

Coming Soon: Paradigm Shift In Genetic Resources Regs

Law360, New York (October 28, 2013, 12:41 PM ET) -- It has been 20 years in the making, but a new regulatory scheme is quickly moving into force. This emerging regime may impact the development of, and intellectual property rights surrounding, an array of products, including pharmaceuticals, biotech products, agricultural products, nutritionals, supplements, cosmetics, perfumes and fragrances and industrial enzymes.

Companies whose products are derived from or include genetic material or biochemical derivatives of plants, animals, microorganisms and other nonhuman biological materials will need to be aware of these developments. Indeed, new requirements are rapidly being established at international, regional and national levels of government.

Although the U.S. has not ratified the international agreements that form the basis for these obligations, U.S. firms will be subjected to legislation and regulations adopted by various countries to implement this new regime.

The International Legal Framework

The Convention on Biological Diversity (CBD) entered into international force in December 1993. With 193 parties, the CBD is an almost universally accepted international agreement. The CBD marked a dramatic shift in the way that genetic and biological resources occurring in a country are treated from a legal perspective.

While such resources were previously considered common heritage belonging to all parties, the CBD provides that each nation maintains sovereign rights over its genetic and biologic resources. And, with that sovereignty, the CBD included access and benefit-sharing (ABS) provisions empowering each country to control access to, and share in any benefits arising out of the utilization and commercialization of, its genetic resources.

These ABS provisions broke new ground in international law and fundamentally altered the manner in which countries may regulate access to and utilization of their genetic resources by companies and researchers.

Two decades later, that fundamental paradigm shift embodied in the ABS provisions is now taking shape as many CBD parties move to ratify the Nagoya protocol on access to genetic resources and the fair and equitable sharing of benefits from their utilization. That agreement was adopted in October 2010 after six years of negotiations and is meant to spur more action than guidelines (Bonn guidelines) adopted by the CBD parties in 2002 to implement the ABS provisions.

The protocol reaffirms the authority of each country to require users to obtain permission before accessing and utilizing genetic resources and any biochemical derivative. Users must also share any benefits stemming from the commercialization of such resources with the source country.

To date, 92 countries have signed the protocol, and 25 have ratified it. The protocol will enter into force shortly after it has been ratified by 50 countries, which is expected in mid-2014.

Beyond the protocol, the parties to other international agreements have approved, or are currently considering, ABS provisions to govern particular types of genetic resources or specific geographic areas where such resources occur. For example, the International Treaty on Plant Genetic Resources for Food and Agriculture now contains ABS provisions that govern the use of certain food crops listed in an annex to that agreement.

The parties to the United Nations Law of the Sea Convention and the Antarctic Treaty are considering ABS measures to govern genetic resources occurring within the oceans and Antarctica, respectively. And, some countries in South America and Africa have adopted, respectively, regional agreements that regulate the utilization of genetic resources that cross multiple borders.[1]

At the same time, to ensure compliance with the ABS provisions in the CBD, the protocol and other multilateral agreements, a group of countries represented by Brazil and India (and including Bolivia, Columbia, Cuba, Dominican Republic, Ecuador, Peru, Thailand and others) are currently pressing for an amendment to the World Trade Organization's agreement on trade-related aspects of intellectual property rights (TRIPS) that would require disclosure of the origin of genetic resources and/or associated traditional knowledge in patent applications.[2]

The same principle is being advanced within the General Assembly of the World Intellectual Property Organization (WIPO), which, on Sept. 30, 2013, called for the development of an international legal instrument to ensure "effective protection of genetic resources, traditional knowledge and traditional cultural expressions." [3]

Implementation and Enforcement at the Domestic Level

Many nations and jurisdictions are now taking steps to bring this international legal framework into force through the adoption of domestic implementing requirements.[4] To that end, on Sept. 12, 2013, the European Parliament approved a new regulation to regulate access to and utilization of genetic resources occurring within the European Union ("Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union").

If approved by the European Council, the regulation would make it unlawful for any person to utilize illegally acquired genetic resources or associated traditional knowledge. All users will also need to exercise due diligence to confirm that genetic resources occurring in the EU were accessed and utilized properly.

India and Brazil have moved to implement the protocol by supplementing existing legislation. Those efforts are being watched closely by other biologically rich nations as they too consider measures to ratify the protocol.

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 and royalties.

Although Brazil has not yet ratified the protocol, it is relying on an executive order and legislation (Provisional Act No. 2.186-16) to govern access to its genetic resources. That legislation also provides for

finances, seizure of products, suspension of product sales and closure of businesses in the case of nonauthorized use of genetic materials.

