
WHO OWNS BIODIVERSITY AND CULTURAL HERITAGE?

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Vaccines, medicines, food, fashion: different industries are keen to make use of genetic resources and the cultural heritage of Indigenous peoples. But who owns such assets, who can make use of them, and at what price? Despite the agreements in place and a UN conference in Cali, all this remains unclear. Giving an overview of the regulatory landscape legal expert Pedro Henrique D. Batista knows which approaches are needed today.

In 2024, the industrialized nations negotiated new international agreements on this issue with countries that are rich in biodiversity. Despite the advances precise and effective international regulation is still needed to guarantee legal certainty and efficient access for entitled users, as well as fair benefit-sharing to protect biodiversity, the sovereignty of the countries of origin, and the fundamental rights of Indigenous peoples.

High-selling products are ever more frequently rooted in the cultural heritage of Indigenous peoples, genetic resources, and the information obtained from them. Genetic material from organisms – often taken from Indigenous land – is used to develop vaccines, medicines, and food products, for example. Fashion, meanwhile, in part incorporates designs based on the art of Indigenous peoples.

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VIEW POINT

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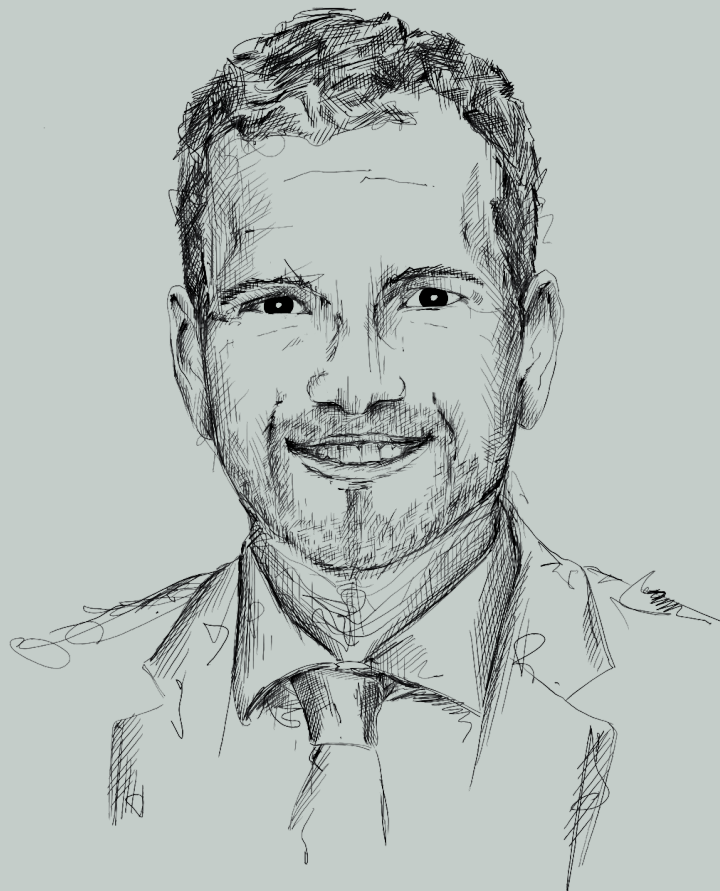


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Whether in fashion, accessories, or biotechnology, such uses are still plagued by an age-old question: to what extent can they take place without the consent of the countries of origin or the Indigenous peoples to whom these resources and cultural artifacts belong?

The last few decades have seen much talk about cases of “biopiracy”, “cultural appropriation”, and “theft of cultural heritage.” These cases reflect the demands of countries that are home to Indigenous peoples and have abundant biodiversity for a fair share in the benefits that come from the use of their biodiversity and culture. These demands are rooted in the rights of Indigenous peoples as well as sovereign rights of countries to their genetic resources and in the protection of their biodiversity.

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Accordingly, many of these countries – particularly in Latin America, Africa, and Asia – have introduced legal protection for genetic resources (such as genes and their sequences) and cultural heritage. Yet this protection at a purely national level is often not sufficient to ensure the desired fair distribution of benefits, since the use of biodiversity and cultural heritage usually takes place in countries with a strong industrial base – such as the USA, Japan, and those of the European Union – and these countries are generally not particularly interested in strong legal protection for the genetic resources and cultural heritage. In particular, they do not want the bureaucratic requirements of the system to create legal uncertainty or barriers to innovation and creative freedom.

In recent decades, several important treaties have been adopted in an attempt to reconcile these conflicting interests. The 1992 *Convention on Biological Diversity (CBD)* and its *Nagoya Protocol* from 2010, for example, require users – such as businesses or research institutions – not only to obtain consent from countries of origin or Indigenous peoples to gain access to their genetic resources and the traditional knowledge associated with them, but also to provide appropriate compensation for the benefits that arise from their use. This might take the form of financial benefits (such as access fees, a share in the profits from production, or research resources) or of non-financial benefits (such as scientific collaboration, technology transfer, or shared ownership of patents).

This bilateral relationship between users and countries of origin (or Indigenous peoples) can nevertheless be particularly costly and time-consuming in some instances. To ensure that innovation is not hampered in areas of particular significance for humanity, the Food and Agriculture Organization’s *International Treaty on Plant Genetic Resources for Food and Agriculture* and the World Health Organization’s *Pandemic Influenza Pre-*

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paredness Framework provide for a multilateral benefit-sharing mechanism for the use of certain crops (such as apples, bananas, potatoes, carrots, corn, or sunflowers) as well as influenza viruses. In these instances, the benefits flow into a special fund that distributes them to countries and projects according to predetermined criteria.

