Regional Intellectual Property Organization).

At the same time, to ensure compliance with such agreements, a group of countries represented by Brazil and India (and including Bolivia, Columbia, Cuba, Dominican Republic, Ecuador, Peru, Thailand and others) have been pressing for adoption of an amendment to the TRIPS agreement that would require the disclosure of the origin of genetic resources and/or associated traditional knowledge in patent applications. This initiative is also being pursued within the WIPO, where Switzerland and other countries have been campaigning for an amendment to the regulations of WIPO's Patent Cooperation Treaty.[2] In this context, various non-governmental organizations have asserted that patent offices in Europe, North America and Japan have allowed claims on "biopirated" genetic resources and traditional knowledge.

At the domestic level, numerous countries are currently moving to adopt their own requirements to implement and ratify the Protocol and other international agreements.[3] For example, India ratified the Protocol in 2012 on the basis of its National Biodiversity Act. Under that Act, the failure to gain approval from the country's National Biodiversity Authority for use or transfer of genetic resources may result in imprisonment for up to five years, fines, benefit sharing fees, royalties, and patent invalidation. Although Brazil has not yet ratified the Protocol, it has adopted an Executive Order and legislation (Provisional Act No. 2,186-16) to govern access to its genetic resources. That legislation provides for fines, invalidation of patents, seizure of products, suspension of product sales, and closure of businesses in the case of non-authorized use of genetic materials. Both India and Brazil, and many other countries, are reportedly considering additional measures to strengthen their authority to govern access to and benefit sharing of genetic resources, which would also include disclosure requirements in connection with patent applications.

An Increasingly Challenging Environment

With the emergence of these new requirements, it is critical for those accessing and utilizing genetic resources to understand and look inwards to ensure full compliance by company personnel and outside vendors. Indeed, with many countries already vigorously enforcing such requirements, the consequences of not fully complying may be draconian. In addition to being tarred in the international media as a "biopirate," those who have allegedly failed to comply may be subject to litigation brought by a government authority challenging the right to study and commercialize a product. Governmental authorities may also threaten criminal prosecutions. And any patent applications that non-complying companies file for products derived from genetic resources may not be granted or may be subject to invalidity claims in countries that have adopted "disclosure of origin" provisions in their patent laws.

There are numerous examples of such actions in the past several years. 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.[4] India's National Biodiversity Authority and non-governmental groups have repeatedly alleged that a large US company violated that country's ABS laws. Still other non-governmental

[2] See http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_23/wipo_grtkf_ic_23_4.pdf

[3] See http://www.cbd.int/abs/measures/default.shtml

[4] See http://www.scidev.net/global/biodiversity/news/brazil-fines-35-firms-us-44-million-for-biopiracy.html

organizations have alleged that a large nutritional products company improperly sought patents on South African plants without first obtaining consent from that government.[5] 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.[6]

Although the United States has not signed or ratified the Protocol or the CBD, US companies and researchers utilizing genetic resources occurring in foreign countries may be subjected to these requirements and enforcement actions. In that context, US firms and organizations may face legal issues cutting across several distinct areas, including compliance, international trade, international litigation, transactional and licensing arrangements, and protection of intellectual property rights. WilmerHale has assembled an interdisciplinary team of attorneys to assist clients on matters arising under this new framework, both at the international and domestic levels. Attorneys at the firm have conducted biodiversity compliance assessments, are very actively involved in international fora on trade issues (including TRIPS and the WIPO), and have focused on the issues surrounding protection of intellectual property, disclosure of origin provisions, and the adoption of ABS agreements.

[5] See http://ictsd.org/i/news/biores/76711/

[6] See http://www.evb.ch/en/p25017368.html

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