VIRAL SOVEREIGNTY AND TECHNOLOGY TRANSFER

In the global infectious-disease research community, there has long been uncertainty about the conditions under which biological resources may be studied or transferred out of countries. This work examines the reasons for that uncertainty and shows how global biomedical research has been shaped by international disputes over access to biological resources. Bringing together government leaders, World Health Organization officials, and experts in virology, wildlife biology, clinical ethics, technology transfer, and international law, the book identifies the critical problems – and implications of these problems – posed by negotiating for access and sharing benefits, and proposes solutions to ensure that biomedical advances are not threatened by global politics. Written in accessible, nontechnical language, this work should be read by anyone who sees global health and biomedical research as a priority for international lawmakers.

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Viral Sovereignty and Technology Transfer

THE CHANGING GLOBAL SYSTEM FOR SHARING PATHOGENS FOR PUBLIC HEALTH RESEARCH

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Contents

Maps

Tables

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Preface

This is a book about how the regulation of biomedical research has been shaped by global trends in "access and benefit sharing," a phrase used specially to describe the distribution and redistribution of global wealth in the form of countries' biological and genetic endowments. Its contributors are national and global experts on the changing ways that biological samples are accessed, genetic sequence data obtained, pathogens transferred, and research benefits, including intellectual property rights, shared. For most of the twentieth century, inquiries into the nature of access to biological resources and the distribution of research benefits were rare and peripheral. Scientists largely based in Europe and North America enjoyed relatively easy access to biological samples in the form of fieldwork undertaken directly in foreign countries and/or conveyance from colleagues and affiliates abroad. Less commonly, scientists based in Europe or North America might work through an "annexed site," the physical presence of an institution, university, or laboratory operating under a foreign license. The "benefits" of research were coextensive with the scientific endeavor itself – more knowledge was produced, informing the next steps of the research process. The distinction between knowledge that resulted in consumer or patient products and knowledge that did not was blurry or nonexistent.

As the twentieth century neared its end, two long-running trends in international law converged on the field of global biological research: 1) growing concern for biodiversity losses in primarily tropical, low- or middle-income countries, and 2) increasing regard for biological resources as part of the "technology transfer" debates undertaken through the United Nations over the course of the 1960s and 1970s. In 1972, the UN held the first of many global conferences, on the Human Environment, at Stockholm, Sweden.[1] In the decade after the 1972 conference, scientists and nongovernmental organizations had elevated the issue of biodiversity as an urgent environmental issue.[2] While ecosystem collapse was identified as a potential problem in multiple regions, the threats to rainforests in the Amazon

[1] Roger Coate, *Civil Society as a Force for Peace*, 9(2) Int'l. J. Peace Studies 57–86 (2004).
[2] D. H. Janzen, *The Future of Tropical Ecology*, 17 Annual Review of Ecology and Systematics 305 (1986); National Research Council (US); M. J. Novacek, *Engaging the Public in Biodiversity Issues*,

basin dramatically illustrated the rapid loss of known, unknown, and potentially crucial biological resources.[3] In 1987, the governing council of the United Nations Environment Programme resolved to create a working group to explore the possibility of developing a legally binding treaty to protect biological resources.[4] In 1991, formal multilateral negotiations began on a Convention for Biological Diversity.

These preparatory meetings resulted in the 1992 UN Conference on Environmental and Development (or "Earth Summit") held in June 1992 in Rio De Janeiro, the outcomes of which included the Convention on Biological Diversity (CBD), the UN Framework Convention on Climate Change, and the UN Convention to Combat Desertification. The CBD traced a direct line to the 1962 United Nations General Assembly's Declaration on Permanent Sovereignty over Natural Resources, which asserted that it was the inalienable right of each state to handle natural resources as they saw fit and that any profits resulting from the use of these resources should be shared "between investors and the recipient state."[5]

Article 15 of the CBD required "fair and equitable sharing of benefits arising out of the utilization of genetic resources," a phrase that gave rise to a great deal of uncertainty even as it shaped national "bioprospecting" laws.[6] Article 16 committed countries participating in the treaty (now nearly all countries in the world) to "take legislative, administrative or policy measures . . . in particular those that are developing countries, which provide genetic resources *are provided access to and transfer of technology which makes use of those resources*, on mutually agreed terms, including technology protected by patents and other intellectual property rights . . ."[7] The Convention on Biological Diversity (and the negotiations leading to it) thus paved the way for the transfer of biological resources to take place through formal mechanisms, often contracts for foreign investment or material transfer agreements, regulated by governments, rather than through informal sharing through scientific networks.[8]

In 1964, developing countries formed the United Nations Conference on Trade and Development (UNCTAD) in order to pursue trade-related development policies.[9] UNCTAD aimed to "maximize the trade, investment and development opportunities

in The Light of Evolution: Volume II: Biodiversity and Extinction (J. C. Avise, S. P. Hubbell, F. J. Ayala eds.) (2008). Available from: www.ncbi.nlm.nih.gov/books/NBK214874/.

