

The protection of genetic resources in the intersection of biological diversity and intellectual property rights

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Diversity is a key component of sustainable development. This stems from the systems theory approach, as a diverse system adapts best to environmental change. From this perspective, diversity is a guarantee of survival, and it serves as a tool of fighting for food security. The complexity and diversity must therefore be protected. One endpoint of diversity is biological and genetic diversity, while the other endpoint is cultural diversity. The protection of biological diversity is linked to the protection of genetic resources. The issues of the protectability of genetic resources is a new direction in intellectual property law, with the declared aim of promoting aspects of sustainable development. There are new, emerging legal institutions at international level which are not yet part of the universal system of intellectual property rights and it is up to international legislation to make them so. A key step was the adoption of the WIPO Treaty in this field in May of 2024. The purpose of this paper is to analyze the current and future possibilities for protection.

I. INTRODUCTION - THE IMPORTANCE OF GENETIC RESOURCES FOR FOOD SECURITY

Eradicating hunger constitutes a crucial component of the social pillar of sustainable development. As the Brundtland Commission elucidated in *Our Common Future*, food represents an essential need that remains unmet in the majority of developing countries, and thereby posing serious global challenges. It is not surprising that the Millennium Declaration identified the eradication of extreme hunger as a prioritized goal, in conjunction with poverty (as the principal cause of hunger), a commitment similarly reflected in the Sustainable Development Goals for 2015.

The tragic irony of the Earth's current predicament is that while consumption and production have reached unsustainable levels of exploitation, approximately 735 million people are suffering from hunger in 2022, an increase of 122 million individuals from 2019, prior to the global pandemic.¹ Humanity produces more than sufficient food to adequately nourish the global population. Yet, while 735 million individuals suffer from

¹ FAO/IFAD/UNICEF/WFP/WHO, *The State of Food Security and Nutrition in the World 2023. Urbanization, agrifood systems transformation and healthy diets across the rural-urban continuum*, Rome 2023, S. 6.

hunger, two billion people are overweight and 800 million are obese.² This stark inequality engenders significant social problems, which are critically important from the perspective of sustainable development.

The World Food Congress of the Food and Agriculture Organization of the United Nations (hereinafter referred as FAO) convened in Rome from November 13 to 17, 1996, and adopted the Rome Declaration on World Food Security. According to the first point of the World Food Summit Plan of Action, food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life. The recognition of the right to food in international law is not novel, as Article 25 of the Universal Declaration of Human Rights (1948) enshrined the right to food as a human right essential for a healthy and prosperous standard of living. Similarly, the International Covenant on Economic, Social and Cultural Rights acknowledges the fundamental rights to adequate food and to a life free from hunger. Concerning the right to food, it is important to emphasize that this encompasses both availability and accessibility, i.e. the physical availability of and access to sufficient food.³

The right to food, as a second-generation fundamental right, necessitates proactive state intervention and willingness to act, which can be manifested, for example, through food strategies aimed at more equitable distribution of resources essential for food production, particularly equal access to seeds.

In this context genetic resources play an integral role. The Convention on Biological Diversity (1992) employs the term biological resources in its broadest sense, which “includes genetic resources, organisms or parts of organisms, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity”. Within this framework, genetic resources refer to any material of plant, animal, microbial or other origin containing functional units of heredity with actual or potential value. The objective of Article 1. of the Convention underscores the importance of fair and equitable sharing of benefits arising from the utilization of genetic resources (commonly known as ‘benefit-sharing’, which includes access to genetic resources, the appropriate transfer of relevant technologies and the provision of adequate financing, in addition to the conservation of biodiversity and the sustainable use of its components).

The International Treaty on Plant Genetic Resources for Food and Agriculture (hereinafter referred to as PGRFA), signed in Rome on November 3, 2001, under the auspices of the FAO, is pertinent to the subsequent analysis. For the purposes of this treaty, plant genetic resources for food and agriculture are any genetic material of plant origin (all plant material, including reproductive and vegetative propagating material, containing functional units of heredity) that possesses actual or potential value for food and agriculture.

