Introduction

Viral Sovereignty, Technology Transfer, and the Changing Global System for Sharing Pathogens for Public Health Research

Sam Halabi and Rebecca Katz

The free flow of biological resources, including pathogens, and the knowledge generated by those studying them, have generated some of the most important diagnostics, therapeutics, and vaccines that have saved billions of lives worldwide. The World Health Organization (WHO)'s Global Influenza Surveillance and Response System, GISRS (formerly Global Influenza Surveillance Network), which connects influenza samples from all over the world to reference laboratories, researchers, and vaccine manufacturers, has generated seasonal and pandemic flu vaccines that have saved hundreds of thousands of lives.[1] GISRS has performed this globally critical function since 1957.[2] Indeed, it is not HIV/AIDS nor noncommunicable diseases like cancer, diabetes or heart disease that have threatened large populations in developing countries – it is primarily influenza and other vaccine-preventable diseases.[3] The development of some vaccines, notably influenza, depends on biological resources in low- and middle-income countries being made available to researchers, organizations, governments, and pharmaceutical firms in the major industrialized countries.[4]

[1] CDC, *CDC Study: Flu Vaccine Saved 40,000 Lives During 9 Year Period*. Available at: www.cdc.gov/flu/news/flu-vaccine-saved-lives.htm.

[2] Jerome H. Reichman, Paul Uhlir, and Tom Dedeurwaerdere, Governing Digitally Integrated Genetic Resources, Data, and Literature: Global Intellectual Property Strategies for a Redesigned Microbial Research Commons, 44 (2016).

[3] Christopher Ingraham, *In 2013, Measles Killed More Kids Than Car Accidents or AIDS*, Wash. Post (Feb. 25, 2015) available at www.washingtonpost.com/blogs/wonkblog/wp/2015/02/25/in-2013-measles-killed-more-kids-than-car-accidents-or-aids/. ("Measles killed 82,100 children under age 5 in 2013, ranking the disease at No. 7 on the list of the top causes of child death, according to recent statistics from the Global Burden of Disease study published in the Lancet. Lower respiratory infections like pneumonia were the number one killer, followed by malaria, diarrhea, nutritional deficiencies, congenital defects and meningitis. More small children died from measles in 2013 than died from drowning, road injuries or aids.")

[4] Eileen Kane, *Achieving Clinical Equality in an Influenza Pandemic: Patent Realities*, 39 Seton Hall L. Rev. 1137, 1143 (2009). ("The most significant pharmaceutical interventions that could be available in a viral pandemic are drawn from two distinct approaches: the administration of vaccines, which present a whole or partial virus to a potential host in order to generate an immune response that will be

In many ways, the importance of this volume is illustrated by the threat influenza pandemics pose, and the structures the world has put in place to prepare for them. Seasonal and pandemic influenza vaccines are possible in significant part because developing countries share influenza samples with GISRS, even though their populations have not historically received a proportionate benefit of resulting vaccines or other medical countermeasures.[5] Yet influenza pandemics have typically originated in low- or middle-income states like China, Indonesia, Mexico, and Vietnam. These states must therefore be willing to share disease samples and biological material relevant to risk assessment, risk management, disease research, and vaccine development.[6] Access to viruses is crucial to the development of vaccines and other forms of treatment and the WHO's system allows countries to effectively "coordinate surveillance efforts" for influenza outbreaks.[7] Through the GISRS, national influenza centers (NIC) submit local virus samples to the WHO for monitoring and research.[8] NICs also provide epidemiological information accessible to all participating laboratories and, in turn, may share samples to develop vaccines and other therapeutics.[9]

This system is less formal but nevertheless crucial for other infectious diseases. Sampling and transfer of human immunodeficiency virus (HIV) has been essential to the development of antiretroviral therapies that have drastically reduced its public health burden.[10] The transfer of samples out of Guinea, Liberia, and Sierra Leone during the 2014–16 outbreak led to rapid diagnostics for Ebola, expanded knowledge

protective against a later infection, and the administration of antiviral medications, which are chemicals that interfere with viral replication.")

