Fast Science and Sluggish Policy: The Herculean Task of Regulating Biodiscovery

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Fast Science and Sluggish Policy: The Herculean Task of Regulating Biodiscovery

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New rules for access and benefit sharing (ABS) of genetic resources and associated traditional knowledge have been established by the Nagoya Protocol but have not kept up with rapid scientific and technological advances in biodiscovery. This suggests the need for innovative, transdisciplinary approaches to regulate ABS and emerging technologies.

The Evolution of Policies for Biodiscovery, Access, and Benefit Sharing

The biodiscovery policy landscape has changed fundamentally over the past 25 years, beginning with the signing of the Convention on Biological Diversity (CBD, https://www.cbd.int/doc/legal/cbd-en.pdf), one of three legally binding agreements arising from the 1992 United Nations Conference on Environment and Development (the Rio 'Earth Summit'). An innovative formulation, the agreement sought to channel the financial power of business and science toward critical environmental and development challenges, while correcting centuries of inequitable exchange between the colonizing 'North' and biologically diverse 'South' [1].

No longer would what the CBD referred to as 'genetic resources' be freely available. 'Users', usually developed countries of the North, would compensate 'providers', often developing countries of the South, for use of their genetic resources. Those using traditional knowledge associated with these resources would be required to get consent from indigenous peoples or local communities holding this knowledge. This area of policy became known as 'access and benefit sharing' (ABS), referring to the need to balance users' demands for access to genetic resources and traditional knowledge, with benefit sharing for providers.

In 2010, this concept was further refined and strengthened. After almost a decade of negotiations, a new agreement under the CBD was reached to give teeth to ABS, the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilisation (https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf). With 50 countries ratifying the agreement, it came into force in 2014.

Worlds Apart

The world was a very different place when the CBD opened for signature in Rio de Janeiro in 1992. Modern biotechnology was surfacing as a revolutionary new possibility for agriculture and health care; the Internet was emerging from concept to practical reality; even digital mobile phones had only just arrived in the market. As Figure 1 shows, when the CBD was negotiated, the genomes of free-living organisms had not yet been sequenced (this happened in 1995 when the genome of the bacterium *Haemophilus influenzae* was sequenced), the first genetically modified crop had not been commercialized (this happened in 1996), and biodiversity- and gene-related patents were still relatively novel.

Despite creating a virtuosic and cutting-edge framework for equity and conservation, the CBD did not – and could not – anticipate the scientific and technological changes that were to follow.

The Lumbering Nature of Policy

In stark contrast to the highly networked and explosive character of science and technology over the last 25 years, the ABS policy process has been deliberative and, over time, increasingly inward looking, focused on specific procedures, provisions, and policy processes rather than major scientific and technological developments. Like many other international policy processes, it is enveloped by UN procedures that promote inclusiveness but are typically slow, lumbering, and inflexible, making it difficult to adapt to fast-moving events in the outside world.

Challenges arising from dramatic differences in the pace of policy development and scientific and technological advances are not unique to ABS. Indeed, a complex patchwork of often outdated laws, funding shortages for implementation, an absence of strategy, jurisdictional confusion, and a lack of capacity plague emerging technology and other policies around the world [2,3]. Across the board in the biotechnology sector, governments have struggled to keep up with the latest developments. Even in the United States, home of the world's largest biotech sector, the regulation of synthetic biology has been described as '. . . complicated, increasingly circuitous, and not for the faint of heart' [4].

Scope and Definitional Ambiguities

Given the rapidity and complexity of change it is of little surprise that similar shortcomings increasingly also define ABS. Some of the disjunctures between ABS policy, scientific and technological advances, and demand for access to genetic resources are illustrated in Figure 1.

