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New technological challenges for policies on biodiversity conservation and genetic resources

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Introduction

Like never before in history it is increasingly challenging to keep updated or relatively informed with regard to new technologies developed and used in the world of biodiversity and genetic resources conservation and use. The amazing biotechnology boom of the 1980s that dazzled humanity with its potential, has led to what some call a Fourth Industrial Revolution which is defined as: "... a transformative change in data and technology capabilities combined with the merging of digital, physical and biological realms."[1] Genomics, proteomics, gene editing, synthetic biology, artificial intelligence, blockchain, among other tools, are transforming the way of conducting research and development (R&D) and generating goods and services in all sectors of human activities. This new Policy Brief on Trade and Environmental Policy analyzes the importance of these developments from the perspective of international public policies and legal frameworks and their relevance for the South American region in particular.

New technologies and their application in research and development in biodiversity and genetic resources

The above-mentioned technologies have very concrete applications. It is not a matter of projections or expectations. At present, they are all being used in different fields related to conservation and sustainable development in general. Although the purpose of this policy document is not to undertake a comprehensive analysis of each technology, it is worthwhile to present an overview of the multiple possibilities in different fields.

Proteomics for example, is the large-scale study of the structure and function of proteins. It is extensively used in the diagnosis of diseases in plants, animals and humans and for the identification of interactions between plants and insects, to understand ecosystem functions. Gene drives are a genetic engineering derived technology that propagates a set of genes throughout a target population. This allows among others, the alteration of insect vectors that spread diseases or reverse mutations in insects conferring resistance to pesticides and herbicides. Nano-biotechnology is a branch of nano-technology that uses nanoparticles as sensors or vehicles for biomolecule delivery in cellular systems, with particularly relevant applications in immunotherapy and wastewater treatment and purification.[2] Gene editing (or genome editing) for its part involves DNA inserted, deleted or replaced in a specific place of the genome of a living organism or cell. It is generally achieved in laboratory conditions that use engineered nucleases or molecular scissors. Gene editing technologies include CRISPR-Cas9, ZFNs o TALENs. This technology is extensively applied in medical treatments and therapies and for crop improvements.[3] Synthetic biology is the convergence between biology, chemistry and physics that allows the design and construction of new biological parts, devices and systems and redesign of existing natural biological systems for useful purposes. Practical applications can be found in the production of biofuels and polymer fibers, the synthesis of natural products, and in the field of biomedicine.[4] Blockchain on the other hand, is basically a growing list of records accumulated in “blocks” which are linked and safeguarded using cryptography, which makes it particularly resistant to modification of the data. Blockchain can indefinitely record transactions in a verifiable and efficient way. It is particularly relevant in the case of genomic and medical data storage and creation of smart contracts.[5] Finally, although not a comprehensive list, 3D molecular imprinting enables the combination of cells, growth factors and biomaterials to fabricate biomedical parts that maximally imitate natural tissue characteristics – for uses in the development of artificial organs and tissue for the repair and replacement of damaged organs.[6]

As a synthesis and integrating tool that can equally combine information technology, artificial intelligence, “big data” (massive volume of data), statistics, biology and natural sciences in general, bioinformatics has become an extremely powerful and essential discipline in the arsenal of science, to understand the natural environment at all its levels – genes, populations, species and ecosystems.

Public policies and international frameworks

There is an increasing gap in the understanding of the relevance and impacts of these technologies and disciplines. Public policies and legal frameworks, particularly in countries in the South (generally speaking) are lagging behind in addressing these fundamental advances and progress, especially over the past few years. It is particularly interesting to compare how the multiple dimensions of these technologies and disciplines are linked to policy and legal aspects related to issues such as patents and copyright, access to genetic resources and biosecurity.