5 Kumanan Wilson, Barbara von Tigerstrom, and Christopher McDougall, *Protecting Global Health Security through the International Health Regulations: Requirements and Challenges*, 179(1) CMAJ 44 (2008), available at www.ncbi.nlm.nih.gov/pmc/articles/PMC2464486/. David P. Fidler and Lawrence O. Gostin, *The New International Health Regulations: An Historic Development for International Law and Public Health*, 34 JLME 85, 86–87 (2006).

6 Kane, *supra* note 4 at 1153–55. ("In an effort to document the patent landscape of the field, the WHO has undertaken a project to map where patents have been sought on any of the relevant H5N1 viral materials. This research demonstrates that a small cluster of patent applications have been filed on various sequences and proteins of H5N1 and several patents have been issued, but the report further notes that patent landscaping must continue as the field matures. The sequence of the H5N1 and novel H1N1 influenza viruses have been determined. The WHO provided notice that genetic sequences from one novel H1N1 virus isolate were available on the GISAID database within several days of the first reports of the outbreak . . . Three separate groups of international researchers filed U.S. patent applications on the DNA sequences of the virus.")

7 *Id.*

8 Samples are often collected from hospitals, clinics, and other laboratories. *Id.*; *see also* Marie Wilke, The World Health Organization's Pandemic Influenza Preparedness Framework as a Public Health Resource Pool, Common Pools of Genetic Resources: Equity and Innovation in International Biodiversity Law (*hereinafter* Common Pools of Genetic Resources), 315–43 (2013).

9 Reichman, *supra* note 2 at 44.

10 Paul Sharp and Beatrice Hahn, *The Evolution of HIV-1 and the Origin of AIDS*, 365(1552) Philos Trans R Soc Lond B Biol Sci. (2010).

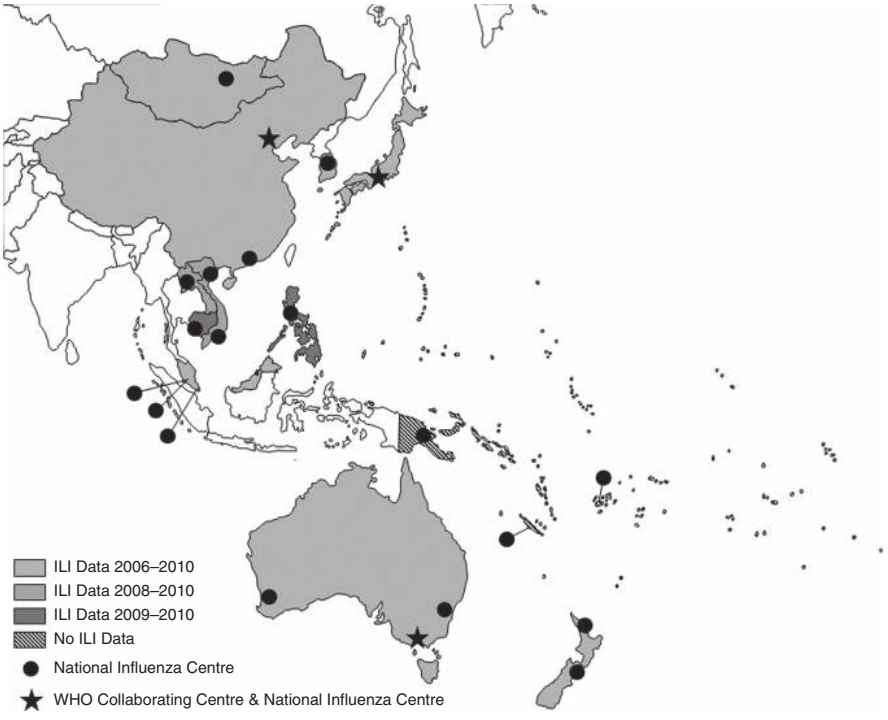

FIGURE 0.1 Epidemiological and Virological Characteristics of Influenza in the Western Pacific Region of the World Health Organization, 2006–2010 PLoS One. 2012;7(5): e37568. doi: 10.1371/journal.pone.0037568. Epub 2012 May 29.

about mechanisms of action for pharmaceutical treatments and several promising vaccine candidates.[11]

Yet proprietary claims over biological resources have fundamentally altered the sharing paradigm in global infectious disease research. In 2006, Indonesia withheld H5N1 avian flu samples from the WHO system, compromising efforts to monitor and produce vaccines in response to an avian flu outbreak that had not only spread worldwide but threatened to become easily transmissible from birds to humans and then between humans.[12] Indonesia asserted that its decision was a response to an

[11] Ana Henao-Restrepo et al., *Efficacy and Effectiveness of an rVSV-vectored Vaccine Expressing Ebola Surface Glycoprotein: Interim Results from the Guinea. Ring Vaccination Cluster-Randomised Trial*. 386 LANCET 857–866 (2015).