For example, the CBD emphasized the physical material of 'genetic resources' – 'genetic material of actual or potential value' – but in 2007, as the Nagoya Protocol was under negotiation, second-generation sequencing platforms came

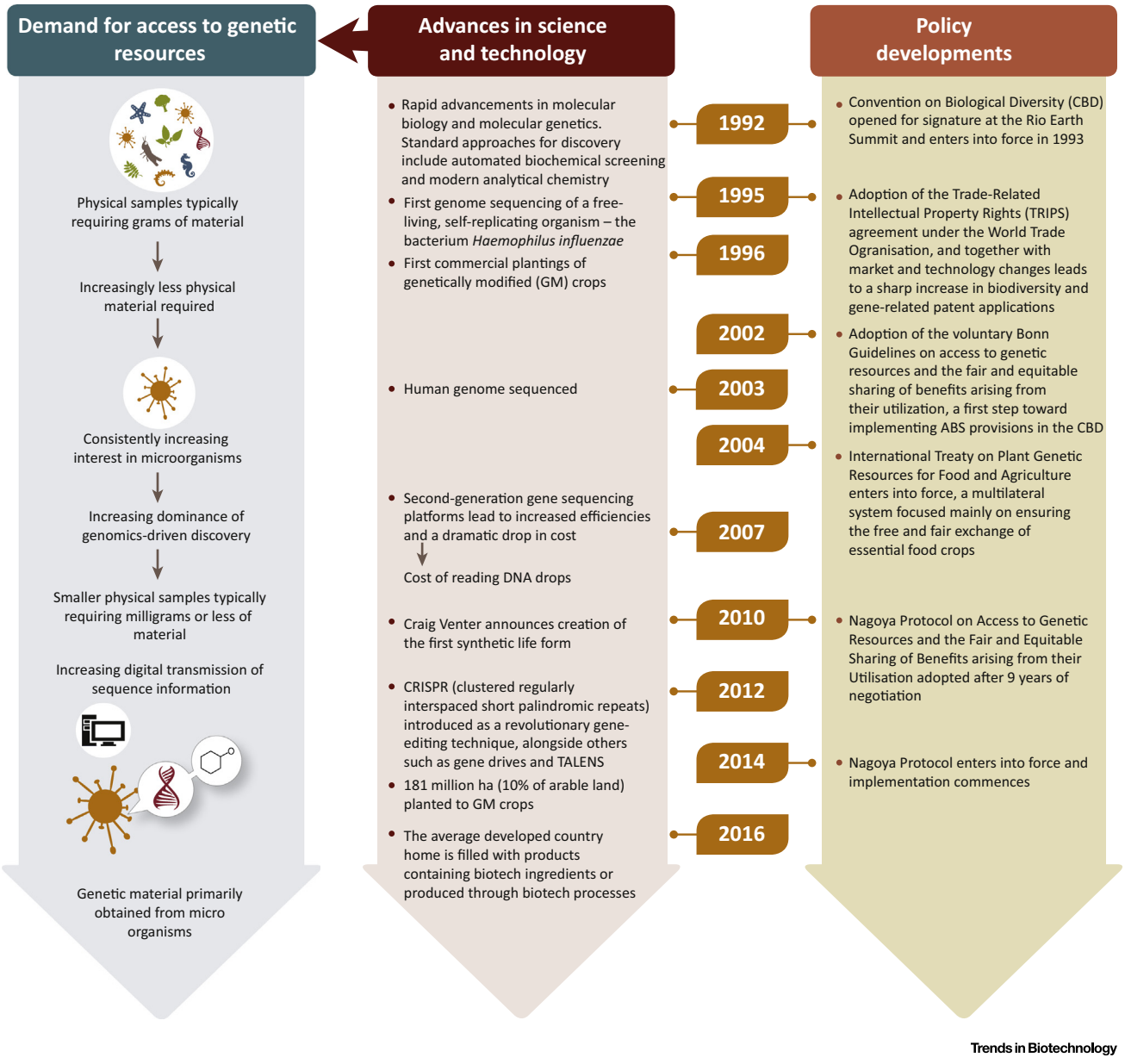

Figure 1. Disjunctures between ABS Policy, Scientific and Technological Advances, and Demand for Access to Genetic Resources. TALENS, transcription activator-like effector nucleases.

on line and suddenly and profoundly reduced the cost of reading DNA (www.genome.gov/sequencingcostsdata). The field of bioinformatics exploded, and genetic information from microorganisms became the focus of research interest – in recent years often transmitted digitally, with little physical exchange of material. The increased digital transmission of genetic sequence information also brought with it the possibility that reliance on physical, biological material could be obviated. Rather than adapt to new realities, however, policy-makers negotiating the Nagoya Protocol continued to emphasize physical materials accessed from *in situ* and *ex situ* sources, 'literally codifying the definitional mistake' found in the CBD, as Ruiz Muller describes [5].