3 Michael J. Heckenberger, J. Christian Russell, Joshua R. Toney & Morgan J. Schmidt, *The Legacy of Cultural Landscapes in the Brazilian Amazon: Implications for Biodiversity*, 362 Philosophical Transactions: Biological Scis. 197, 197 (2007).

4 UNEP Resolution 14/26, adopted in 1987.

5 Permanent Sovereignty over Natural Resources, G.A. Res. 1803, U.N. GAOR, 17th Sess. Supp. No. 17. U.N. Soc. A/5127, 15 (1962); Stockholm Declaration, G.A. Res. 2998, U.N. Doc. A/CONF/48/14 (Dec. 15, 1972).

6 Thomas Kursar, *What Are the Implications of the Nagoya Protocol for Research on Biodiversity?*, 61(4) BioScience 256–57 (2011).

7 Bonn Guidelines Paragraph 43 (emphasis added).

8 Sam Foster Halabi, *Multipolarity, Intellectual Property, and the Internationalization of Public Health Law*, 35 Mich. J. Int'l. L. 715 (2014).

9 John Toye, UNCTAD at 50: a Short History 3 (2014).

of developing countries and assist them in their efforts to integrate into the world economy on an equitable basis."[10] Shortly after its formation, UNCTAD began to focus on technology transfer as a part of this mission.[11]

In general, technology may be transferred through patent licensing, joint ventures, research cooperation, technology servicing, foreign direct investment, technology sharing agreements, and training.[12] The CBD quickly provided a pathway for global biological research and technology transfer to become closer partners. Informed by CBD principles (although before the text was finalized), US pharmaceutical firm Merck entered into an agreement with the government of Costa Rica, under which the National Biodiversity Institute (INBio), a nonprofit scientific organization created by the government of Costa Rica, would provide 10,000 samples of plants, animals, and soil to Merck. Merck enjoyed the exclusive rights to study these samples for two years, and retained the patent rights on drugs developed using the samples. In return, Merck agreed to pay INBio $1 million as well as to transfer $130,000 worth of laboratory equipment.[13] The agreement also specified royalties to be paid to the Costa Rican government's Ministry of Natural Resources.[14] Many countries adopted "bioprospecting" legislation that tied permission for biological research to technology transfer including the involvement of local scientists and the sharing of resulting benefits or intellectual property rights.[15]

These developments quickly impacted research specific to animal and human health. The 1980s and early 1990s witnessed the emergence of new infectious diseases like HIV as well as the resurgence of older diseases like cholera. In 1995, shortly after the finalization of the CBD, the World Health Assembly, the governing body of the World Health Organization, instructed WHO's Director General to revisit the International Health Regulations (1969) – which only covered cholera, plague, and yellow fever – because they neglected "the emergence of new infectious agents" and failed to provide for an adequate response of those that were covered.[16] The World Health Assembly attributed these failures to the erosion of barriers

[10] DN Dwiveldi, International Economics: Theory and Practice 464 (2013).

[11] UNCTAD, Second Session of the United Nations Conference on Trade and Development, second session(UNCTAD II). 31 January–29 March 1968. New Delhi (India) 272 available at http://unctad.org/en/Docs/td97vol1_en.pdf; Peter Drahos, Global Governance of Knowledge: Patent Offices and Their Clients xiv (2010).

[12] Hiroko Yamane, Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines 52 (2011).

[13] MD Coughlin Jr., *Using the Merck-INBio agreement to clarify the Convention on Biological Diversity*, 31(2)Columbia Journal of Transnational Law 337–75 (1993), available at www.ciesin.org/docs/008–129/008–129.html.

[14] *Id.*

[15] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 8, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS].

