The Potential Impacts of the Nagoya Protocol on Global Public Health Research

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The State Department is initiating a public process to consider the implications of Access and Benefit-Sharing (ABS) regimes for global health and biomedical research. The Federal Register Notice announcing this initiative can be found here. The State Department is interested in the impacts that implementation of the Nagoya Protocol may be having on international research collaborations, pathogen sample sharing, infectious disease research, pandemic and epidemic preparedness and response, medical countermeasure development efforts, and investor interest in vaccine development. The State Department is also requesting recommendations on what the World Health Organization (WHO) and other organizations can do to effectively protect public health equities in the context of the Nagoya Protocol and national-level ABS implementation.

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization was opened for signature in October 2010 and entered into international force on October 12, 2014. To date, it has been ratified by 118 countries; the United States has neither signed nor ratified the agreement. The Protocol was meant to establish a transparent legal framework to govern access to and utilization of genetic resources. It authorizes each country to require those seeking access to its genetic resources to first obtain permission to do so. The Protocol also authorizes each party to share in the benefits arising from research and commercialization of genetic resources. This is typically accomplished through negotiation of an ABS agreement between the party seeking access and the provider country.

Under the Protocol, the term "genetic resources" is defined to mean "genetic material of actual or potential value." “Genetic material” is, in turn, defined to mean "any material of plant, animal, microbial or other origin containing functional units of heredity." Collectively, these terms have been construed by most of the Protocol parties to include human pathogens, such as bacteria, fungi and viruses. As a result, the use of pathogens for public health purposes is subject to the ABS requirements and procedures of individual countries. That is potentially problematic since the development of vaccines and other medical products to address urgent global health threats could be substantially delayed by the need for ABS agreements between manufacturers and countries. The negotiation of an ABS agreement is often a protracted and challenging process.

This problem is exacerbated by the position of many of the Protocol parties that the term "genetic
resources” includes “digital sequence information” (DSI) of pathogens—that is, the genetic sequence data of viruses, bacteria and fungi in a digital format. The US, European Union and Japan have consistently argued that the Protocol only applies to tangible biological materials. But many other countries, including Brazil, Ethiopia, India and Malaysia, assert that the Protocol also applies to information from genetic resources, including DSI. In their implementing legislation for the Protocol, these countries and others are applying ABS requirements to DSI from pathogens. This includes DSI that has been deposited in GenBank in the US, the Nucleotide Archive in the EU and Japan’s DNA Data Bank.

In light of the potential impacts that the Protocol may have on the development of vaccines and other medical products, WHO is considering adoption of an alternative ABS system to govern the sharing of pathogen genetic materials. The Protocol exempts genetic resources from its requirements if such materials are subject to a “specialized international access and benefit-sharing instrument.” One such agreement that could be expanded is WHO’s Pandemic Influenza Preparedness (PIP) Framework. It provides for global sharing of pandemic influenza viruses within a network of public health laboratories. Organizations and companies outside of this network may also access this pool of viruses after making a partnership contribution to and signing a material transfer agreement with WHO, in which they agree to share benefits.

To enhance its engagement with WHO and bodies of the United Nations on these and other ABS matters, the State Department has specifically invited stakeholders to provide examples of (a) monetary or non-monetary benefits to the global public health system that are facilitated by international sharing of pathogens, biospecimens, pathogen genetic sequence data and/or relevant metadata; (b) influenza-specific issues and examples that could affect global influenza pandemic preparedness and response or efforts to combat seasonal influenza; and (c) non-ABS challenges of and barriers to sharing pathogens internationally or that otherwise have significant implications for global pandemic or epidemic preparedness and response efforts that might merit additional attention or analysis.

The State Department will hold at least two public meetings to discuss these issues. The first of these meetings will take place on June 25, 2019, and the second will be on September 20, 2019. Both meetings will be held at the State Department in Washington, DC. Interested parties may attend these meetings and/or submit written comments to the docket at regulations.gov (DOS-2019-0016). These submissions will be considered periodically by the State Department beginning on July 10, 2019. Any future meetings will be announced at https://www.state.gov/bureaus-offices/under-secretary-for-economic-growth-energy-and-the-environment/bureau-of-oceans-and-international-environmental-and-scientific-affairs/office-of-international-health-and-biodefense/.

WilmerHale closely follows international developments under the Nagoya Protocol and other global ABS agreements, including WHO’s PIP Framework and the International Treaty on Plant Genetic Resources. The firm also tracks the efforts of individual countries to establish and enforce implementing legislation for the Protocol, and it assists clients in the negotiation of ABS agreements with provider countries. In 2016, WilmerHale secured the first Internationally Recognized Certificate of Compliance issued to a US entity under the Protocol on the basis of ABS
agreements negotiated with the foreign government and an indigenous community.

For more information on the State Department initiative or other matters involving the Nagoya Protocol and ABS issues, please contact Bruce S. Manheim.

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