² FAO, Urgent need to tackle overweight and obesity across the Asia-Pacific region, 2019, www.fao.org/asiapacific/news/detail-events/es/c/1239237.

³ Hans Morten Haugen/Manuel Ruiz Muller/Savita Mullapudi Narasimhan, Food Security and Intellectual Property Rights: Finding the Linkages, in Tzen Wong/Graham Dutfield (eds.), *Intellectual Property and Human Development. Current Trends and Future Scenarios*, Cambridge 2011, S. 106-109.

It is evident that the common element of these definitions is the existence of hereditary material, i.e. the storage of DNA sequences. The Convention on Biological Diversity addresses these resources in a broader context, encompassing plant, animal and microbial terms, recognizing the complexity of the biological system. In contrast, the PGRFA specifically regulates the genetic resources of food and agricultural crops.

II. INTERNATIONAL SYSTEM FOR ENSURING ACCESS TO GENETIC RESOURCES

The system for the protection of genetic resources is intricate and comprehensively regulated by the aforementioned conventions. Due to space constraints, this analysis will highlight only a few critical aspects from the perspective of intellectual property rights.

Article 15 of the Convention on Biological Diversity, entitled “Access to genetic resources”, mandates that member states shall endeavor (in a soft law formulation) to facilitate access to genetic resources for other member states for environmentally acceptable purposes. In the spirit of reciprocity, member states should endeavor to pursue joint scientific research and development on genetic resources acquired from another state. The results of such research and the benefits arising from the commercial and other exploitation of the utilized genetic resources should be shared fairly and equitably with the state from which the genetic resources originate, in accordance with the principle of benefit-sharing.

Access and benefit-sharing, emphasized in the Convention on Biological Diversity, are further elaborated in the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (hereinafter referred as Nagoya Protocol), which was adopted on October 29, 2010, and entered into force on October 12, 2014. The fundamental objective of Nagoya Protocol is to create a more explicit and transparent legal regime for access to genetic resources and benefit-sharing that favors both the country of origin of the genetic resources, with a particular focus on indigenous and local communities, and the user country.⁴ Article 10. encourages the member states to develop a global multilateral mechanism to address access and benefit-sharing for genetic resources and associated traditional knowledge that are transboundary or for which prior informed consent cannot be given or obtained. The benefits generated through such a global mechanism should be used globally to support the conservation and sustainable use of biodiversity and its components.

The PGRFA, which was signed in 2001 and in 2023 has 150 member states, holds great significance concerning access. Its primary aim is to promote a multilateral system to enhance access and benefit-sharing for genetic resources for food and agriculture. During the preparatory work, the participating states agreed on the need to establish a list of nearly 60 items of crops and forages whose genetic resources can be accessed free

⁴ Sebastian Oberthür et. al., *Intellectual Property Rights on Genetic Resources and the Fight Against Poverty*, Belgium 2011, S. 15-17.

of charge through the multilateral system.⁵ This Convention facilitates the exchange of seeds and genetic materials to maintain genetic diversity of crops worldwide and also stimulates scientific research — particularly in developing countries — to develop climate-smart agriculture, thus contributing to the Millennium Development Goal of increasing food security.

Since the entry into force of the PGRFA in 2004, the multilateral system it has established has achieved extraordinary success. It covers more than 1.6 million plant genetic resources and is now considered a model for the creation and regulation of gene banks of other types of genetic resources. A well-functioning dispute resolution process has been developed within the FAO and a four-tier benefit-sharing system has been established, involving information exchange, technology transfer, capacity building and financial benefit-sharing. The latter is executed through a financial fund called the Benefit-sharing Fund, which is the first operational global financial fund for sharing the financial benefits of genetic resources. The fund aims to invest directly in projects that support farmers and local communities in developing countries to conserve crop diversity, adapt to a changing environment, promote food security and build innovative multi-stakeholder partnerships.⁶

III. INTELLECTUAL PROPERTY ASPECTS OF GENETIC RESOURCES

In the subsequent sections, this paper will highlight the general linkages of genetic resources and intellectual property rights, the significance of genetic resources in the realm of patenting, and finally a newly adopted convention dedicated to the protection of genetic resources.

