Title. Implementation of Nagoya Protocol on Access and Benefit-Sharing in Peru: Implications for researchers

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Abstract

Ethnopharmacological relevance: The Peruvian Amazon holds more than 1000 plant species with commercial potential and the national sales of natural products derived from medicinal and aromatic plants have exceeded $ 400 million per year. Research and development activities carried out on the genetic and biochemical composition of Peruvian flora have to abide by national and international regulations, such as the Nagoya Protocol (NP).

Aim of the study: The aim of this paper is to describe the implications of the current implementation of the NP in Peru for performing research on national genetic resources.

Materials and methods: A review of the current legal framework and status of the NP in Peru was performed accompanied by first-hand experience undertaken by submitting a request for access to genetic resources related to wild continental species.

Results: So far, Peru has issued 16 Internationally Recognized Certificates of Compliance (IRCCs) through 2 of the identified National Authorities. Some of the difficulties and challenges observed have to do with the degree of effective implementation of the Access and Benefit-Sharing (ABS) system, the fact that the application process is not sufficiently clear, and the wide gap between this formal system and what occurs informally outside of it. In response to this, training and implementation projects have been launched and a new law on the access to genetic resources has been proposed.

Conclusions: The difficulties observed still represent an obstacle to scientific research and the development of new commercial products based on Peruvian traditional knowledge and genetic resources. Although improvements have been made to the ABS framework, there remain major challenges to encouraging and ascertaining the equitable and sustainable use of Peru's biodiversity.

Keywords

Nagoya Protocol; Access and Benefit-Sharing; Collective Knowledge; Intellectual Property; Biotrade;

Glossary

ABS - Access and Benefit-Sharing

ABSCH - Access and Benefit-Sharing Clearing-House

CNA - Competent National Authority

CBD - Convention on Biological Diversity

CNBio - National Commission Against Biopiracy

CONADIB - National Commission of Biological Diversity

CONCYTEC – National Council of Science, Technology and Technological Innovation

DIGEMID - Directorate General of Medicines, Supplies and Drugs

DIGESA - General Directorate of Environmental Health

DIN - Directorate of Inventions and New Technologies

GEF - Global Environmental Facility

IGC - Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

INDECOPI - National Institute for the Defence of Free Competition and the Protection of Intellectual Property

INIA - National Institute of Agricultural Innovation

IRCC - Internationally Recognized Certificate of Compliance

MAT - Mutually Agreed Terms

MINAM - Ministry of Environment

NFP - National Focal Point

NP - Nagoya Protocol

PIC - Prior Informed Consent

PRODUCE - Ministry of Production

SERFOR - National Forest and Wildlife Service

SIPO - State Intellectual Property Office

TK - Traditional Knowledge

WIPO - World Intellectual Property Organization

1. Introduction

1.1 From the Convention on Biological Diversity to Nagoya Protocol

The Convention on Biological Diversity (CBD or Rio Convention from Rio de Janeiro, Brazil) was the first international treaty in 1992 to deal with ownership of genetic resources (Hesketh, 2015). Its three objectives are: the conservation of biological diversity; the sustainable use of its components; the fair and equitable sharing of the benefits arising from the utilization of genetic resources (CBD, 1992). The CBD was later reinforced by the Nagoya Protocol (NP), adopted on 29 October 2010 in Nagoya, Japan, and entered into force on 12 October 2014. This agreement states that access to genetic resources can occur only with prior informed consent by the provider country and a fair and equitable distribution of benefits between the resource applicant and the resource provider must be specified through mutually agreed terms. In addition, it requires the parties to adopt different measures to ensure that the genetic resources used within their jurisdiction have been accessed in accordance with their national legislation (CBD, 2010). Thus, the NP is intended to be an instrument to deal with any case of misappropriation of intellectual property (GIZ, 2016).

The Access and Benefit-Sharing (ABS) mechanism as part of the CBD treaty was intended as a response to centuries of savage exploitation of biodiversity and lack of recognition of the ownership rights of source countries (Heinrich and Hesketh, 2019). Quinine from Peruvian *Cinchona* species is a classic example in this sense (Heinrich, 2013). Another example, also from Peru, is the resin of dragon's blood (*Croton lechleri* Müll.Arg.), used traditionally especially in the Amazon area, and sustained by a good clinical and pharmacological evidence-base, but no benefits to local communities are known (Heinrich, 2013).

According to the NP “States have sovereign rights over the genetic resources found within their national jurisdiction”, therefore each state can define the way of access to its natural resources when it comes to research and development (Heinrich and Hesketh, 2019). Peru has been party to the NP since it has entered into force, after having signed it on May 4, 2011. The process of ratification of the NP took almost three years and was possible due to the joint effort of several governmental, academic and civil society institutions, through the inter-institutional platform “Ad Hoc Group on Access and Benefit-Sharing”, within the framework of the National Commission of Biological Diversity (CONADIB).