[12] David Fidler, *Influenza Virus Samples, International Law, and Global Health Diplomacy*, 14(1) EMERG INFECT DIS. 88–94 (2008). ("This controversy began toward the end of 2006, when Indonesia decided not to share influenza A virus (H5N1) samples with WHO for risk assessment (e.g., surveillance) or risk management (e.g., vaccine development) purposes. Indonesia's decision reportedly stemmed from its reaction to an Australian company's development of an avian influenza vaccine derived from a virus strain that Indonesia provided to WHO. WHO's acknowledgment that patents had been sought on modified versions of influenza (H5N1) samples shared through the Global

Australian company's development of a vaccine derived from a virus sample Indonesia provided to the WHO.[13] The cycle demonstrated the inequities inherent in the global vaccine distribution system: "Developing countries provided information and virus samples to the WHO-operated system; pharmaceutical companies in industrialized countries then obtained free access to such samples, exploited them, and patented the resulting products, which the developing countries could not afford."[14] "Without access to Indonesia's influenza strains, global surveillance was jeopardized, as was the refinement of diagnostic reagents and the development of intervention strategies, which depend on the information surveillance provides."[15]

The norms of sharing for global infectious disease research had deep historical and economic roots. Because life as a general matter (including seeds, plants for agriculture, and other biological resources) was historically viewed as the "common heritage" of humanity, there were few barriers to researchers, firms or even foreign governments transferring biological resources out of one country and to another, often from a country with less technological capacity for research to one with more. Customs and import laws regulated biological samples as they moved across borders, but for the most part, those laws rarely interrupted infectious disease research.[16] Within the scientific community, this large-scale transfer of resources occurred through three primary channels: conveyance, field work, and annexed research sites.[17]

The scientific process relies upon verification of analyses and conclusions, exchange of data and other resources, and attribution to researchers for contributions that advance knowledge. Consequently, researchers formed (and form) sharing and reciprocity customary practices that encourage scientists to share samples and related data with colleagues in countries with more advanced laboratory and technical capabilities or the former may request inputs from the latter. Under this model, researchers request biological samples including human pathogens from colleagues, sometimes with the understanding that some other resource or knowledge will be shared with the researcher who responds to the request. For example, Ali Mohamed Zaki, an Egyptian physician working in Saudi Arabia, contacted scientists at Erasmus Medical Center in the Netherlands for technical help after he suspected a novel virus (MERS-CoV) caused the severe respiratory symptoms and death of a patient.[18] According to Zaki:

Influenza Surveillance Network (GISN) without the consent of the countries that supplied the samples reinforced Indonesia's discontent.")

13 *Id.*

14 *Id.* at 88.

15 *Id.*

16 Olive Sturtevant, *The ABCs of Importing and Exporting Products, Samples and Biologics across International Borders* available at https://c.ymcdn.com/sites/www.celltherapysociety.org/resource/resmgr/2014_AnnualMtgPresentations/QO4_O.Sturtevant.pdf.

17 Patricia Garcia, *International Partnerships: View from the South*, available at www.mcgill.ca/globalhealth/files/globalhealth/09PattyGarcia.ppt.