1. Conceptual issues related to TRIPS, the Convention on Biological Diversity and the PGRFA

Jurisprudence unequivocally establishes that genetic resources found in nature are not man-made intellectual products and, therefore, cannot be the subject of intellectual property rights per se. Nonetheless, several pertinent linkages with intellectual property rights emerge. These include the so-called defensive or negative protection of genetic resources, the requirements for disclosure of genetic resources in patent applications, or the legal status of intellectual property rights derived from such resources. A critical question also arises regarding the reconciliation of the private property nature of intellectual property rights with the communal essence of genetic resources, which embody biodiversity safeguarded by the aforementioned conventions. Does the intellectual property regime potentially harm biodiversity and the access and benefit-sharing (ABS) system?

⁵ Graham Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, London – Sterling 2004, S. 40.

⁶ FAO, *The Benefit-sharing Fund in brief*, 2016.

A thorough examination of the relationship between the intellectual property rights regime and the conservation of genetic resources necessitates an analysis of two pivotal multilateral agreements: the Agreement on Trade Related Aspects of Intellectual Property Rights (hereinafter referred to as TRIPS) which is the annex of the Agreement establishing the World Trade Organization, adopted in Marrakesh in 1994, and the Convention on Biological Diversity.

The Convention on Biological Diversity itself contains provisions pertinent to intellectual property rights. Article 16 delineates several rules concerning access to and transfer of technology, with Paragraph 5 acknowledging that “the Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.” While this commitment recognizes the potential negative impacts of the intellectual property rights regime on biodiversity conservation, the overall regulation aims for a coherent and non-contradictory framework, particularly as reflected in Paragraph 2, which recognizes the necessity for adequate and effective protection of intellectual property rights.

The provisions of the Convention on Biological Diversity alternately emphasize the preferential nature of intellectual property rights, biodiversity and technology transfer, mirroring the desire of the various stakeholders to achieve a compromise. This approach embodies the fundamental North-South conflict (developed and developing countries), whereby the developed North endeavors to maintain its advantage in biotechnology and genetic engineering, while the biodiversity-rich South demands technology transfer in exchange for genetic resources. The developed countries sought to achieve this within their advanced and strong intellectual property systems, safeguarding their competitive actors. Conversely, developing countries would avoid that intellectual property rights compromise the sustainable use and conservation of biodiversity. This dynamic culminated in Paragraph 5 and contributes to the reason why the USA having signed but never ratified the Convention and remained outside the 196 member states.⁷

Regrettably, TRIPS and the Convention on Biological Diversity are philosophically at odds. The strong intellectual property rights-based technology transfer under TRIPS fails to align with the interests of developing countries, contravening Article 16 of the Convention on Biological Diversity, which stipulates that such transfer should not undermine biodiversity conservation. This discord is exacerbated in the TRIPS-Plus era of bilateral agreements, where contracting states promote robust intellectual property rights against developing countries’ interests.

Moreover, several conceptual contradictions exist between the two conventions, stemming from their differing purposes and contexts. The primary objective of TRIPS is to extend private ownership, with particular emphasis on the protection of the large corporate sector, and to maintain technological dominance, thereby perpetuating a high-

⁷ Martin Kohr, *Intellectual Property, Biodiversity and Sustainable Development: Resolving the Difficult Issues*, London – New York 2002, S. 53.

ly owner- and trade-centric system where environmental and human considerations are secondary. In contrast, the Convention on Biological Diversity emerged as an international response to the rapid loss of biodiversity, recognizing the prominent position of indigenous peoples and local communities as holders of genetic resources and traditional knowledge, and regulating access to genetic resources and the fair and equitable sharing of benefits arising from their use to ensure the sustainable use of biodiversity. Attributes, like global environmental awareness, local communities and the access and benefit-sharing system are incompatible with TRIPS, which focuses on the economic empowerment of private property.⁸