1.2 ABS, an opportunity for Peru

Peru is considered to be one of the most biodiverse countries in the world; 10% of all higher plants species identified worldwide can be found within its territory (MINAM, 2010). Also, it is estimated that the Peruvian Amazon holds more than 1000 plant species with commercial potential (FAO, 1994) 400 of which are native plants with applications in pharmaceutical industry (Kámiche Zegarra, 2010).

Peruvian national sales of natural products derived from medicinal and aromatic plants exceed $400 million per year (UNCTAD, 2018). This is in line with the global increasing demand for biotrade and environment-friendly products with sales that boomed from $40 million in 2003 to more than $5 billion in 2016. Such growth offers huge opportunities for Peru, that could largely benefit from an efficient and effective implementation of an Access and Benefit-Sharing (ABS) scheme (Silvestri, 2016) to achieve some of its fundamental objectives. For example, it would be possible to: (a) slow down the loss of biodiversity by distributing the benefits derived from the use of genetic resources with the countries that provide them, who are generally rich in biodiversity but poor in financial resources (Silvestri, 2017; Godt, 2009); and (b) compensate indigenous and local communities for the use of their traditional knowledge in

relation to biodiversity, given that this information has been widely used for advancements in science, and no reward for that has been granted (Aguilar, 2001).

Despite its richness in terms of indigenous traditional knowledge and biodiversity, Peru, like many other countries, is struggling to update its administrative procedures and regulations in order to respond in a timely manner to researchers and private companies that request formal access to genetic resources. For national and international researchers, it is important to understand that any possibility of studying Peruvian plants and any other genetic resource, and the possibility of creating patentable inventions, requires an authorization granted by the competent Peruvian authorities. The implication for researchers is to consider whether or not to get involved in such a procedure.

The aim of this work is to describe the current level of implementation of the NP in Peru for performing research on national genetic resources by presenting challenges and opportunities also related to the global context, and to analyse its implications for the country and for the development of new products based on its biodiversity.

2. Materials and Methods

A literature review on the application of the NP with a focus on Peru's situation was performed. The Access and Benefit-Sharing Clearing-House (ABSCH), which represent the main reference website to learn about the application of the NP worldwide, was consulted (ABSCH India, 2018). Major publications including peer reviewed articles were analysed and discussed. Special consideration was given to the Interim National Report on the Implementation of the Nagoya Protocol issued by the Peruvian Ministry of Environment (MINAM) and published in the ABSCH website (MINAM, 2018), as well as on other

reports issued by the different Peruvian authorities, including the recently published Sixth National Report to the Convention on Biological Diversity 2014-2018 (MINAM, 2019a).

Moreover, a first-hand experience on the application of the protocol in Peru was undertaken by submitting a request for access to the national authority responsible for the genetic resources related to wild continental species, that is the National Forest and Wildlife Service (SERFOR). Direct field experience on the implementation of NP/CBD of some of the authors of the article (FM, AH, MH, and VB) constitutes an important part of the results presented in this research as does the experience of the authors in other biodiverse regions (AH, MH, MP).

A review of the legal framework for the application of Nagoya Protocol in Peru was performed. The main laws recorded and discussed are: a) Law N° 27811 on the Regime for the protection of collective knowledge of indigenous peoples related to biological resources; b) S.D. Nº 003-2009-MINAM Supreme Decree that approves the Regulation R.M. N° 087-2008-MINAM for Access to Genetic Resources; c) Decision Nº 391 of Andean Community establishing the Common Regime on Access to Genetic Resources; d) Decision Nº 486 of Andean Community Establishing the Common Industrial Property Regime; e) Law Nº 28216 on the protection of access to Peruvian biological diversity and the collective Knowledge of indigenous peoples.

3. Results & Discussion

From the website of the Access and Benefit-Sharing Clearing-House (ABSCH), as of March 2020, there have been 1222 Internationally Recognized Certificates of Compliance (IRCCs) granted in 21 of the 123 countries which are party to the NP. The main countries of origin of the IRCCs are India (741), France (233), Spain (60), Kenya (38), Vietnam (30), South Africa (29), Panama (20), and Peru (16). The other

thirteen countries contribute 55 IRCCs. Other Latin American countries that have issued IRCCs include Mexico (8), Guyana (5), Uruguay (3), Guatemala (2), Dominican Republic (2), and Argentina (1). A more internationalized review involving case studies from Latin American countries falls out of the scope of this study and could be a matter of further investigation.