18 Islam Hussein, *The Story of the First MERS Patient*, Nature Middle East, June 2, 2014, available at www.natureasia.com/en/nmiddleeast/article/10.1038/nmiddleeast.2014.134. ("Zaki had diagnosed 'patient zero' of the deadly virus at a Saudi Arabia virology diagnostic laboratory established in 1993. Besides

> [Erasmus] confirmed my initial findings and asked me to send them a small portion of patient zero's sample because they wanted to do some more testing and they were running out of RNA. I didn't have any mechanism to ship a live virus sample while maintaining the cold chain during transit. So, I filtered the sputum sample and mixed the filtrate with Vero cells, packaged the tightly capped tube in appropriate biohazard containers and shipped it with a private carrier at room temperature as a diagnostic sample. It worked. They received it in the Netherlands and managed to recover the live virus, the first genetic analysis of this novel virus published in *New England Journal of Medicine*.[19]

The scope of acquisition of biological samples represented by Dr. Zaki's experience is vast.[20] There were millions of such transfers over the course of the twentieth century.[21]

"Field work," as used here, refers to the acquisition of biological samples in a country by a foreign researcher who later returns to his or her country to conduct research on the collected samples.[22] For example, in the early 2000s, French researchers conducted interviews in Brazil and French Guiana to find out about local antimalarial remedies, including those derived from the indigenous *Quassia amara* shrub, and also returned to France with samples of *Quassia amara*.[23] "Field work" acquisition is the kind of transfer specifically regulated by the Convention on Biological Diversity and the Nagoya Protocol.[24]

coronavirus, Zaki also diagnosed Dengue fever for the first time in Saudi Arabia in 1994. And in 1997, he isolated a new tick-born flavivirus, known as Alkhurma, which causes severe hemorrhagic fever.")

19 *Id.*

20 Maryam Shabikhani et al., *The Procurement, Storage, and Quality Assurance of Frozen Blood and Tissue Biospecimens in Pathology, Biorepository, and Biobank settings*, 47 Clin. Bioch. 258–66 (2014). ("The world population has seen exponential growth and is projected to increase from the current 7.2 billion to 9.6 billion by the year 2050 [1]. With this sizeable expansion in the human population, there will be a correspondingly large increase in biomedical biospecimens. In the United States alone, the number of biospecimens is estimated to have tripled over a decade to reach approximately 600 million in 2010 [2]. Furthermore, there has been a rapid evolution of increasingly affordable 'next-generation' technologies that permit global or targeted evaluation of the genome, epigenome, proteome, and metabolome of tissues and cells and that are critical to personalized medicine- the tailoring of targeted therapies for each patient.")

21 Jimmie Vaught, Marianne Henderson, and Carolyn Compton, *Biospecimens and Biorepositories: from Afterthought to Science*, 21 Cancer Epidemiol Biomarkers Prev. 253–55 (2012). ("Given the millions of samples collected for clinical and research purposes, for most of the history of biobanking there has been a serious lack of attention to controlling the quality and consistency of collection, processing and storage of biospecimens.")

22 Florian Rabitz, *Biopicacy after the Nagoya Protocol: Problem Structure, Regime Design and Implementation Challenges*, 9(2) Brazilian Political Science Review 30, 37 (2015).

23 N. Cachet et al., *Antimalarial Activity of Simalikalactone E, a New Quassinoid from* Quassia amara *L. (Simaroubaceae)*, 53 Antimicrob Agents Chemother. 4393–98 (2009), available at www.ncbi.nlm.nih.gov/pubmed/19667291. ("We report the isolation and identification of a new quassinoid named simalikalactone E (SkE), extracted from a widely used Amazonian antimalarial remedy made out of *Quassia amara* L. (Simaroubaceae) leaves. This new molecule inhibited the growth of *Plasmodium falciparum* cultured in vitro by 50%, in the concentration range from 24 to 68 nM, independently of the strain sensitivity to chloroquine.")

24 Daniel Robinson, *Locating Biopiracy: Geographically and Culturally Situated Knowledges*. 42 Environment and Planning, 38–56 (2010).

Annexed research sites are essentially the extension of a research institution located in another country. Samples of genetic resources may be collected locally, and part of the research on those genetic resources is conducted within the host country. This may be done by foreign or local researchers.