This philosophical divergence manifests in the clash between the principle of national treatment under TRIPS, where foreigners can obtain patents on genetic resources under the same conditions as nationals, and the principle of national sovereignty of Convention on Biological Diversity, where states retain the right to use and conserve their genetic resources according to their environmental objectives, potentially discriminating against foreigners. Similarly, individual versus collective rights pose a significant dichotomy: TRIPS emphasizes individual rights, whereas genetic resources and associated traditional knowledge typically lack individually identifiable rights holders. There is also a tension between new technology and traditional knowledge, as TRIPS is inherently designed to protect new intellectual products and thus encourage innovation, but it also discriminates against developing countries where long-standing traditional knowledge is important and is not protected, as opposed to the Convention on Biological Diversity, which places a strong emphasis on this. This is actually the confrontation of pre-industrial and post-industrial ideology.⁹

In comparison, the PGRFA presents a clearer stance on the relationship between genetic resources and intellectual property rights. Article 12.3 (d) provides that “recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System” This explicit prohibition reflects a stringent and distinct approach from that of Convention on Biological Diversity, unequivocally recognizing genetic resources as common heritage within the public domain, free from private ownership constraints.

2. Protection of genetic resources during patenting

Article 27 of TRIPS delineates the parameters for patentable inventions. It adopts a broad concept, asserting that any invention can be patented if it is new, involves an inventive step, and is capable of industrial application across any field of technology. The member states may retain the discretion to exclude plants and animals from protection but must ensure either patent or *sui generis* protection for plant varieties or a combination of these protections. This provision may come into serious conflict with the stipulations

⁸ Kohr, S. 54.

⁹ Jonathan Curci, *The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property*, Cambridge 2010, S. 50-58.

of the PGRFA regarding intellectual property rights. China's pivotal role in innovation and patenting exemplifies this conflict. China, a party to TRIPS but not to the PGRFA, could patent an invention derived from a genetic resource within the PGRFA's multilateral system and subsequently seek recognition of this patent in other countries, invoking Article 27.1 of TRIPS. However, the 150 member states of the PGRFA would be unable to comply with TRIPS requirement to recognize the patent protection of such invention without violating Article 12.3 (d) of the PGRFA, which explicitly prohibits granting intellectual property rights based on genetic resources within the multilateral system. In such a scenario, China could initiate WTO dispute settlement proceedings for violation of TRIPS, because TRIPS member states may invoke an agreement outside the WTO regime in order to deny the proper application of TRIPS what is detriment to another TRIPS member state.

In the context of patenting, negative protection refers where genetic resources are not subject of a new *sui generis* protection, but are excluded from existing forms of protection and kept in the public domain. From the perspective of view of patent law and the integrity of patents, the critical issue is that only such modified genetic resources that meet the criteria for patentability should be protected, while naturally existing genetic resources — as part of the public domain — should remain free from private ownership.

International patent conventions and national laws impose extensive disclosure obligations for patent applications. If these obligations are not sufficiently executed or if thorough searches are hampered by caseload of patent examiners, defective patents may be granted without complying the minimum requirements. To mitigate this risk, several member states of the World Intellectual Property Organization (hereinafter referred as WIPO) have already enacted internal regulations to align their intellectual property protection systems with the objectives of the Convention on Biological Diversity and the PGRFA. These regulations encompass obligations that serve the negative protection of genetic resources, including

- disclosing the genetic resource (and associated traditional knowledge) in the invention,
- identification of the country of origin of the genetic resource, or even within that country a specific location,
- filing the prior informed consent of the party providing the genetic resources and a benefit-sharing agreement between the parties on mutually agreed terms.¹⁰

The effectiveness of screening and monitoring these obligations is significantly enhanced by the availability of comprehensive electronic patent databases, which continually expand and facilitate access to relevant information.

¹⁰ WIPO, Technical Study on Patent Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, Geneva 2004, S. 65., WIPO, Developing a National Strategy on Intellectual Property and Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources, Geneva 2014, S. 4.