Nevertheless, in order to put Peru's ABS framework into perspective, the political, environmental and biological context is essential. For example, Brazil's case is significant being that it is a neighbour of Peru and the custodian of most of the genetic resources of the Amazonian rainforest. Brazil has no IRCCs. Although a signatory to the CBD, the country has not ratified the NP. Still, Brazil has updated its ABS national system to include the provisions of the NP and the current legal framework is mainly built upon Law Nº 13123/2015 and Decree Nº 8772/2016 (Silvestri et al., 2020). The current Brazilian ABS system no longer requires prior authorization or a permit to access genetic resources. Instead, it requires only a registration in SisGen, "*an online self-registration and notification system that requires access to any Brazilian genetic heritage and to associated traditional knowledge to be informed, managed and monitored*" (Silvestri et al., 2020), thus making access procedures more simplified. On the negative side, it has been said about the implementation of the CBD in Brazil that: *"The restrictive legislation in Brazil conflicts with global initiatives to foster Biodiversity Sciences"* (Alves et al., 2018) by unintentionally creating redundancies and added bureaucracy that hinder efficient research on biodiversity. On the other hand, India, which has the most IRCCs globally, was one of the first countries to ratify the NP. Its ABS application process is a simple online procedure; India is the only country to place a link to the online ABS application on the ABSCH website (ABSCH India, 2018).

Therefore, an assessment of the Peruvian policy, its implementations and the specific opportunities and challenges can be an essential step to understand how equitable and sustainable access can be ascertained.

3.1 Implementation of NP in Peru

Peru's ABS National Focal Point (NFP), that is the national institution tasked with making information on ABS available (CBD, 2010) is the Ministry of Environment (MINAM) that operates through 5 Competent National Authorities (CNA). Apart from the MINAM itself that is the governing body, among the CNAs we find 3 institutions in charge of authorizing and subscribing contracts for access to genetic resources and associated intangible components, and verify compliance with the agreements. These are:

a) National Forest and Wildlife Service (SERFOR), responsible for granting access to genetic resources related to wild continental species;
b) The National Institute of Agricultural Innovation (INIA), responsible for cultivated or domesticated continental species;
c) Ministry of Production (PRODUCE) through the Vice Ministry of Fisheries and Aquaculture, having jurisdiction over marine and hydrobiological species in continental waters;

The fifth CNA is the National Institute for the Defence of Free Competition and the Protection of Intellectual Property – INDECOPI, that is responsible for protecting the Traditional Knowledge (TK) of indigenous peoples associated with said genetic resources. In this sense, its activities are focused on the registration of TK, registration of license of use agreements and monitoring of the rights of protection associated to TK, as well as the registration of patents. INDECOPI maintains the Register of Collective Knowledge and the Register of Licences for the Use of Collective Knowledge. INDECOPI, through Law N°27811, established the obligation to ask for the prior informed consent of the indigenous people through their representative organizations when someone wants to access to collective knowledge, and to subscribe a license contract for commercial and industrial purposes (INDECOPI, 2002). The law also aims at promoting the fair and equitable distribution of the benefits derived from the use of this collective

knowledge (INDECOPI, 2002). One of INDECOPI's task is to prevent patents from being granted to inventions developed from TK of the indigenous peoples of Peru, without taking these obligations into account. Once the benefits negotiation phase under the ABS framework is reached, the representative organization of indigenous peoples (this can be a Federation, Association, Confederation, or other indigenous organizations at national, regional or local level) (INDECOPI, 2016) should inform the greatest possible number of indigenous peoples who possess the same knowledge and take their interests and concerns into account (INDECOPI, 2002).

Peru's checkpoints, in charge of monitoring and enhancing transparency about the utilization of genetic resources (CBD, 2010) are located at the end of the access chain. These are:

a) The Directorate of Inventions and New Technologies (DIN) of INDECOPI, which has the authority to resolve requests, among others, for invention patents, by verifying, if necessary, the contract of access to the genetic resources and/or the license contract for the use of collective knowledge of the indigenous peoples;
b) The National Commission Against Biopiracy (CNBio) that exercises control over illegal access to genetic resources and associated traditional knowledge, through searches of granted patents and patent applications in the main patent offices worldwide.

3.2. IRCCs issued in Peru

The full list of IRCCs issued in Peru as of March 2020 is available in **Appendix 1**. Eight of the permits there summarized are for use internally in Peru. Six are from academic institutions in U.S.A. and two are from academic institutions in Germany. All the certificates are for non-commercial purposes, although one of these has been signed by the INIA with a private company, Cosmo Ingredients, while the rest have

been signed with researchers supported by an academic institution. In the case of the access contract signed between INIA and Cosmo Ingredients, the whole process, from initial application to the final access contract signed, lasted around 24 months. This is in line with what stated by MINAM (2019b) which in its reports indicates that the time for evaluating applications varies between three months to four years. In the case of PRODUCE, to date no access contracts have been granted, however, there are applications pending for more than two years (MINAM, 2019b). To date there are also 3 applications submitted to INIA currently under revision that are expected to lead to new IRCCs in the next few months (MINAM, 2019b).

