RESTRICTIONS GOVERNING INTERNATIONAL TRADE IN GENETIC RESOURCES ENTER INTO FORCE

BRUCE S. MANHEIM*
Partner, WilmerHale, Washington, DC

On 12 October 2014, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits from their Utilization ('the Protocol') entered into international force. The Protocol is meant to further an international legal framework to govern access to and utilisation of 'genetic resources', a term that has been broadly defined to include genetic material of actual or potential value, and any naturally occurring derivative compound thereof. As numerous countries take actions to implement the Protocol, companies and universities utilising genetic resources from plants, animals, bacteria and other organisms must be especially mindful of these emerging international and domestic requirements. Indeed, the Protocol may impact research and development of an array of products, including pharmaceuticals, biotech products, agricultural products, nutritionals, supplements, cosmetics, perfumes and fragrances, and industrial enzymes. At the same time, related international instruments may affect intellectual property rights surrounding such products.

The Convention on Biological Diversity and Other International ABS Agreements

The Convention on Biological Diversity ('the CBD') was opened for signature during the Earth Summit in 1992 and, to date, has been ratified by 194 countries. The CBD marked a dramatic shift in the way that genetic resources are treated from a legal perspective. Previously, such resources were considered the 'common heritage of mankind' and, therefore, available for all to access and use. The CBD, however, established that each nation maintains sovereign rights over genetic resources occurring within its geopolitical borders. And, with that sovereignty, each country was authorised under Article 15 of the CBD to 'control access to and share in any benefits arising out of the utilisation of its genetic resources'.[1] These access and benefit-sharing ('ABS') provisions broke new ground in international law, and fundamentally altered the manner in which countries regulate access to and utilisation of their genetic resources.

Following adoption of the CBD, the parties to other multilateral agreements established ABS requirements as well. 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.[2] Other countries have adopted regional agreements to govern access to and benefit-sharing involving genetic resources that cross multiple borders. These include Decision 391: Common Regime on Access to Genetic Resources, Andean Pact[3] and the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore within the Framework of the African Regional Intellectual Property Organization.[4] The parties to the UN Law of the Sea Convention and the Antarctic Treaty are considering measures to govern genetic resources occurring within the oceans and Antarctica, respectively.

Nonetheless, since adoption of these landmark ABS provisions in the CBD, many countries have struggled with implementation and enforcement of such requirements. In 2002, the parties adopted voluntary guidelines (the Bonn

* Bruce Manheim has assisted major US and European pharmaceutical, nutritional and biotech companies on compliance issues, internal compliance policies, and the development and negotiation of access and benefit-sharing agreements arising under the Biodiversity Convention and the Nagoya Protocol.

1) The term 'genetic resources' used in the CBD does not include human genetic material.

2) http://www.planttreaty.org/content/texts-treaty-official-versions.

3) http://www.cbd.int/abs/measures/measure.shtml?id=6110.

4) http://www.cbd.int/abs/measures/measure.shtml?id=73307.

Guidelines) to assist with the development of legislative, administrative or policy measures on ABS and negotiation of contractual arrangements between countries providing genetic resources ('Providers') and those who utilise such resources for research and commercial development ('Users'). Although the Bonn Guidelines were an important first step, they fell short of spurring implementation of the CBD's ABS provisions. Accordingly, in 2004, the parties agreed to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of effectively implementing the ABS provisions of the CBD. After six years of intense negotiations, that regime – the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits from their Utilization – was opened for signature on 11 February 2011.

The Nagoya Protocol

The Nagoya Protocol reaffirms the fundamental principle from the CBD that each state has sovereign rights over and control of its genetic resources. In exercising that authority, each country maintains core obligations under the Protocol.

Access Obligations

Each party must take measures to ensure that access to its genetic resources is subject to its prior informed consent ('PIC'). To that end, parties must establish fair and non-arbitrary rules and procedures that establish legal certainty, clarity and transparency. Those procedures must indicate how to apply for prior informed consent and they must provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time. When access is granted, these procedures must provide for the issuance of a permit or the equivalent thereof.

Benefit-sharing Obligations

Each party must adopt measures requiring that the benefits arising from utilisation of its genetic resources are shared in a fair and equitable manner and on the basis of mutually agreed terms ('MAT'). Utilisation is broadly defined to include research and development involving the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology. Biotechnology is, in turn, defined to mean any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Community Obligations

The Protocol calls on each party to take measures, in accordance with domestic law, to ensure that genetic resources and traditional knowledge ('TK') held by indigenous and local communities are accessed only with the prior approval and involvement of such communities and that access and benefit-sharing are based on mutually agreed terms. Although the Protocol does not itself define the term 'traditional knowledge', the CBD refers to TK as the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.

Compliance Obligations

Each party is obligated to support compliance with its domestic legislation and the regulatory requirements of other parties that provide genetic resources. To that end, parties must, among other things, cooperate in cases of alleged violations of another party's requirements. They must also take measures to monitor the utilisation of genetic resources after they leave the country by, for example, designating effective checkpoints at any stage of the value-chain: research, development, innovation, pre-commercialisation or commercialisation.

Institutional Obligations

Each party is required to designate a national focal point ('NFP') and competent national authority ('CNA') to serve as a contact for information, grant access or cooperate on issues of compliance. At the same time, each party must make certain information available to an ABS Clearing House established by the Protocol. Such information includes legislative, administrative and policy measures on ABS, information on the NFP and CNAs, and permits that have been issued allowing access to genetic resources.