[16] World Health Organization. Revision Process of the International Health Regulations. Available at: www.who.int/ihr/revisionprocess/revision/en/index.html

between goods and people.[17] The IHR revision process overlapped with negotiations over technology transfer in the global free trade regime.[18] In 2003, the outbreak of SARS facilitated the 2005 revisions.[19]

The IHR (2005) was expanded to encompass the detection and prevention of all infectious diseases.[20] Their scope was broadened "to include any event that would constitute a public health emergency of international concern."[21]

> The Regulations now encompass public health risks whatever their origin or source (Article 1.1), including: (1) naturally occurring infectious diseases, whether of known or unknown etiological origin; (2) the potential international spread of non-communicable diseases caused by chemical or radiological agents in products moving in international commerce; and (3) suspected intentional or accidental releases of biological, chemical, or radiological substances.[22]

Acknowledging the importance of communication and cooperation to successful detection and prevention of communicable diseases, States Parties are obligated to "develop the means to detect, report, and respond to public health emergencies . . . [and] establish a National IHR Focal Point (NFP)[23] for communication to and from WHO . . ."[24]

While the IHR (2005) did not directly address research furthering their purpose (e.g. research into animal and human health), the concepts of "communication" and "cooperation" inevitably implicated that research. On the one hand, the spirit of the IHR encouraged open discovery and sharing of research into diseases, diagnostics, therapeutics, and vaccines that might touch and concern IHR components like detection, surveillance, communication, and response. However, some of the most significant pathogens specifically named in Annex 2 of the IHR (e.g. Ebola, influenza, SARS) necessarily involved research using genetic resources covered by the

[17] Rebecca Katz & Julie Fischer, *The Revised International Health Regulations: A Framework for Global Pandemic Response*, 3 Global Health Governance, 1, 2 (2010), available at http://blogs.shu.edu/ghg/files/2011/11/Katz-and-Fischer_The-Revised-International-Health-Regulations_Spring-2010.pdf. The threat of the Ebola virus and the emerging HIV/AIDS crisis (among other viruses) were major factors the global community considered when advocating revisions to the existing IHR. *Id.*

[18] David Fidler, The Revision of the IHR, ASIL Insights (April 2004) available at www.asil.org/insigh132.cfm

[19] Katz & Fischer, *supra* note 17, at 2.

[20] The stated purpose is to "prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade." *International Health Regulations (2005)*, World Health Organization 1 (2005).

[21] Katz & Fischer, *supra* note 17, at 2.

[22] Fidler, *supra* note 18.

[23] The NFP is a "national centre, established or designated by each State Party [and] must be accessible at all times for IHR (2005)-related communications with WHO." *International Health Regulations (2005): Toolkit for Implementation in National Legislation*, World Health Organization 1, 7 (2009), available at www.who.int/ihr/NFP_Toolkit.pdf. As of July 2009, 99 percent of all States have established an NFP.

[24] Katz & Fischer, *supra* note 17, at 4.

CBD including Article 15 on access and benefit sharing and Article 16 on technology transfer.

In late 2006, the latent tension between sharing data relevant for outbreak response and asserting ownership over pathogens became manifest. Indonesia withheld samples of a highly infectious avian influenza strain from the World Health Organization on the basis that while free sharing of biological resources was expected, sharing of resulting products, especially influenza vaccines, was not.[25] Citing the CBD as a primary legal basis for their decision, the government interpreted the IHR (2005) to apply only to sharing of public health information, not biological materials.

In 2010, the Conference of the Parties to the CBD adopted the voluntary, but binding, Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol) which requires researchers (whether commercial or nonprofit) interested in genetic resources to develop plans to obtain the consent of the states where those resources originate and to share benefits associated with their utilization (access and benefit sharing). The treaty became effective in 2014 and has propelled discussions in the research and public health communities about meanings and best practices with respect to the objectives of the scientific research process, the equitable considerations of the CBD and Nagoya Protocol, and, of course, public health needs. If a country's genetic resources are crucial to developing diagnostics, therapeutics, and vaccines against a public health threat, what conditions, if any, may it impose on access to those resources? How can negotiations over access and benefit sharing be reduced in time and expense for both emergency and nonemergency situations?

It is these questions this book aims to answer. Writing as members of the Global Virome Project's Ethical, Legal, and Social Implications Working Group and as scholars of international public health law and policy, we convened, with the support of the O'Neill Institute for National and Global Health Law at Georgetown University and the National Institute for Allergy and Infectious Diseases of the US National Institutes of Health, national, regional, and international leaders on the complex intersection between sovereign control over resources, technology transfer, and the needs of public health researchers. The result is, we believe, the first sustained scholarly contribution to this topic, and one we hope will guide researchers, policymakers, legislators, and regulators.

[25] David Fidler, *Influenza Virus Samples, International Law, and Global Health Diplomacy*, 14(1) Emerg Infect Dis. 88–94 (2008).