Further ambiguities have emerged as a result of the CBD's definitional emphasis on 'functional units of heredity'. As Bagley and Rai [6] remark, it is unclear 'how the notion of "functional unit of heredity" [will] map onto the new science.' With synthetic biology, researchers have become increasingly interested in parts of genes, in addition to the focus on the full genome and proteome. There is also increased interest in noncoding genetic material or 'junk DNA', revealing the integral role they play in increasing the ability of organisms

to evolve, and in regulating gene expression [7].

Disjunctures in Science and Policy

As science and technology have progressed, definitional boundaries have become indistinct. Genes from different organisms, and from different parts of the world, might for example be combined into a new patented organism, with some components synthesized. In 2010, when the Nagoya Protocol was adopted, Craig Venter announced the creation of the first synthetic life form, copying an existing bacterial genome but drawing on genetic material from different organisms. By 2016, a brand new, artificial species had been created [8]. At this writing, at least 116 synthetic biology products and applications were reported to be near or on the market (synbioproject.org) and industrial biotechnology is found in nearly every commercial sector. The introduction of genome-editing techniques such as CRISPR/Cas9 (CRISPR/Cas9 (clustered regularly interspaced short palindromic repeats and associated systems), gene drives, transcription activator-like effector nucleases (TALENS), and oligonucleotide-directed mutagenesis over the past five years, revolutionary techniques due to their speed, reliability, and low cost [9], has further raised the bar. Such developments have cast more doubt about the viability of regulations based on the state of the art 25 years ago.

Rather than come to terms with these and other new developments in science and technology, however, the Nagoya Protocol process has dug deeper into a 1990s' view of genetic resource use. The Protocol emphasizes a transaction in which physical material is shared across borders, encouraging checkpoints to monitor use after genetic resources 'leave a country', and establishing rules for prior informed consent and mutually agreed terms between 'Contracting Parties'. A range of other measures attempt to regulate an exchange that does not accommodate the rapid rise in the electronic transmission of digital sequence information, nor the ease with which users can obtain such information on open access databases. It is perhaps not surprising that, prior to the last Conference of the Parties, the Nagoya Protocol process increasingly focused on industries that rely upon biological resources – raw bulk materials such as botanicals, natural cosmetics, and foods, since in these cases an exchange of physical material clearly occurs in a tangible manner [10].

At the same time, genetic information has never been more valuable or widely used, and the need for regulation and oversight of some kind has never been greater. At a meeting of parties to the CBD in Cancun, Mexico in December 2016, countries agreed to study the use of digital sequence information and its implications for the Nagoya Protocol. Some civil society organizations have also called on Parties to investigate 'digital biopiracy', whereby companies can access gene sequences on the Internet and then use them, including by recreating physical DNA via synthetic biology techniques, without the agreement of (or any benefit to) biodiverse countries or communities from whom the genes originated. Over 160 civil society organizations also called for a moratorium on gene drives, centered on potential threats to biodiversity, as well as national sovereignty, peace, and food security (www.synbiowatch.org/gene-drives/gene-drives-moratorium).

Whether ABS measures, largely managed by Ministries of the Environment, are the appropriate place for such regulation remains questionable. In addition to scientific and technological changes and the expanding definitional scope of genetic resources, an incongruous blend of issues converges around ABS. These range from political questions of retribution through to concerns about profiteering and bioethics. What is clear is that regulatory frameworks for emerging technologies need an innovative approach that steps out of disciplinary boundaries and Ministerial mandates and is underpinned by a strong understanding of science, technology, ethics, and economics. At the same time, they need to incorporate some of the values and principles embodied by ABS – including equity, consent, mutual agreement, and benefit sharing – and be open to regular review, reflection, and adaptation. Whether the policy arena is ready for such change remains a moot point.

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