National Implementation of ABS Requirements

To date, 91 countries have signed the Nagoya Protocol and 59 nations have ratified or acceded to the agreement.[5] With ratification, many nations and jurisdictions have adopted new regulatory measures or taken other steps to implement the foregoing provisions of the Nagoya Protocol.[6] For example, in April 2014, the European Parliament and the Council of the European Union adopted a new Regulation (Regulation No 511/2014) to regulate access to and utilisation of genetic resources. It obliges all users to exercise due diligence to ascertain that genetic resources and associated traditional knowledge have been accessed in accordance with all applicable legal requirements, and that any benefits are fairly and equitably shared in accordance with mutually agreed terms. The Regulation applies to genetic resources over which states exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol. The EU Regulation became effective with the entry into force of the Protocol, but several key provisions will enter into force a year later (Oct 12, 2015).

Elsewhere, 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.[7] 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 a Provisional Measure (MP 2.186-16) (Provisional Act No 2,186-16) and other authorities to govern access to its genetic resources.[8] The failure to comply with this MP may result in fines, confiscation of samples and products, suspension of the sale of products, closing down establishments, and suspension or cancellation of the registry, patent, licence or authorisation. Revisions of Brazil's ABS legislation are reportedly underway.

Still other nations have adopted regulations that broadly construe the scope of genetic resources subject to ABS requirements. For example, under its National Environmental Management Biodiversity Act, South Africa regulates all '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'. Moreover, some countries and non-governmental organisations are taking the position that the Protocol's ABS obligations apply to the utilisation of genetic resources and biological materials that were collected long before the Protocol was adopted or entered into force. This has become a key issue because many genetic resources from source countries have already been collected and are currently housed *ex situ* in collections around the world.

Enforcement of ABS Requirements

With adoption of these laws, many countries are vigorously enforcing their PIC and ABS requirements. As a result, any company or research entity seeking to access and utilise genetic resources must be careful to ensure full compliance with such requirements. Yet this may be quite difficult, since these foreign requirements are often difficult to discern and substantial uncertainty surrounds questions of community consent for use of its genetic resources and associated traditional knowledge. Nevertheless, the consequences of not fully complying may be draconian. In addition to being tarred in the international media as 'biopirates', those who have allegedly failed to comply may be subject to enforcement actions brought by a government authority challenging the right to study and commercialise a product. Governmental authorities may also threaten criminal prosecutions.

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 US $44 million based on claims that they violated the country's ABS requirements.[9] India's

5) To date, the following countries have ratified or acceded to the Nagoya Protocol: Albania, Belarus, Benin, Bhutan, Botswana, Burkina Faso, Burundi, Cambodia, Comoros, Côte d'Ivoire, Democratic Republic of Congo, Denmark, Dominican Republic, Egypt, Ethiopia, European Union, Fiji, Gabon, Gambia, Guatemala, Guinea, Guinea Bissau, Guyana, Honduras, Hungary, India, Indonesia, Jordan, Kenya, Lao People's Democratic Republic, Lesotho, Madagascar, Malawi, Mauritius, Mexico, the Federated States of Micronesia, Mongolia, Mozambique, Myanmar, Namibia, Niger, Norway, Panama, Peru, Rwanda, Samoa, Seychelles, South Africa, Spain, Sudan, Switzerland, Syrian Arab Republic, Tajikistan, Uganda, United Arab Emirates, Uruguay, Vanuatu, and Vietnam.

6) http://www.cbd.int/abs/measures/default.shtml.

7) http://nbaindia.org/content/25/19/1/act.html.

8) http://www.cbd.int/doc/measures/abs/msr-abs-br-en.pdf.

9) http://www.scidev.net/global/biodiversity/news/brazil-fines-35-firms-us-44-million-for-biopiracy.html.

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 organisations have alleged that a large nutritional products company improperly sought patents on South African plants without first obtaining consent from that government.[10] Elsewhere, indigenous groups along with several organisations 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.[11]

Another way in which parties are enforcing ABS requirements is through their patent laws. Some countries 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'. 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. Similar disclosure requirements can be found in the laws of other countries, including Brazil and India.

In this context, a number of countries are pressing for an amendment to the TRIPS Agreement that would establish an international requirement compelling the disclosure of the origin of genetic resources and/or associated traditional knowledge in patent applications. This initiative is also being pursued within the World Intellectual Property Organization (WIPO), where negotiations are underway to develop a new international instrument establishing a disclosure of origin requirement for all parties. A draft of the agreement would require each party to require patent applicants to disclose the source and country of origin of the claimed genetic resource and traditional knowledge and to provide relevant information regarding compliance with ABS and PIC requirements of the source country. In the event that an applicant fails to do so, its application may not be further processed or may be declined.

Conclusion

As illustrated by the foregoing examples, foreign government authorities are targeting US and European companies under laws governing access to and utilisation of genetic resources. That will continue to be the case as these authorities move to ratify and implement the Protocol. In this respect, it is important to emphasise that US companies and research centres may not escape these requirements even though the United States has not signed or ratified the Protocol or the CBD. Rather, US firms are subjected 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, US organisations 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 Nagoya 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. It will also be critical for those utilising 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 and, where applicable, even at the community level in particular countries. Indeed, as various countries adopt legislation and policies to implement the Protocol, 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.

10) http://ictsd.org/i/news/biores/76711/.

11) http://www.evb.ch/en/p25017368.html.