Finally, the *Agreement on Marine Biodiversity in Areas beyond National Jurisdiction* (BBJN) was signed in 2023 as part of the United Nations Convention on the Law of the Sea. Among other things, this agreement governs the sharing of benefits in the event that genetic resources are used from waters over which no country has jurisdiction.

Despite these advances, gaps in protection and the imprecise formulations of these treaties mean that only a small proportion of commercial benefits are shared with the countries of origin or Indigenous peoples. Moreover, important elements of cultural heritage remain unprotected. Yet there are complaints from industry, too, about substantial legal uncertainty in relation to their obligations, since access rules are often unclear and vary considerably across different countries. Consequently, there is still a need for further international regulation.

Against this background, the year 2024 could be considered the year of biodiversity and cultural heritage, as no fewer than four important international agreements were simultaneously negotiated in these areas.

The most successful thus far is the *Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge* of the World Intellectual Property Organization (Wipo), which was adopted last May. It aims to bolster legal certainty and create transparency to ensure compliance with national access and benefit-sharing rules. The treaty includes an obligation for patent applicants to indicate the country of origin, or at least the source of the genetic resources or traditional knowledge, in patent applications. Where this obligation is not met, national sanctions are generally applied outside of patent law, which may include fines, market bans, or exclusion from public tendering procedures. The patent can also be declared invalid if the patent applicant fraudulently fails to state the origin or states it incorrectly.

It remains to be seen how far this agreement will ensure effective legal protection of genetic resources and cultural heritage. The patent applicant is still permitted not to state the country of origin where this is unknown, and there is still a lack of clarity regarding the implementation of control mea-



asures and sanctions on a national level. In parallel, two further treaties have been negotiated at the Wipo, one to protect other traditional knowledge and one to protect traditional cultural expressions (such as dances, clothing, jewelry, and designs by Indigenous groups). In these instances, it is expected that use of such cultural assets will require consent from the corresponding Indigenous peoples. However, the countries have not yet been able to agree on key aspects of the protection system, such as the definition of protected cultural assets, ownership of rights, exceptions, and term of protection, so it is unlikely that the negotiations will make rapid progress.

Ultimately, digitalization is also an important factor in this area. Digital sequence information (DSI) – such as the nucleotide sequence of a gene – has been increasingly used for development of biotechnology products and services, for example, in the areas of pharmaceuticals, food, cosmetics, and biofuels. Given the particular challenge of identifying the country of origin and bilateral negotiations on access to and use of a great volume of information, the parties to the Convention on Biological Diversity agreed at their 16th Conference (Cop 16 in Cali, Colombia) in early November to set up a multilateral mechanism to share the benefits resulting from the use of this information.

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THE UNAUTHORIZED USE OF A RESOURCE MAY BE PERMITTED IN ONE COUNTRY BUT PROHIBITED IN ANOTHER

In short, DSI users – particularly companies operating in the areas of pharmaceuticals, nutraceuticals, cosmetics, biotechnology, laboratory equipment for sequencing, and use of DSI and related services – will now have to share the financial and non-financial benefits resulting from such use multilaterally. Based on the profit or revenues from DSI-related products and services, the shared financial benefits will be transferred to an independent international fund that will specifically support biodiversity conservation, Indigenous peoples, and capacity building.

Nevertheless, the mechanism is not legally binding and does not apply in relation to sequence information whose access and use is governed by an agreement between the user and the country of origin. It remains to be seen how the mechanism will be implemented in practice by the Contracting Parties and how far it will influence DSI regulation in other international organizations (for example, within the framework of the above-mentioned agreements of the Food and Agriculture Organization and the World Health Organization).

So, who owns biodiversity and cultural heritage? The regulatory complexity means there is no straightforward answer. It varies depending on the protected assets, the applicable agreement, and the valid exceptions.

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This regulatory variety reflects the differences in the nature of the protected goods, which can be tangible (e.g., genetic resources) or intangible (e.g., traditional knowledge, DSI) and have different right-holders (e.g., countries of origin, Indigenous people) – or simply have no rightholder.

Moreover, international regulation enables a variety of interpretations regarding how the rules should be implemented at the national level. The precise material and temporal scope of protection, compliance measures, and sanctions, for instance, may deeply vary from country to country. This can lead to situations where the unauthorized use of a specific resource or knowledge is permitted in one country but prohibited in another. Additionally, international law does not ensure that procedures related to the access to genetic resources and traditional knowledge are efficient, which is disadvantageous for users.

In light of this, it is important for companies and researchers in the biotechnology sector to be aware of this regulatory conundrum in the course of their activities. This does not preclude international law from being improved. An important foundation would be laid if international lawmakers were able to set out clear, precise, effective and more comprehensive regulatory mechanisms in order not only to promote a better harmonization of national laws, but also to ensure legal certainty and efficient access for entitled users and also a fair benefit-sharing. A legally binding dispute resolution mechanism between countries to determine the proper implementation of international law could ensure regulatory unity.

Divergence of interests between countries may hinder advances in international law. However, nothing prevents countries interested in achieving efficient and effective legal protection for genetic resources and traditional knowledge from adopting such measures at a regional or multilateral level. If similar rules on efficiency, scope of protection, compliance and sanctions are adopted by a group of countries, companies and researchers operating in the global biotechnology market would be incentivized to comply to them in order to avoid multiple sanctions. This would prevent countries from competing to offer more favorable access conditions, which would lead to a ‘race to the bottom’ regarding the amount of benefit-sharing required.

In summary, effective and efficient regulation at the international level—or, alternatively, at the regional level—can facilitate the work of researchers and companies while ensuring fair and equitable benefit-sharing.

