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Nations Press for International Restrictions to Govern Genetic Sequence Data

Efforts Are Underway in Various International Fora, Decisions May be Made Soon

Bruce S. Manheim


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A clash over access to and use of genetic sequence data (GSD) is currently brewing on several international fronts. To date, GSD has been routinely deposited in open-source databases such as GenBank of the National Center for Biotechnology Information, DNA Data Bank of Japan, and the European Nucleotide Archive. Access to GSD within these databases is typically free and unrestricted, as DNA Banks have not imposed conditions on those who access this information for research or commercial activities. That practice has advanced research and development in synthetic biology and other areas, but it is now being challenged at the international level.

Under international agreements established by the UN, Food and Agriculture Organization (FAO), and WHO, many nations are calling for access and benefit-sharing (ABS) requirements to govern GSD. These nations argue that users of genetic resources are avoiding their ABS obligations under these agreements by using GSD. To plug that loophole, they would require those accessing GSD to obtain permission and share the benefits arising from their activities. The debate is playing out across various venues covering different genetic resources, and it will have important and long term consequences for the synthetic biology industry.

Nonhuman Genetic Resources under the Biodiversity Convention

The UN Convention on Biological Diversity (CBD) authorizes each country to control access to and utilization of its nonhuman genetic resources. To implement these provisions, the CBD parties adopted the "Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits from their Utilization" (Protocol) in 2011. Under the CBD and Protocol, any organization seeking to utilize genetic resources for research and development activities must obtain "prior informed consent" (PIC) from the source country and, based on mutually agreed terms (MAT), share benefits arising from utilization of the genetic resources.

When the CBD was adopted more than two decades ago, the parties contemplated that the ABS provisions would apply to physical biological material. They did not anticipate how, if at all, the PIC and MAT requirements for ABS would cover GSD, particularly in a digital form. During the past three years, the parties have focused on that question and the extent to which GSD associated with genetic resources should be subject to ABS requirements under the CBD and Protocol. The issue has taken on great significance following a technical group's findings in 2015: that users may avoid their ABS obligations by gaining access to GSD from various sources, including pubic databases.

During the next 18 months, the CBD parties will take several key steps to address this issue. They will conduct a "fact-finding and scoping study"

which, based on input from stakeholders, will evaluate the conditions governing the use of GSD. A technical working group will also be convened to develop recommendations by early 2018 for the CBD's Subsidiary Body on Scientific, Technical, and Technological Advice—the scientific advisory body that provides recommendations to further implement the CBD. The CBD parties will then consider those recommendations and measures to address GSD at their next meeting in November 2018.

Plant Genetic Resources under the Plant Treaty

The FAO's "International Treaty on Plant Genetic Resources for Food and Agriculture" (Plant Treaty) established a multilateral system (MLS) to govern utilization of 64 crop and forage species. Under the MLS, national and international collections share common rules allowing for facilitated access to seeds and other materials from these species. Any user that accesses this collective pool of plant genetic resources to commercialize a product for food and agriculture must make fixed royalty payments to a benefit-sharing trust fund pursuant to a standard material transfer agreement (SMTA). Those payments are then to be used to support conservation and sustainable use of plant genetic resources.

The Plant Treaty entered into force in 2004 but, to date, no benefit-sharing payments have been made to the trust fund. In March 2017, a working group established by the parties to strengthen benefit-sharing under the MLS made similar findings to those reported under the CBD. Specifically, the group reported that GSD associated with plant genetic resources is published in open source public databases and third parties are increasingly accessing GSD to create new traits for crop and forage species. Yet, because those third parties have not been required to sign the SMTA, they have not made payments to or shared benefits with the MLS.

While the use of GSD is not the principal reason that payments have not been made to the MLS, the Treaty parties are nonetheless moving to address the issue in the broader context of fixing the MLS. Specifically, they are considering adoption of a subscription system that would require those who access plant genetic resources within the MLS to pay an up-front benefit-sharing fee for all end-use products. This would presumably not make it as important how the products were developed and if GSD was used for that purpose. That measure, along with revision of the SMTA to include GSD, will be considered when the parties next meet in October 2017.