Still, other nations have adopted regulations that broadly construe the scope of genetic resources subject to ABS requirements. The South African government, for instance, regulates “indigenous biological resources,” which are defined to include any chemical compounds and products obtained through the use of biotechnology that have been altered with genetic material or chemical compounds found in indigenous species.”[5]

Many countries and nongovernmental organizations are reportedly taking the position that ABS obligations apply to the utilization of genetic resources and biological materials that were collected long before the protocol was adopted or will enter into force.[6] This is important because many genetic resources from source countries have already been collected and are currently housed ex situ in collections around the world.

Finally, on the patent front, a growing group of nations have amended their laws to forbid the issuance of patents for inventions relying on illegally acquired genetic resources or associated traditional knowledge.

China’s patent law, for example, requires an applicant to disclose “the direct source and the original source of the genetic resources.”[7] If the applicant cannot document that such resources were accessed properly, the patent may not be granted.

Similarly, South Africa’s patent law provides that patents will not be issued unless the patent applicant “furnishes proof” of title or authority to make use of indigenous biological resources or traditional knowledge.[8] The draft EU regulation does not go that far, but it does call upon 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.

Operating within an Increasingly Challenging Environment

Although the protocol has not yet entered into force, many countries are already vigorously enforcing domestic ABS obligations. In July 2012, Brazil reportedly fined 35 companies (including U.S. companies) a total of \$44 million based on claims that they violated the country’s ABS requirements.[9] India’s National Biodiversity Authority and nongovernmental groups have alleged that a large U.S. company violated that country’s ABS laws.[10]

Other non-governmental organizations claim that a large nutritional products company improperly sought patents involving South African plants without obtaining consent.[11] And, indigenous groups have sought to invalidate patents involving a drug product, asserting that the applications were based on illegal misappropriation of traditional knowledge.[12]

As illustrated by these and other examples, foreign government authorities are targeting U.S. and European companies under laws governing access to and utilization of genetic resources. That will continue to be the case for U.S. companies even though the U.S. has not signed or ratified the protocol or the CBD.

U.S. firms are subject to these laws since jurisdiction is grounded in use of the country’s genetic resources — not the nationality of the company using such resources. As a result, U.S. organizations operating in this area will increasingly face legal issues cutting across a number of areas, including compliance, criminal investigations, international trade restrictions, transactional and licensing arrangements and protection of intellectual property rights.

To be sure, actions can still be taken to influence the direction of implementing actions, and there is still time to shape the debate at the international level on key issues. Periodically, the parties to the protocol sponsor meetings to exchange information and ideas about actions that are being taken to implement the agreement. These represent an opportunity to influence implementation of the protocol.

Similarly, negotiations on mandatory patent disclosure provisions continue under the TRIPS agreement and within the WIPO; they are not a done deal yet. And, by way of example, negotiations between the European Parliament and the European Council are expected to begin shortly, with early reports suggesting that the council may seek to soften the requirements of the final EU regulation.

But, it will also be critical for those utilizing genetic resources to look inwards and ensure full compliance by company personnel and outside vendors. The recent focus on implementation and ratification of the protocol has unquestionably made a difficult compliance environment even more challenging.

Stakeholders should secure an understanding of the evolving legal framework, both at the international level as well as on the domestic front. Indeed, as the protocol nears entry into force and various countries adopt implementing legislation, companies and researchers operating in this area should seriously consider developing policies and procedures that reduce the risk of legal liability, patent invalidation adverse publicity and reputational damage that may flow from an alleged violation of this new regime.

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[1] See 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.

[2] See http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm

[3] See <http://www.ip-watch.org/2013/09/30/wipo-assembly-approves-new-work-mandate-on-gr-tk-protection/>

[4] See <http://www.cbd.int/abs/measures/default.shtml>

[5] See <http://www.cbd.int/abs/measures/measure.shtml?id=7598>

[6] See <http://www.evb.ch/en/p25021511.html>

[7] See <http://www.cbd.int/abs/measures/measure.shtml?id=70393>

[8] See <http://www.cbd.int/abs/measures/measure.shtml?id=70818>

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

[10] <http://www.forbes.com/sites/williampentland/2011/08/12/india-sues-monsanto-over-genetically-modified-eggplant/>

[11] See <http://ictsd.org/i/news/biores/76711/>

[12] See <http://www.evb.ch/en/p25017368.html>

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