Based on the information of the access contracts signed by SERFOR and INIA, most of the contracts signed include benefits aimed at the conservation of biological diversity, identifying the importance related to its protection and sustainable use, and expanding knowledge around the species involved, allowing them to be valued.

According to the Interim Report (MINAM, 2018), so far the application of the NP has generated both monetary benefits, with direct payment for collection and salary payment to experts for identification and collection activities, as well as non-monetary benefits that are considered greater and include: participation of national professionals in the process; the strengthening and development of the National Support Institution or the provider institution; the transfer of scientific and technological knowledge to national professionals; the putting in place of conditions for in-country research that contributes to the conservation and sustainable use of biological diversity; and the strengthening of mechanisms for knowledge and technology transfer (MINAM, 2018).

3.3 Challenges and difficulties

Although access and benefit sharing in the use of genetic resources is one of the goals of the National Biodiversity Strategy - EPANDB 2021, the recently published Sixth National Report to the Convention on Biological Diversity (MINAM, 2019a) recognizes that progress has been made at an insufficient rate: as of 2018, only 30% of the regulatory framework established with the Nagoya Protocol has been implemented in Peru. In addition, researchers who have analysed Peru's ABS system (Silvestri, 2016), and other government reports (MINAM, 2018), indicate that Peru faces several important challenges and difficulties in relation to the subject of ABS. We can highlight the following facts from the above references:

a) Following the implementation of NP in Peru, researchers were asked specific information about their research activities, including what they plan to do during a visit to a provider country and to prepare a benefit-sharing plan. Researchers report several concerns (Kupferschmidt, 2018); one of these is practical and has to do to the fact that this adds to their work a huge burden of regulations to face. In the case of Peru, the procedure of access to genetic resources is complex and bureaucratic. There is no adequate dissemination of the steps to follow and requirements for users to be able to submit an application in the first place, which in fact discourages the negotiation of ABS contracts (Silvestri, 2016). Also, once the application is received and processed, in some cases issuing access authorizations demands up to two or four years (MINAM, 2019b).

b) There is weak monitoring and supervision regarding compliance with the terms and conditions of access contracts (Silvestri, 2016). Although compliance measures and verification points have been established in accordance with the provisions of the Nagoya Protocol, there is no control over the legality of access to genetic resources and traditional knowledge associated with the use of these when they come from any country other than Peru. Verification points are considered to

be insufficient in number (MINAM, 2018). The current challenge is to establish additional verification points that cover the stages of: i) research; ii) development; and iii) commercialization. This could be achieved by appointing other interested and competent national parties such as the National Council of Science, Technology and Technological Innovation (CONCYTEC), the General Directorate of Environmental Health (DIGESA) and the Directorate General of Medicines, Supplies and Drugs (DIGEMID).

c) Lack of personnel and budget dedicated to the implementation of the legal framework has been observed (MINAM, 2018). While the system has a total staff of 12 managers, 5 coordinators and 35 specialists, in almost all institutions the number of managers is greater than or equal to the number of specialists. Only in the case of INDECOPI is there a pyramidal distribution of the staff with a much larger number of specialists (26) over managers (2) (MINAM, 2018). The continuous rotation of managers and contact person within the national authorities is another issue of concern for researchers (MINAM, 2018). Another challenge reported is the need for more training on ABS among the actors involved in the process: authorities, national and regional officials, the scientific community, native communities and the general public.

d) It is considered necessary to promote the institutional co-ordination between the governing body (MINAM), the CNAs, the National Support Institutions, the Checkpoints and other involved actors, as well as strengthening their capacities for monitoring and supervision (MINAM, 2018). Being sectored authorities, the CNAs have shown difficulties in the interpretation of the jurisdiction that corresponds to each institution in terms of certain aspects of the law and access administration, as for example with the distribution of certain taxonomic groups among the CNAs (microorganisms, wild relatives of a cultivated species, etc.). There is also poor co-ordination

between the authorities that grant access to genetic resources and the authorities that presides over the protection of traditional knowledge (MINAM, 2018).

e) The role of the "National Support Institution" seems to be poorly defined, being considered as a mere controller; if this situation is not improved, valuable scientific collaborations in favour of local scientific institutions will be lost (Silvestri, 2016). The National Support Institution was intended as the national counterpart dedicated to scientific or technical research, that accompanies the foreign applicant in the process of accessing genetic resources and participates with it in access activities (Comunidad Andina, 1996).