Diverse forums and institutions have been addressing (more or less intensively) different aspects of these technologies. The World Intellectual Property Organization (WIPO), has been particularly active in the analysis on how intellectual property tools, mainly patent applications for inventions, copyright and trade secrets must be adapted to appropriately protect these technologies and their creators. This may require a balance between the needs of developing countries (particularly in South America), which are not yet very interested, trained or informed about the multiple uses and advantages of these technologies.[7] To this effect, the WIPO Development Agenda seeks to analyze a way in which intellectual property can have positive impacts on the possibility for technological development in countries, especially those with less technological and human capacities to generate, manage and use the technologies such as those described.[8]

The World Health Organization (WHO) has also shown growing interest on issues linked to the development of these technologies and their impact on health. For example, a few years ago, an intense debate was generated on the implications of genetic information, concerning influenza virus lines. This was particularly relevant in the context of the debate on access and sharing of benefits arising from the utilization of these virus lines and the principles of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (2010). As a result, in 2012, the WHO approved the document “Pandemic Influenza Preparedness: Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits”, that establishes basic principles to share the viruses for research and development.[9]

The Convention on Biological Diversity (CBD, 1992) and the Nagoya Protocol on Access to Genetic Resources have been particularly important as instruments to visualize the different tensions and interests between countries, the industry, academic sector and other actors. The basic rule that promotes these two international instruments is, in simple terms: whilst it is necessary to facilitate access to genetic resources and other biological components for research and development, there should equally be the fair and equitable sharing of benefits arising from such access, including through the access to biotechnology and other relevant technologies. This seemingly “simple” principle has been the subject of major debates and controversy - the “devil is in the details”. To begin with, technological developments as described above have greatly disrupted the discussion to the extent that the material and tangible biological element begins to lose relevance against the informational dimension “extracted” from the material, allowing research and development to be undertaken.[10] The concepts of “digital genetic information” or “natural information” present a challenge yet to be solved for public policies and laws and regulation that seek the development of the CBD and Nagoya Protocol principles. This is particularly relevant given the practical impossibility to control information flows and even starting to understand the dimensions of already existing databases with such information.[11]

The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (2001) has also not escaped from discussions on technological advances and the meaning of "genetic resources" in the context of this new paradigm. From 2016 onwards, both the Treaty Secretariat and the Commission on Genetic Resources for Food and Agriculture have undertaken simultaneous research to explore the implications of digital genetic information, synthetic biology, genomics, etc. on the Treaty itself and its regulations and principles on access and benefit sharing. In fact there is an ongoing process to improve the multilateral system on participation in the benefits derived from access and use of plant genetic resources for food and agriculture, mainly in the case of monetary benefits. These benefits have been practically non-existent, apart from a few voluntary contributions from countries.[12] There is a special interest in the role of databases and the availability of data and genetic information in terms of intellectual property and the possibility to anticipate the fair and equitable distribution of the benefits.[13]

The United Nations Convention on the Law of the Sea (UNCLOS) has also initiated its own internal debate in order to evaluate the need of developing an ad hoc instrument to regulate access to and use of marine genetic resources. The potential of bioprospecting in the seas, including in extreme deep-sea environments is quite considerable and the activities taking place are increasing. In this context and given that many of these activities take place in zones beyond national jurisdictions, the design of coherent public policies and regulatory principles is essential.[14]

What is surprising within this institutional "picture" is that the relevance informational element, critical in research and development processes on genetic resources and biological or biochemical components in general (i.e. molecules, enzymes, proteins, etc.) had not been noticed before – at least within policy and legal circles. Since the times of Darwin and Mendel there has been a certain intuition on this informational dimension, that was later confirmed and verified with the discoveries and research of Watson and Crick on DNA structure and function. Furthermore, fully established disciplines on information economy (for which Nobel Prizes have been awarded) and reflections on intellectual property principles, should have quickly led to understand that the real purpose of access is not material, but rather the information, as essential in research and development and in the application of different technologies described in the previous section. For some, this has been a foundational error of the CBD which defined genetic resources as "material". Its implications are only now being realized.[15]

Examples of its application around the world

To undertake even a preliminary cataloging of concrete examples in which these technologies are being used, defies the scope of this Policy Brief, but there is a particularly relevant case that integrates the analysis of convergences and relevance of policy and legal matters. In 2018, the World Economic Forum (DAVOS) launched the Earth Bio-Genome Project that, in simple terms, aims to sequence and catalog the genome of all species of plants, animals and unicellular organisms, beginning in the Amazon region. It intends to store data and information in the Earth Bank of Codes, between other prestigiously recognized international repositories.[16] On the basis of advances of the Human Genome Project driven by the National Health Institute of United States of North America, the Bio-Genome Project is a massive effort to contribute to global biodiversity conservation, generate scientific knowledge and especially, trigger actions so that genetic resources and biological components can generate goods and services in a multiplicity of fields.