In conclusion, the intersection of TRIPS, the Convention on Biological Diversity, and the PGRFA presents complex challenges and conflicts, particularly in balancing the protection of intellectual property rights with the conservation of biodiversity and equitable sharing of benefits. As the global community navigates these intricate legal landscapes, it is imperative to foster mechanisms that harmonize these divergent objectives, ensuring that advancements in biotechnology and intellectual property rights do not compromise the sustainable use and preservation of genetic resources.

3. The new WIPO Treaty on Genetic Resources

On May 24, 2024, the member states of WIPO have adopted a groundbreaking new treaty addressing genetic resources. The negotiations for the treaty were initiated in 1999 with the proposal by Colombia, and officially commenced at WIPO in 2001. The 25 years of negotiations wasn't an easy journey, but – as Director General Daren Tang – added, it is a strong signal that multilateralism is alive at WIPO.¹¹ The title of the convention is WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, which demonstrates the scope of the treaty. Genetic resources and traditional knowledge are often treated together, while the distinct third direction of new legislation, the protection of traditional cultural expression is quite separated.

The treaty comprises 22 articles, with the first six articles forming its substantive core, while the remainder provide general technical provisions. Although the treaty has been adopted, it will enter into force three months after 15 parties have deposited their instruments of ratification or accession. Notably, the treaty expressly designates the European Union as an eligible contracting party. Importantly, the treaty's obligations do not have retroactive effect and shall not be applied in relation to patent applications which have been filed prior to its entry into force.

A key conceptual debate during the negotiations was whether the protection of genetic resources should be considered within the broader intellectual property rights framework or narrowly, within its interaction with patent law. The adopted text opted for the latter. While genetic resources are inherently most pertinent to patent law, it would be prudent to consider the broader horizon of intellectual property context. For instance, plant variety protection systems outside patent law exhibit such close substantive connections that limiting the scope to patents alone is inadequate. Article 8 of the treaty mandates a revision four years after its entry into force, potentially extending the disclosure requirement to other intellectual property areas, thereby achieving broader protection for genetic resources.

Article 1 determines the aims of the treaty. The primary objective of the 25 years long negotiations was to prevent the unauthorized appropriation of genetic resources and associated traditional knowledge. Eventually, the adopted text uses cautious language, aim-

¹¹ WIPO Member States Adopt Historic New Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge. https://www.wipo.int/pressroom/en/articles/2024/article_0007.html.

ing to enhance the overall functionality of the patent system rather than explicitly preventing unauthorized appropriation. The objectives are:

- enhance efficacy, transparency and quality of the patent system with regard to genetic resources and traditional knowledge associated with genetic resources, and
- prevent patents from being granted erroneously for inventions that are not novel or inventive with regard to genetic resources and traditional knowledge associated with genetic resources.

Article 2 provides interpretative provisions in a relatively moderate number as compared to the previous versions. Here the text basically follows the terminology of previous international conventions governing genetic resources defining key terms such as genetic material, genetic resources and in situ conditions.

Article 3 regulates the core of negative protection, i.e. the requirement of disclosure, where the treaty applies the stronger wording from the previous alternatives laid down in the drafts. It introduces mandatory disclosure, when the patent application involves genetic resources. In this case primarily the country of origin of genetic resources shall be disclosed, and if it is impossible, the source of the genetic resources shall be indicated, like research centers, gene banks, ex situ depository or indigenous peoples and local communities. The same requirement is applicable to the traditional knowledge associated with genetic resources, where primarily those indigenous peoples or local communities shall be identified who provided the traditional knowledge.

The obligation of intellectual property offices in this respect extends to providing guidance on the disclosure requirements, but the treaty does not place the burden on them to verify the veracity of these declarations. On the one hand, this is understandable, as these authorities are not in a procedural position to verify the veracity of the declarations as a quasi-investigative body, and without adequate human capacity this would not be feasible. On the other hand, it weakens the level of protection, since it is unlikely that distant indigenous communities would initiate an invalidation procedure against a wrongly granted patent, thereby reducing the substantive protection of genetic resources.