f) The greatest demand for genetic resources is focused on research, but we observe a gap between the regular access to genetic resources that passes through the ABS system and the one that occurs outside of it. According to MINAM (2019b) up to 2017, only 30% of the research and development activities identified (86 out of 290) were passing through the ABS system.

g) A difficulty not exclusive to Peru concerns monetary ABS agreements. At least 5% of the gross sales resulting from the commercialization of the products developed from the collective knowledge must be given back to the provider organization (INDECOPI, 2002). To this must be added 10% to the Fund for the Development of Indigenous Peoples, whose initial objective was to strengthen indigenous organizations, achieve its development, and safeguard its traditions and knowledge. This measure is so far considered ineffective (MINAM, 2019a). First, the Fund has not yet been created. Secondly, since the promulgation of Law 27811, no agreement for the use of traditional or collective knowledge has been signed; and no request has been registered (MINAM, 2018). We can find two explanations: from the user side, that the monetary benefits are considered

too high by private companies; and from the provider side, that the indigenous and local communities have limited knowledge of the legal framework and no control over an illegal access by national and foreign users. Also, reports consider that there is still no clear identification of those populations that possess traditional knowledge associated with biological resources, whose rights have not been covered by Law 27811 (MINAM, 2018); the development of community protocols is still in an incipient state.

h) The use of patent protection for intellectual property in the field of ethnopharmacology/natural product research has often received negative comments (Heinrich and Hesketh, 2019). Researchers suggest that the real issue is not the patenting of natural products, but the lack of engagement with the provider countries (Heinrich and Hesketh, 2019).

3.4 First-hand experience with Nagoya Protocol in Peru

The request for access to genetic resources submitted in May 2019 as part of the present research was reported by the officials of the competent national authority (SERFOR) as one of the very few requests made by a foreign institution (University of Chieti, Italy); such information was acquired during an informal dialogue with SERFOR competent personnel in charge of our ongoing application for IRCC.

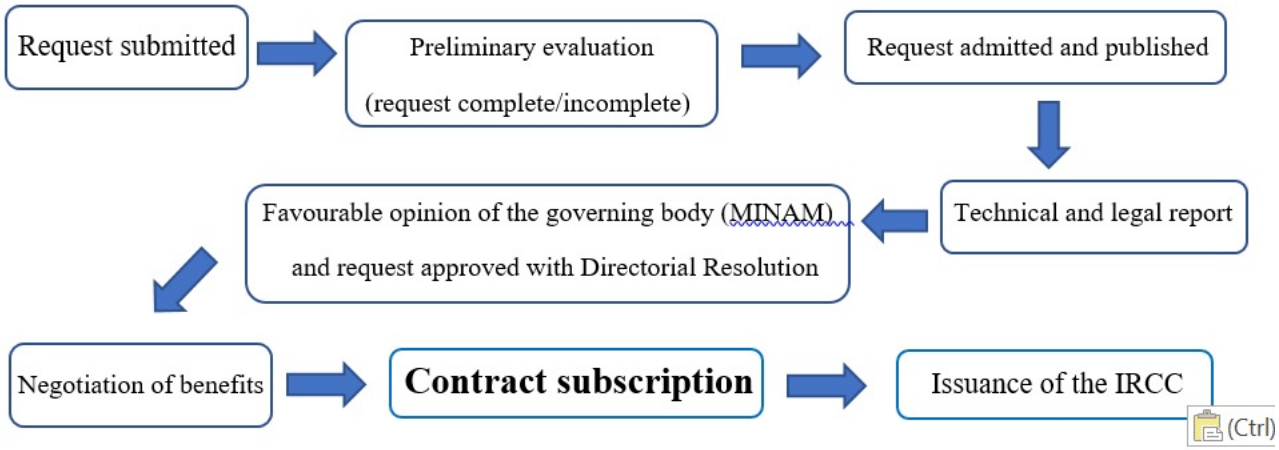
The first step to submit a request for access to genetic resources is to prepare all the corresponding documents, which are very similar among the various institutions, and in the case of SERFOR include:

1. Formal request addressed to the director of the competent authority;
2. Contract or agreement with the owner of the property where the biological resource containing the genetic resource is located, and with the owner of the biological resource, as appropriate;

3. Contract or agreement with the corresponding Native Community, to access the collective knowledge or intangible component related to the genetic resource, as appropriate;
4. Letter of commitment from the National Support Institution and agreement signed between this and the applicant;
5. Curriculum vitae of the researcher responsible for the project and its working group and endorsement letter issued by the institution to which the researcher belongs;
6. Detailed research project proposal, also containing a schedule of the activities.