The Bio-Genome Project is led by some of the most important and prestigious universities and research centers in the world, both in developed and developing countries, including the Sao Paulo Research Center (Brazil), the Beijing Institute of Genomics (China), the Department of Agriculture and Smithsonian Institute (U.S.A), Royal Botanical Gardens (United Kingdom), among others, grouped in a high level collaborative consortium.

This collaborative effort demands multiple disciplines and technologies in order to be carried out, including bioinformatics, genomics, proteomics, Artificial Intelligence and the use and management of data (Big Data). A particularly interesting point that the Bio-Genome Project emphasizes is the possibility to apply "blockchain" as a tool to comply with ABS rules and principles and the Nagoya Protocol in particular. To comply with the requirement of "prior informed consent" and "mutually agreed terms" in the field of sample collecting actions and monitoring compliance of benefit-sharing agreements, it suggests that contracts - trough "blockchain"- can help to provide transparency and guarantee legal certainty required to undertake collecting activities of genetic resources and biological components in countries in the Amazon Basin.

This initiative is also interesting as it raises a number of questions related to its implementation process. For example, what levels of accessibility will there be to digital genetic information stored in the Earth Bank of Codes or the Amazon Bank of Codes? What type of intellectual property could be invoked for the protection of this data and information or its repositories? How can the origin of these specimens be determined, and subsequently the data and information for compliance purposes of the Nagoya Protocol and ABS rules in general? Is the Nagoya Protocol applicable? How will the fair and equitable distribution of benefits materialize? These are some of the questions that can be considered for this project in particular, but they have a broader scope, as they are equally applicable to other similar initiatives. It should be noted that this is an effort where the informational dimension appears as the central subject matter and object of interest.

Ultimately, more essential and in-depth questions continue to be relevant: who has rights and the control over this information and the technologies that allow its use?[17] As a reflection of the debates in the 1990s, these questions become more complex due to the very nature of information - disseminated and diffused – and the practical impossibility of invoking sovereignty over it. In other words, why would a country like Peru invoke sovereignty on a gene sequence of a determined species that can also be found in Bolivia and Ecuador? What implications would this type of question have on the possibilities to control, and maybe more importantly, develop a regulatory system that would be fair and equitable in the distribution of benefits derived from the utilization of this sequence.

An additional factor of complexity can be added and which is especially important for countries in the region: the cultural element. With a significant portion of indigenous peoples localized in the Andean and Amazon regions, the occidental paradigms of progress and development are not necessarily consistent with the approaches of progress of these groups. Although these approaches have in some way been gradually conciliating, there is still a long way to go. The technologies described in this document address dimensions that are particularly sensitive in the indigenous world, such as the possibility to manipulate life and its components. This element must also be considered in the debate.

Box 1
Artificial Intelligence and conservation

One of the most promising technologies to contribute to biodiversity conservation and environmental protection may be Artificial Intelligence (AI). It has multiple and unsuspected applications. For example, Artificial Intelligence and Game Theory is already applied to model scenarios that allow fighting against poaching and illegal fishing. This helps parks rangers, coast guards and those responsible for conserving the natural patrimony, to be ahead of any criminal action with a high degree of certainty, based on the application of AI in these scenarios.[18] In another example, AI combined with autonomous vehicles (i.e. drones) is beginning to substitute the inefficiencies of old models to control and monitor marine spaces and fisheries health. The potential of this duo of technologies may help to inform the decision-making processes more efficiently.[19] A third example, NASA, through satellite images and AI is currently monitoring the presence and distribution of phytoplankton due to the effects of climate change on sea temperatures. The presence of microalgae is essential to prevent the elevation of CO2 concentration on the planet.[20] The applications for AI are countless and their effectiveness is bought. For countries in the region, it is essential to maintain the progress and applications up to date in the fight to preserve the natural patrimony.