Over the many decades in which biological resources flowed from originator countries to laboratories across the world, systems developed to both commercially exploit those resources and to build specific systems that addressed matters of particular concern to the international community. GISRS, mentioned above, facilitated the collection and transfer of influenza samples from all over the world. The Spanish influenza pandemic of 1918–19 killed approximately 3 percent of the world's population and the influenza virus thereafter became an important area of international cooperation.[25]

The GISRS system monitors the evolution of influenza viruses and provides recommendations as to which candidate vaccine viruses should be included in seasonal and pandemic vaccines.[26] The system is structured around six WHO collaborating centers located in Australia, China, Japan, the UK, and the US, four WHO essential resource laboratories, and 141 institutions recognized by the WHO as national influenza centers (NICs) located in 111 countries. NICs collect clinical specimens for the detection of influenza viruses through national surveillance networks. Until 2006, this system regularly collected influenza samples from around the world, distributed them to collaborating centers, and shared them with non-profit and for-profit actors to develop vaccines and antivirals.[27]

THE TRANSITION FROM OPEN SCIENTIFIC EXCHANGE TO PROPRIETARY CONTRACTS

Over the course of the 1960s and 1970s, many low- and middle-income countries reexamined the directional flow of global biological research as part of a broader evaluation of the distribution of technological capacity worldwide, and the importance of technology for development and for meeting basic human needs. In 1964,

[25] Sam Halabi and John Monahan, *Regulatory Capacity in Low- and Middle Income Countries: Lessons from the H1N1 Pandemic. in* Food and Drug Regulation in an Era of Globalized Markets (S. F. Halabi ed., 2015). ("The historical and global dimensions of influenza-related mortality are astounding and explain why since at least 1918 there have been vocal groups of public health activists who have warned of the catastrophic potential of future influenza pandemics and encouraged investments in community readiness.")

[26] WHO, Self-Assessment of the WHO Global Influenza Surveillance and Response System (GISRS), Report to the PIP Advisory Group (2014) available at www.who.int/influenza/pip/virus_sharing/gisrs_self_assessment.pdf.

[27] David Fidler, *Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic Influenza H1N1*, 7(5) PLoS Med. (2010). ("Similarly, states in which vaccines and drugs are manufactured have sovereignty over the manufacturing process and the products themselves, until they are exported. States that import vaccines and drugs then have sovereignty over such resources and, absent a binding obligation, may allocate them however they wish.")

the United Nations Conference on Trade and Development (UNCTAD) formed in order to pursue commerce and trade-related development policies.[28] UNCTAD's mandate encouraged it to "maximize the trade, investment and development opportunities of developing countries and assist them in their efforts to integrate into the world economy . . ."[29] Building technological capacity was a crucial part of this agenda.[30]

Because the development of a technological base was perceived as intricately tied to control over industrial processes applied to raw materials, it was sovereignty over natural resources that informed much of the technology distribution debate. On April 19, 1972, Mexican President Luis Echeverria urged the adoption of a Charter of Economic Rights and Duties of States aimed at exerting greater authority over natural resources.[31] At the time, those resources were thought to be mostly commodities like petroleum, rubber and agricultural goods.[32] But the general call for control over natural resources expanded in the early 1990s to include biological and genetic resources, including human pathogens. Biodiverse rich but economically poor countries argued that there was a "unidirectional flow of samples" out of developing countries for both commercial and noncommercial research and development.[33] These countries emphasized the need for biological research to enhance "the development of local capacity, infrastructure and expertise" of the originating countries.[34]

[28] John Toye, UNCTAD at 50: a Short History 3 (2014).

[29] D. N. Dwiveldi, International Economics: Theory and Practice 464 (2013).

[30] 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).

[31] Summary of Address, UNCTAD Proceedings, Third Session, U.N. Doc. TD/180, Vol. 1A, Part I at 184, 186 (1972). ("Unless direct foreign investment shared managerial responsibility, transferred technological innovations, and. provided access to benefits obtained from foreign markets, it merely prolonged colonial domination. Multinational companies could also make a, significant contribution to modernizing the economies of the developing countries, whose national capacity for creating, assimilating and adapting technology must be increased.")

[32] Charles N. Brower and John B. Tepe Jr. *The Charter of Economic Rights and Duties of States. A Reflection or Rejection of International Law?*, 9 Int'l. Lawyer 295 (1975). ("All states have the right to associate in organizations of primary commodity producers in order to develop their national economies to achieve stable financing for their development, and in pursuance of their aims assisting in the promotion of sustained growth of the world economy, in particular accelerating the development of developing countries.")

[33] Daniel Yergin and Joseph Stanislaw, The Commanding Heights: The Battle Between Government and the Marketplace That Is Remaking the Modern World 88–90 (1998).