Standard forms of these documents are accessible through the website of the competent authorities[1]. It is emphasized that all these documents must be presented in Spanish. Once the request is submitted, the process leading to its approval and the issuance of the IRCC certificate is graphically presented in **Figure 1**.

Figure 1



[1] INIA: https://www.inia.gob.pe/requisitos-acceso-rrgg/; SERFOR: https://www.serfor.gob.pe/servicios-de-investigacion/autorizacion-acceso-recursos-geneticos

In the case of the request for access submitted as part of the present research, after three months the preliminary evaluation of SERFOR proposed several changes, especially referring to the research plan as such and – as specified below – one must ask how relevant these are in the context of access and benefit sharing and in resulting in delays to the research activities. Some observations refer to technical aspects of the research proposal; this was about the phytochemical and pharmacognostical study of a medicinal plant traditionally used in Peru. Some observations ask for details about the biological and chemical analysis to be performed on the plant material. This kind of information are usually disclosed in a research proposal used to apply for funding, and the request for further details appears to us inappropriate in this context also because the competent authority, in this case SERFOR, does not have the technical expertise to evaluate a scientific proposal in such level of details. Moreover, there were no clear reassurances about the strategy adopted by SERFOR to protect and keep confidential the information acquired from the proposal. Another ambiguous observation was about the request to justify the pharmacognostical aspect of the study on the basis of evidences concerning the use and the efficacy of the selected medicinal plant. Considering that our project would represent the first scientific investigation on the selected plant species, it was no possible to respond to such observation. This highlights the weakness of not having technical and scientific expertise inside the authority in charge to evaluate the research proposals. In accordance to what reported above by other researchers, in our experience this considerable amount of paperwork to face, just to submit a request for access, is a matter of concern. From the applicants' perspective the procedure of access to genetic resources has proven to be to complex and bureaucratic and we decided to stop the request to access a genetic resource in Peru. Considering that several IRCCs took up to 5 years to be released, we consider our decision, although early, certainly appropriate.

Additionally, the ambiguity of Peruvian regulations seems to generate contrasts with what is indicated in the international reference laws. During our first-hand experience we point out a potential conflict with international laws, in this case Decision 391 (Comunidad Andina, 1996), since Peru's law includes an exemption for "research activities involving the use of non-timber natural resources, to produce natural products (nutraceuticals and functional foods)" (MINAM, 2009). This could offer a huge chance to private companies to circumvent the ABS scheme. Because the category of nutraceuticals is not regulated in Peru, the introduction of this very specific exemption seems to be even more ambiguous and enigmatic. This could allow foreigner companies to register in their countries Peruvian plant products as nutraceuticals without following Peruvian ABS scheme.

3.5 Assessment of this example

Some of the difficulties observed are linked to the degree of effective implementation of the ABS system, the lack of clarity of the application process, the slow response and the wide gap between this formal system and what occurs informally outside of it. Although the highest demand for access is for research, the complexity of the procedure to apply the NP in Peru seems to penalize international research collaborations, rather than facilitating it as suggested by its objectives. This appears to confirm what has been observed in other studies (Deplazes-Zemp et al., 2018). The ineffective application of the NP in Peru could also lead companies and researchers to move their interests to neighbouring countries that have a similar biodiversity and a less demanding regulatory framework, such as Brazil. A further hurdle can often be the reluctance to embrace intellectual property rights, which hinders the essential open dialogue and cooperation between commercial partners and biodiversity-rich countries such as Peru (Heinrich and Hesketh, 2019).

3.6 The cart before the horse; a company's perspective

If we approach the Nagoya Protocol from the companies' perspective, it could be considered premature to undertake such an apparently complicated system before even knowing if the conditions exist for investing in the research and development of a new product. A practical example may illustrate this perspective.

Indena is an Italian-based, research driven company; a responsible of the regulatory department of the company co-authored the present article. The company is devoted to the research, production and sales of botanical derivatives for use, mainly, in the medicinal, health food and cosmetics markets. In order to carry out this business, the company must plan two areas of activity:

First, research on a country's plant species. Ethnopharmacology, the scientific study of ethnic groups and their use of drugs mainly based on botanical remedies (Hesketh, 2015), offers a strong rationale for the development of innovative modern botanical derivatives. This way of exploring old remedies with a modern and scientific approach is strongly linked to a possible involvement of local traditional knowledge.

Secondly, Indena must consider the sustainability of its genetic resources supply chain; this is a common concern in the field of natural product research and development, as pointed out by the recently coined dedicated term "eco-pharmacognosy" (Cordell, 2011, 2014a, 2014b). In the event that a research project has a positive outcome and a new product is launched, the first burden for a company is being able to source enough quantities of the relevant biomass to satisfy market needs in the long term.