Source: Ruiz (2019)

The challenges and obstacles for countries in the region (South America)

Witnessing the scenario looming ahead with the Fourth Industrial Revolution, it is essential that the countries in the region understand the scope and implications of these technologies and prepare public policy and legal frameworks that appropriately accommodate these advances.

With the exception of some prestigious institutions (i.e. the International Potato Center, the International Center for Tropical Agriculture, the International Maize ad Wheat Improvement Center, the Biotechnology Institute of Universidad Nacional Autónoma de México (UNAM), Universidad Peruana Cayetano Heredia, Instituto Sinchi, EMBRAPA), biotechnological developments and the like have not consolidated nor expanded in the region. Countries are far more behind in the field of Artificial Intelligence, “Big Data” and information technologies in general, as tools converging with biotechnology, bioinformatics, genomics, etc. That expertise in interdisciplinarity is confined to fewer institutions, mainly in Brazil and Mexico.

Nor is it a matter of being naïve or excessively enthusiastic, as accessibility to these technologies and the expertise for their management and administration is expensive. Accessibility to technologies is hampered in many cases by intellectual property. The licenses to use some them require large budgets. Likewise, considerable human capacities are demanded to duly take advantage of this arsenal of technological tools. A core of experts committed to national development and with PhD´s as a minimum academic requirement, would guarantee sustainability of initiatives and efforts in all fields.

This is in addition to the State’s commitment, concretely expressed in public budgets assigned for research. Small public budgets are a practical barrier to enhance technological capacities in countries. Countries in the region are still significantly far from allocating adequate percentages of their GDP to scientific innovation and research.[21]

Conclusions

- The convergence and almost fusion among the biological, digital and physical worlds is having profound impacts on life sciences, biodiversity conservation and, ultimately, in the development of societies around the world.

- Knowledge intensive and transversal technologies such as genomics, gene editions, synthetic biology, bioinformatics, Artificial Intelligence, "blockchain", nano-biotechnology, among others, are changing the way in which research and development is being undertaken, where human resources and their capacities are equally or more important than the technological tools themselves.

- The resulting innovations in the field of health sciences, agriculture and production of industrial goods have notably altered the legal picture in many ways, mainly in terms of intellectual property applicable to these innovations and with regard to ABS, while the object of interest is no longer the tangible/material element to become the informational dimension.

- For countries in the region in particular, despite having to rely on biodiversity and genetic resources as the material base source of data and information, they are significantly behind not only in the knowledge and use of these technologies -with a few exceptions- but in general do not have public policy or legal frameworks to adequately face this new phenomenon and paradigm of development.

Recommendations

- There is the need to conciliate the tensions between some internal tendencies in countries, like in Peru and others rich in biodiversity. On one hand, opportunities provided by biodiversity and genetic resources through strategies, plans and even laws, are stimulated, promoted and highlighted in the policy agendas. But on the other hand, there is a trend to over-regulate or inefficiently regulate which directly discourages research and investments in projects, business and research in biodiversity in general. Tensions generate uncertainty and instability, and thereby, impact the interests of different actors in developing projects and investing in research and development.

- In this regard, many of existing science and technology strategies and plans need to be implemented. Brazil, Colombia, Chile, Mexico and Peru among others, have binding and non-binding instruments in place that promote technological development. A number of public institutions that promote science and technology (e.g. CONCYTEC in Peru, SENACYT in Panama, COLCIENCIAS in Colombia) should increase their investments in support of the development and management of the different technologies described in this Policy Brief.