[34] Ciara Staunton and Keymanthrj Moodley, *Data Mining and Biological Sample Exportation from South Africa: A New Wave of Bioexploitation under the Guise of Clinical Care?*, 106(2) South African Medical Journal 136 (2016). ("The data from these biological samples and the samples themselves are a valuable resource in medical research, helping to identify the roles that genes play in disease development and accelerating new drug development. For decades there has been a unidirectional flow of samples out of Africa to various destinations in developed countries, with no benefit to local populations or local researchers. Such 'parachute research' has impacted negatively on the

In 1972, the UN also held the first of many global conferences, on the Human Environment at Stockholm, Sweden.[35] In the decade after the 1972 conference, scientists and nongovernmental organizations had elevated the issue of biodiversity as a global policy priority.[36] In 1987, the governing council of the United Nations Environmental Programme resolved to create a working group to explore the possibility of developing a legally binding treaty to protect biological resources.[37] In 1991, formal multilateral negotiations began on a Convention for Biological Diversity.

Eventually these preparatory meetings culminated in the 1992 UN Conference on Environmental and Development (or "Earth Summit") held in June 1992 in Rio De Janeiro, the result of which included the Rio Declaration, 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 exploitation of these resources – commercially, technologically, etc. – should be shared "between investors and the recipient state."[38]

Some governments made it more difficult for foreign scientists and bio-prospectors to obtain resources from their territories.[39] Other governments began to limit or question their participation in one of the critical hubs of the Green Revolution, CGIAR (Consultative Group for International Agricultural Research).[40]

The CBD resulted, codifying in a legal instrument that developing countries should not only control access to genetic resources, but also benefit from any commercial value generated from their utilization.[41] The CBD adopted as one of its objectives the promotion of conservation, and sustainable use, of biological

development of local capacity, infrastructure and expertise. As genomic research is advancing in SA, every effort should be made to encourage its development and ensure that SA biological samples and data are used locally. International collaborations can further develop and improve local capacity, but this must be non-exploitative and involve a sharing of facilities, expertise and expense.")

35 Declaration of the United Nations Conference on the Human Environment (Stockholm Declaration, 1972).

36 D. H. Janzen, *The Future of Tropical Ecology*, 17 Annual Review of Ecology and Systematics 305 (1986). ("But the real future of tropical ecology lies in whether, within our generation, the academic, social and commercial sectors can collaboratively preserve even small portions of tropical wildlands to be studied and used for understanding, for material gain, and for the intellectual development of the society in which the wildland is embedded.")

37 UNEP Resolution 14/26, adopted in 1987.

38 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).

39 Reichman et al., *supra* note 2, at 89–90.

40 Some countries began to demand the return of resources that they fear would be the subject of attempts at patenting or obtaining other intellectual property rights. *Id.* at 90.

41 Convention on Biological Diversity, *open for signature* June 5, 1992, 1760 *U.N.T.S.* 79. There are 198 states party to the CBD. The United States is not a party.

diversity while seeking "fair and equitable" sharing of benefits derived.[42] The CBD's goal of "access and benefit sharing" includes both plant genetic resources as well as the relevant technology associated with their development.[43] It also codified the protection of indigenous peoples and the traditional knowledge they had developed especially for medical and agricultural applications, including a principle of compensation when firms or others commercialized that knowledge.[44] The CBD created a legal zone in which biodiverse rich countries could set terms for exploitation and the protection of their citizens to share in the benefits of any commercialization of their resources.[45] More than sixty nations have created Access and Benefit Sharing (ABS) regimes via their domestic laws, with particular activity from biodiverse rich states like Brazil, China, Costa Rica, Kenya, the Philippines, and South Africa.[46]

Article 2 of the CBD defines "genetic resources" as "genetic materials of actual or potential value" which includes "any material of plant, animal, microbial, or other origin containing functional units of heredity."[47] Subsequent agreements expanded this definition. Even then, the broadness of "actual or potential value" allows consideration of "nonmonetary benefits" into the equation of benefit sharing. Article 15 incorporates prior informed consent (PIC) and mutually agreed terms (MAT) as conditions for both access and use of resources.[48] Article 16 incorporates the demand for technology transfer as a form of benefit that could be available to

[42] CBD art. 1.