Article 5 deals with sanctions and remedies for non-compliance with disclosure requirements prescribed. This article provides wide range of freedom for the contracting parties to put in place appropriate, effective and proportionate legal, administrative and/or policy measures to tackle with the failure of disclosure. The wording seems to be quite weak as regards to the effective protection of genetic resources. The member states shall provide an opportunity to rectify the incomplete disclosure, unless it was driven by fraudulent conduct. However, the lack of proper disclosure does not shall result in revocation or invalidation of the patent, and optionally the contracting parties may provide post grant sanctions where there has been fraudulent intent in regard to the disclosure requirement. Stronger sanctions would be welcomed to support the above-mentioned objectives.

The fulfillment of the objectives demands a vast number of data, which are easily accessible to the stakeholders and the examiners of the national patent offices. Article 6. refers to the need for information systems. The contracting parties — not mandatory, but optionally — may establish information systems of genetic resources and traditional knowledge, in consultation with indigenous peoples and local communities. While accessibility for patent examination purposes is required, the optional nature of this provision risks insufficient implementation. However, if such an information system exists, it shall be made accessible to the offices for the purposes of search and examination of patent application. For the establishment of such databases similar strict wording would be advised, otherwise there is no guarantee that such information systems will be even created. The Assembly of the contracting parties also may form technical working groups to address this issue.

The diplomatic conference has made considerable changes on the previous versions of the draft to reach consensus. The deletion of former Article 9 is a serious loss from the perspective of overall assessment of the protection of genetic resources. It was a matter of principle, that genetic resources in their natural or isolated form cannot be considered as inventions or other intellectual property and therefore cannot be the subject of intellectual property rights. In the absence of this provision, the national and regional patent case law must establish and enforce this principle, drawing on precedents such as the *Myriad* and *Mayo* cases from the United States.¹²

IV. CONCLUSION

Currently, a significant contradiction exists between the TRIPS and the Convention on Biological Diversity as it was described above. There are two potential solutions to resolve this conflict. The first, more reassuring and clearer, yet considerably more challenging option is to amend and harmonize the two conventions in the spirit of sustainable development. This would affect TRIPS more significantly than the Convention on Biological Diversity, as it would fundamentally require a change in the concept of TRIPS in order to make it an effective instrument for the conservation of biodiversity. Given the slow pace of international legislation and the complex web of polarized interests, this option appears impractical as it would likely result in new compromises and further contradictions. The second, currently more viable option is the full exploitation of the flexibilities inherent in TRIPS. These flexibilities allow for deviations that could undermine the TRIPS system, potentially leading to a collective shift in course. However, this would require coordinated actions by individual states, resulting in a patchy global landscape given the unequal utilization of these flexibilities and the need for external technical assistance by many developing countries. Organizations such as WIPO and the WTO could play a crucial role in providing this assistance to improve national systems.

¹² Barna Arnold Keserű, A biológiai találmányok jogi védelme, in András Jakab/Miklós Könczöl/Attila Menyhárd/Gábor Sulyok (eds.), *Internetes Jogtudományi Enciklopédia*, 2023, <http://ijoten.hu/szocikk/a-biologiai-talalmanyokjogi-vedelme>, paragraphs [12]-[13].

The newly adopted WIPO treaty on genetic resources could also serve as a solution to protect genetic resources upon its entry into force. Overall, the treaty follows a different logic for the protection of genetic resources compared to traditional intellectual property rights. Traditional forms approach from a positive perspective, focusing on the right holder, establishing protection on an absolute structure of legal exclusivity and licensing rights. In contrast, the treaty focuses on negative protection. The treaty does not start from the premise of identifying the holders of genetic resources, nor does it clarify their existence or the relationship between indigenous peoples, local communities, and the country of origin geographically. Instead of granting positive rights, the treaty aims to prevent the protection of intellectual works created through the unlawful use of genetic resources. While the treaty's cautious language and certain weaknesses require further refinements, its adoption marks a key step toward harmonizing patent law with biodiversity conservation and the equitable sharing of benefits derived from genetic resources. The overall functioning of this treaty will be greatly influenced by the results of technical working groups addressed to information systems, driven by the fact, that without interconnected and accessible databases the wide range of genetic resources cannot be evaluated by the patent examiners.

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