- At the regional level (e.g. CAN or OTCA) there are no institutionalized spaces that allow debate among countries and experts on the advances and possibilities of these technologies, to subsequently inform and nurture discussions at the national level. In this regard, a suggestion is made to form a "Permanent Technical Group on Transformative Technologies and their Challenges", with a dynamic agenda that not only benefits South America but is also streamlined into international debates and forums. This type of space would also allow to share experiences and understand comparative enabling conditions which can support extensive use of new technologies.

- Biotechnology and Artificial Intelligence and their applications demand, above all, properly trained human resources for their application and implementation. The multiple applications of these technologies to conservation equally require a degree of knowledge among decision-makers and managers in order to understand that investments in their development and adaptation at the national level are investments, and not unnecessary expenses.

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2 See, https://www.ntnu.edu/physics/bionano

3 Apart for the fascinating scientific background to this technology, a controversy and legal dispute has brewed around its ownership, pitting MIT Broad Institute and Harvard University against Berkeley University of California in an intense legal battle. See, Jeweel, C., Balakrishnan, V.S. *The Battle to Own the CRISPR – Cas9 gene-editing tool*. WIPO Magazine. April, 2017. Available at, http://www.wipo.int/wipo_magazine/en/2017/02/article_0005.html

4 See, http://www.syntheticbiology.org

5 See, https://en.wikipedia.org/wiki/Blockchain

6 See, https://en.wikipedia.org/wiki/3D_bioprinting

7 This must be considered with a nuance: countries such as Brazil, China, India and México, for example, have notably strengthened their national capacities for the management and administration of many of these technologies and disciplines. The once North-South division or developed v. underdeveloped countries is much more diffuse these days.

8 See the WIPO report on tendencies in technology and intellectual property, *WIPO Technology Trends 2019, Artificial Intelligenc*e. Available at, https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1055.pdf

9 This instrument elaborated during the WHO Tenth Plenary Session. Available at, https://apps.who.int/iris/bitstream/handle/10665/44867/9789243503080_spa.pdf;jsessionid=1B3F1B92DF5B6D179CEA89A944374EF6?sequence=1

10 The foundations of 'life' are thus coming increasingly into view in a way that may not in fact require acts of collection in countries of origin. Furthermore, the increasing ability to transform biology into an informational good (i.e. DNA and amino acid sequence data) is likely to render physical checkpoints of limited utility in efforts to control such possessions. See, Oldham, P. (2004) *Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology*. Submission to the Executive Secretary of the Convention on Biological Diversity. Center for Economic and Social Aspects of Genomics (CESAGen). United Kingdom. Available at http://policydialogue.org/fi les/events/Oldham_Global_Status_and_Trends_Microorganisms.pdf

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17 In the U.S.A. and Europe, the discussion is not only political and legal. It has already reached the judicial level. In this regard, judicial precedents referred to property in technologies on gene editions (CRISPR) for example, and the intense battles for their control and commercial exploitation, will define further advances in R&D – and accessibility to these technologies. See, *Panel Advances Key Public Interest Issues in Gene Editing Technology*. Available at, https://www.ip-watch.org/2017/09/21/panel-brings-key-public-interest-issues-gene-editing-technology/

18 The work of USC Center of Artificial Intelligence for Society is, in this regard, pioneer. See, https://www.cais.usc.edu/projects/ai-for-conservation/

19 See, Workshop Report. Artificial Intelligence for Conservation (2017) Available at, https://environmentalsolutions.mit.edu/wp-content/uploads/2017/10/AI_WorkshopReport_FINAL.pdf

20 See, Three Ways in which AI is helping to Save the World. Available at, https://ensia.com/features/three-ways-artificial-intelligence-is-helping-to-save-the-world/

21 The case of Peru is symptomatic. With possibly the richest biodiversity in the region, it spends less than 0.1% of its GDP on innovations and technological development. These levels of investment make it impossible to tie the enthusiastic discourse on the potential of biodiversity, with real possibilities of its use, and in the last instance, its conservation. See, https://gestion.pe/economia/concytec-inversion-ciencia-tecnologia-e-innovacion-apenas-llega-0-12-pbi-247855

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