[43] Jonathan Carr, *Agreements that Divide: TRIPS vs. CBDand Proposals for Mandatory Disclosure of Source and Origin of Genetic Resources in Patent Applications*, 18 J. OF TRANSNAT'L LAW AND POLICY 131, 133 (2008). ("In Article 16(3), countries of origin, especially developing countries, are given access to technology that incorporates the use of that country's biological resources. This includes patentable biotechnology. A key aim of the CBD is to promote the sustainable use of natural resources, while incorporating power to impact the application of intellectual property rights on the biotechnological industry.")

[44] CBD art. 8.

[45] Michiel Korthals and Bram De Jonge, *Two Different Ethical Notions of Benefit Sharing of Genetic Resources and Their Implications for Global Development*, 28 NEW GENETICS AND SOCIETY 87, 89 (Mar. 2009).

[46] Nicolas Pauchard, *Access and Benefit Sharing under the Convention on Biological Diversity and Its Protocol: What Can Some Numbers Tell Us about the Effectiveness of the Regulatory Regime?*, 6 RESOURCES 1–15 (2017). (" Concerns about the possible free use of GR despite the adoption of the Convention incited the States Parties to implement a set of binding rules dealing with the ABS elements of the CBD. In 2002, in Cancun (Mexico), several megadiverse countries set up the Group of Like-Minded Megadiverse Countries (GLMMC) (Bolivia, Brazil, China, Colombia, Costa Rica, Democratic Republic of the Congo, Ecuador, Ethiopia, Guatemala, India, Indonesia, Iran, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, South Africa, and Venezuela). The origins of this group of countries go back to 1998, when Conservation International, a US non-profit environmental NGO established a list of the countries harboring the majority of Earth's species, the 17 megadiverse countries (Australia, Brazil, China, Colombia, Democratic Republic of the Congo, Ecuador, India, Indonesia, Madagascar, Malaysia, Mexico, Papua New Guinea, Peru, Philippines South Africa, United States, and Venezuela). This group is the political expression of the interests of this minority of Southern States accounting for the majority of the existing GR.")

[47] CBD art. 2.

[48] CBD art. 15(2).

provider countries.[49] It specifically ties terms of access to intellectual property rights providing that "patents and other intellectual property rights may have an influence on the implementation of [the Biodiversity Convention], [so Parties] shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives."[50]

While the CBD permits the possibility of regional and multilateral approaches to the issues the treaty covers, it implies by its terms prior informed consent and an agreement be negotiated with every provider/user transaction.[51] The bilateral approach, if implemented effectively, potentially provides an enormous amount of control over intellectual property rights asserted over genetic resources in developing countries.[52] Article 15's requirement for informed consent for access presumes the commercial potential of all research efforts.[53]

Article 15 of the CBD required "fair and equitable sharing of benefits arising out of the utilization of genetic resources," which in turn shaped many countries' "bioprospecting" laws.[54] Before 2010, CBD Article 15 had been largely guided by the nonbinding Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization. The Bonn Guidelines recommended the following provisions for contracts between sovereign states and commercial entities:

(a) Regulating the use of resources in order to take into account ethical concerns of the particular Parties and stakeholders, in particular indigenous and local communities concerned;
(b) Making provision to ensure the continued customary use of genetic resources and related knowledge;
(c) Provision for the use of intellectual property rights include joint research, obligation to implement rights on inventions obtained and to provide licences by common consent;
(d) The possibility of joint ownership of intellectual property rights according to the degree of contribution.[55]

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 mediums

[49] CBD art. 16(1).
[50] CBD art. 16(5).
[51] Reichman et al., *supra* note 2, at 96.
[52] *Id.* at 106.
[53] *Id.* at 109.
[54] Thomas Kursar, *What Are the Implications of the Nagoya Protocol for Research on Biodiversity*?, 61(4) BioScience 256–57 (2011). ("The CBD has promoted conservation and defended against biopiracy, but the expectation has not been met that the CBD would substantially propel biodiversity research partnerships. The stagnation over an 18-year period has been frustrating. The core problems are that for fear of biopiracy, developing countries have inhibited biodiversity research, and developed nations, for fear of financial and legal hurdles, have failed to promote studies on the uses of biodiversity.")
[55] Bonn Guidelines Paragraph 43.