To invest in both of these activities, Indena first and foremost requires legal certainty. First, the certainty in local ABS rules is important when planning and managing research projects. Secondly, a reasonable

timing to get prior informed consent (PIC) and mutually agreed terms (MAT), especially to agree benefit sharing, keeping in mind the target of supply chain sustainability. Without these important assurances, Indena cannot risk the investment needed to determine if conditions exist to investigate new opportunities from the biodiversity of Peru.

The problem of certainty for business planning is consistent with the experience, in other provider countries, of one of the authors (AH) who is director of British company Indigena Biodiversity Limited (not to be confused with Indena). Indigena Biodiversity partners with UK-based research and commercial companies, to explore opportunities for research on genetic resources endemic to provider countries including in Latin America. The research and commercial partners find it premature to define the precise details required for a MAT agreement at an early stage of research, when it could take many years to develop a product and assess its market position. Without the flexibility of negotiating the benefit terms of a MAT until a later stage of development, those companies would prefer not to risk the initial investment in investigating new genetic resources.

3.7 Digital sequence information and pathogens

A current topic of discussion around NP is the possibility to include "digital sequence information" in an international agreement against misappropriation of intellectual property. For example, researchers might be obliged to ask for permission before using publicly available gene sequences obtained from plants or animals originating there. This could stifle research, hamper the fight against disease outbreaks, and even jeopardize food safety.

Most of the NP parties consider human pathogens, such as bacteria, fungi and viruses as genetic resources that fall under the scope of the Protocol (Manheim, 2019), given that these are defined as "any material of

plant, animal, microbial or other origin containing functional units of heredity". As a result, the use of pathogens for public health purposes is subject to the ABS requirements and procedures of individual countries. A concern expressed by the US State Department is that 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 provider countries, given that the negotiation of an ABS agreement is often a long and challenging process (US State Department, 2019). This problem may be exacerbated by the position of many of the Protocol parties that consider the term "genetic resources" to include "digital sequence information" of pathogens. 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 (US State Department, 2019).

In the face of the possible appearance of emergency health situations (epidemics or pandemics), Peru believes that mechanisms should be activated to facilitate access to genetic resources that can be used to prepare vaccines, diagnostic kits, medicines, etc. (MINAM, 2018). However, considering that these are currently developed by countries with a more advanced biotechnological sector, provider countries such as Peru are at risk, not only of becoming mere suppliers of genetic resources for human pathogens, but also to be customers of these biological medicinal products prepared through the use of the very same genetic resources whose access has been granted by Peru. Considering this, the Interim National Report on the Implementation of the Nagoya Protocol proposes establishing speed-up procedures not only for granting access authorizations, but also for the fair and equitable participation in the derived benefits, without ignoring the fulfilment of requirements such as PIC and MAT (MINAM, 2018). As part of the benefits to be negotiated for the use of genetic resources from pathogens, the Interim Report suggests establishing cooperation mechanisms between the countries with the highest technological development

and the national health sector, in order to create, develop and strengthen local human resources, as well as institutional and infrastructure capacities, in the perspective that in the near future, Peru could be able to manufacture its own vaccines and cease to be only a provider of genetic resources (MINAM, 2018).

3.8 Dealing with biopiracy - past reactions and future solutions

(a) Reactions of the Peruvian government to past biopiracy

In 2002 INDECOPI summoned a group of institutions to perform a technical analysis of some complaints regarding cases of misappropriation or biopiracy, specifically referring to maca (*Lepidium meyenii* Walp.). This so-called "Grupo de la Maca" (Maca Group) determined that biopiracy regarding maca was not an isolated case but part of a global trend (INDECOPI, 2003). The Group demonstrated the problems faced by mega-diverse countries like Peru in relation to the international patent system (GIZ, 2016) before the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). This was the first step toward the creation of the National Commission Against Biopiracy (CNBio) whose monitoring work has been widely recognized nationally and internationally. During 2018 Peru's CNBio won 45 cases of misappropriation of intellectual property worldwide regarding the misuse of traditional knowledge linked to Peruvian biological resources (SPDA, 2019). This normally leads to a withdrawal or rejection of the protested patent application or patent grant, although it is not possible to trace the outcome of every single case, and only for some of them INDECOPI informs on the final result (INDECOPI, 2019). Among the most frequent cases identified in 2018, we find several related to the use of dragon's blood (*Croton lechleri* Müll.Arg.) with 26, maca with 24, and sacha inchi (*Plukenetia volubilis* L.) with 8. These are some of the 69 biological resources of Peruvian origin that the CNBio has put among its priorities to carry out a permanent monitoring on patenting (INDECOPI, 2018). In the case of maca, patent cases are filed predominantly by a single country, China (Heinrich and Hesketh, 2019). The same seems to be happening

with sacha inchi. In 2017, CNBio detected two patent applications filed by the China Eucalypt Research Center with the State Intellectual Property Office (SIPO) of China and started an investigation on the applicant for information on the source of access to the genetic resource. “Peru should consider the possibility of participating much more actively in the research and development processes relating to plants and biological materials”, as affirmed in the 2003 Peru WIPO IGC submission (INDECOPI, 2003).