Influenza Genetic Resources under the PIP Framework

The Pandemic Influenza Preparedness (PIP) framework was adopted by the WHO in 2011. Under this system, influenza viruses with the potential to cause a human pandemic are shared within a network of public health laboratories known as the Global Influenza Surveillance and Response System (GISRS). Access to influenza viruses by non-GISRS entities is subject to a "partnership contribution" and a material transfer agreement (SMTA 2) that requires users to share the benefits of access such as vaccines, diagnostics, and antivirals with WHO for use in countries that may need them.

The PIP framework is similar to the Plant Treaty in that it also creates a global pool of genetic resources and prescribes ABS rules to govern their use. As such, the framework is subject to the same challenges presented by third parties who bypass benefit-sharing obligations by using GSD from public databases. The PIP Advisory Group (PIPAG; a group that makes recommendations to improve the framework) has focused on this issue during the past four years. Following the issuance of a June 2016 report that identified "the optimal characteristics" of a system for handling GSD, the PIPAG made several recommendations for new measures that reflect a delicate balance.

On the one hand, the PIP AG recommended that GSD remains publicly accessible in sustainable databases to enable timely, accurate and accessible sharing of these data for pandemic risk assessment and rapid response. At the same, however, it called for expanding the dramework's definition of PIP biological materials to include expressly GSD. That revision would have the effect of imposing benefit-sharing obligations on third parties that use such information, even if it is publicly available. These recommendations and measures will be further considered when the WHO Assembly next meets in May 2017.

Marine Genetic Resources under the Law of the Sea Convention

With its entry into force in 1994, the UN Convention on the Law of the Sea (UNCLOS) established a global legal framework for activities on the world's oceans. During the past few years, the UNCLOS Parties have been considering adoption of a new agreement to govern the use of marine genetic resources in areas beyond national jurisdiction. To that end, the parties convened a preparatory committee (PrepCom) to develop substantive recommendations for such an agreement. Most recently, in April 2017, the PrepCom issued a nonpaper outlining the elements for such an agreement.

Those elements include an ABS mechanism to govern access to and utilization of marine genetic resources. The parties are divided, however, on the nature of that ABS system and the extent to which it would apply to GSD. Several countries, including Argentina, Brazil, and Costa Rica, emphasized that the system should capture GSD from marine genetic resources. Others, including Switzerland and Japan, suggested that the parties should not address the issue until it is resolved under the CBD. For its part, the US flatly opposed any benefit-sharing requirement to GSD from marine genetic resources.

In September 2017, the parties will decide whether to call for an intergovernmental conference to consider the text of an agreement to govern marine biodiversity in areas beyond national jurisdiction. In advance of these meetings, the parties will further consider the nature of an ABS system for ma-

rine genetic resources and the extent to which GSD associated with such resources should be subject to any ABS system under a new agreement. Accordingly, as with recent developments under the CBD, Plant Treaty and PIP framework, decisions relating to the use of GSD associated with another important category of genetic resources may be made soon.

Conclusion

As various nations consider application of international ABS requirements to GSD, research organizations and synthetic biology companies should closely follow these developments to determine how they may impact their use of GSD. Moreover, those accessing GSD should consider, if possible, the extent to which unilateral ABS agreements requirements may govern their use of such information. Deliberations at the international level have focused attention on this issue, and some countries (e.g., Brazil, Mexico) have taken the position that GSD from genetic resources originating in the country is subject to domestic ABS requirements. These countries may be especially vigilant in enforcing such requirements when products developed from GSD threaten to supplant or undercut natural products and traditional practices in the country. GEN

Bruce S. Manheim (bruce.manheim@wilmerhale.com) is a partner in the Strategic Response Group at WilmerHale in Washington, DC. Web: www.wilmerhale.com/strategic_response_counseling