(b) Dealing with the present and future - NP implementation

April 2018 marked the beginning of the four-year project "Effective Implementation of the Access and Benefit Sharing and Traditional Knowledge Regime in Peru in accordance with the Nagoya Protocol" funded by the Global Environmental Facility (GEF) and led by the national Peruvian authorities involved in the NP[2]. The objective of this project is "to put into practice the Nagoya Protocol for access to genetic resources", as an opportunity to strengthen the national framework and reduce illegal access. Many of the previously reported weaknesses, challenges and difficulties are supposedly being addressed by this project, which seeks to: (i) establish an efficient functioning of the ABS mechanisms in accordance with the NP, (ii) strengthen the capacity of the various stakeholders in relation to access to genetic resources and traditional knowledge, (iii) implement pilot projects and initiatives on ABS that contribute to the sustainable use of Peru´s biodiversity, (iv) train public workers to make correct decisions when evaluating the requests for access (MINAM, 2018). Additionally, to respond to the lack of information about the NP among knowledge-providing communities, a strategy is being implemented to raise awareness of the ABS scheme and the NP, which aims to disseminate among indigenous peoples the norms and mechanisms on protection of traditional knowledge, and develop a capacity-building program for indigenous peoples and communities in negotiation on traditional knowledge.

[2] https://unctad.org/meetings/en/Presentation/ditc-ted-12092018-BioTrade-IV-Noejovich.pdf

In addition, a proposal from MINAM to update the regulations for access to genetic resources and their derivatives is currently in its final stretch (MINAM, 2019b); the new law was initially expected to be approved by the end of 2019 but, at the time of the present manuscript (submitted in 02-2020), has not yet been issued. Among the notable changes of this new proposal we find the elimination of the exemption on nutraceuticals, given that the same government authorities seem to be aware of the obvious contradiction that this exclusion generates. Other changes include the addition of an exemption for basic research related to the identification, delimitation and classification of species for taxonomic, systematic, phytogeographic purposes that do not have any commercial implication (MINAM, 2019b). Such studies will go through a simpler procedure as a research authorization that is already being applied in the case of ethnobotanical research. The general objective of this new law is to facilitate research and mark a clear difference between access to genetic resources for non-commercial research, on one hand, and for commercial purposes, on the other hand. The new proposal also aims at giving greater importance to the National Support Institution, specifying its role in assisting the foreign applicant in access activities, as well as its rights and obligations.

4. Conclusions

The present evaluation of the implementation of biodiversity policies shows that Peru has made good initial progress on its efforts to implement the Nagoya Protocol. However, the analysis shows core challenges that need to be resolved. This highlights how the application of complex rules, although inspired by ethically correct principles and marked by good intentions, could be counter-productive, especially in developing countries or similar, at least in this preliminary phase. There needs to be active consultation with all stakeholders, both nationally and internationally.

Experience facilitates the process. Peru, like many other countries, only recently has been accumulating some experience on this topic. The challenge now is to improve the process. In addition, it can be observed that most of the researchers who have obtained the IRCCs certificates had participated directly, or indirectly through their academic institutions, in previous processes of access to genetic resources, under the national legal framework pre-NP. The hope is that in the future this ability will not be limited to a handful of researchers, but that the process will become more accessible to other researchers who can provide new scientific knowledge and/or technologies. Currently, researchers might also consider waiting until the approval of the new law proposed by MINAM (2019b) instead of keep trying to obtain access under the current system.

Overall, to achieve a successful implementation of the Nagoya Protocol, an ABS framework should encourage international partnerships. The mechanism should be based on mutual trust; involve all stakeholders; and include clear and straightforward access requirements. Minimum royalty figures should be avoided; instead local and foreign partners should be free to negotiate mutually acceptable terms. In this way, open dialogue can be encouraged, which can lead to a result that is beneficial for all parties. An ideal application of the Nagoya Protocol could also result in the promotion of the use of genetic resources for the purpose of innovation and biotechnological development according to the needs of the country and one concrete result could be the development of national laboratories and research centres in innovation and biotechnology. Further efforts are necessary also to analyse in detail the real applicability of the principles of NP in relation to the rights related with the traditional knowledge of indigenous peoples.

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