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WIPO

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IONMUN'26
World Intellectual Property Organization
(WIPO)
STUDY GUIDE

Co-Under Secretary-General: Esmanur Çapraz
Co-Under Secretary-General: Doruk Şentürk

Agenda Item:
Governing intellectual property rights over digital sequence information and genomic data assets

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1. Letter from the Secretary General

Dear Participants,

First of all, it is my utmost pleasure to serve you as the Secretary General for the first edition of ION Model United Nations Conference. I am more than proud for making this conference happen with my colleagues and looking forward to see every attendee.

Essentially MUN's are great opportunities to increase your consultation capabilities, your assertiveness and understand how policy is implemented. I can honestly state that MUN impacted my perspective on life in a positive way. For this reason, it is my mission to transfer the experiences I have gained to the new generation and to ensure that they affect them in the same way.

Lastly as the executive team, in order to put this conference together we really plod away. We really worked hard to burn the soul of IONMUN26. And do not forget ION is the timeless voices for peace.

Sincerely,
Doruk Sapmaz

2. Letter from the Co-Under-Secretary General

Dear Delegates,

It is my greatest pleasure to welcome you all to this committee. My name is Esmanur Çapraz, and I will have the honor of serving as your Co-Under Secretary General throughout this conference. On behalf of the entire academy of this committee, I would like to express how excited we are to meet each and every one of you and witness the insightful debates that will take place during our sessions.

Before anything else, I would like to extend my sincere gratitude to the Executive Team whose members are Doruk Sapmaz, Mustafa Aslan and Can Kurnaz, the Academic Team, and the Organization Team for their dedication and hard work in making this conference possible. I would also like to thank my dearest Co-Under Secretary General, Doruk Şentürk, for all of his greatest support and for giving me the pleasure of preparing this committee. Most importantly, I would like to thank you, our delegates. Your enthusiasm, preparation, and willingness to engage in meaningful discussion are what truly bring this committee to life. Whether this committee was your first choice or not, I sincerely hope that you will find the experience both intellectually stimulating and enjoyable.

This study guide has been prepared to provide you with a strong foundation for your research and preparation. However, it should only serve as a starting point. It is your responsibility as delegates to further investigate your assigned country's policies, previous actions, and perspectives regarding the agenda. Thorough research and a clear understanding of your country's position will be key to your success in committee.

Should you have any questions during your preparation process, please do not hesitate to contact me. I would be more than happy to assist you in any way possible.

I wish all of you the best of luck in your preparations and look forward to an engaging, productive, and memorable conference.

Best regards,

Esmanur Çapraz
Co-Under Secretary General of World Intellectual Property Organization

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3. Letter from the Co-Under-Secretary General

Dear delegates, distinguished academic team and fellow participants;

I am honored to welcome you all to the Ion Model United Nations Conference (IONMUN'26). As Doruk ŞENTÜRK, it's a pleasure to serve you as an Co-Under Secretary-General of the WIPO committee with Esmanur Çapraz

I was 12th student in Maya Science and Technology High School and I graduated.

Digital Sequence Information (DSI) and genomic data assets refer to the digitized representations of genetic resources, such as the nucleotide sequences of DNA and RNA cbd.int. These assets are foundational to modern biotechnology, allowing scientists to analyze biological traits, develop novel therapeutics, and track evolutionary history without needing physical access to the biological sample. Because my target is being a molecular biology and genetics engineer, this committee and agenda are special to me.

Lastly, I want to thank the executive team, Doruk Sapmaz, Mustafa Aslan and Can Kurnaz, for giving us an opportunity to serve as under secretary general in this delightful conference with my sister and my co-usg Esmanur Çapraz for her partnership and existence. I cannot wait to meet all of you personally and I hope you can have a great time with the time you spend in the conference. You can contact me at any kind of situation or problem, do not hesitate to ask me any questions about the committee. See you soon!

Sincerely,

Doruk ŞENTÜRK

Co-Under Secretary General of WIPO

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4. Introduction

4.1. Introduction to the Committee

The World Intellectual Property Organization (WIPO) is a specialized self-funding agency of the United Nations established in 1967 with its headquarters in Geneva, Switzerland. Operating as the global forum for intellectual property (IP) services, policy, information, and cooperation, the organization boasts 194 member states and works to develop a balanced and accessible international IP system that rewards creativity, stimulates innovation, and contributes to economic development while safeguarding the public interest. Intellectual property itself refers to creations of the mind, such as inventions, literary and artistic works, designs, symbols, names, and images used in commerce, which are legally protected through patents, copyright, and trademarks.

WIPO's primary operational function is to simplify the process of protecting these assets across multiple borders simultaneously, a task that would otherwise require separate, costly, and legally complex applications in every individual country. To achieve this, the organization administers several highly efficient international registration systems, most notably the Patent Cooperation Treaty (PCT) for inventions, the Madrid System for the international registration of marks, and the Hague System for the international registration of industrial designs. By filing a single international application through these frameworks, creators can seek protection in dozens of countries at once, drastically reducing administrative hurdles and legal fees for businesses expanding into global markets.

Beyond its registration services, WIPO acts as a critical legislative body that administers over 20 international treaties that harmonize intellectual property rules and standards worldwide, ensuring that member states adhere to uniform legal expectations. The organization also offers alternative dispute resolution services through its Arbitration and Mediation Center, providing neutral, efficient, and cost-effective mechanisms to resolve international commercial disputes involving IP, such as internet domain name conflicts.

Furthermore, WIPO serves as a massive global repository of technical and legal data, maintaining public databases like PATENTSCOPE and the Global Brand Database, which contain tens of millions of records that innovators use to research existing technologies and avoid infringement. Finally, the agency is

deeply committed to narrowing the global knowledge gap by providing technical assistance, infrastructure support, and legal training to developing nations, largely driven by the WIPO Academy, which equips students, entrepreneurs, and policymakers with the essential legal skills needed to leverage intellectual property for national economic growth.

4.2. Mandate and Role of WIPO

WIPO's mandate serves as the compass for navigating international copyright challenges. It creates a platform where intellectual property rights are championed globally, offering a structured approach amidst diverse IP regulations. The organization's functions enhance accessibility, ensuring that innovation does not fall through the cracks. WIPO's objectives are akin to an architect's blueprint, carefully crafted to protect intellectual creativity and promote economic resilience. By uniting disparate IP regulations under one umbrella, WIPO global IP protection transforms potential conflict into cooperation. The delicate balance of protecting creators' interests while facilitating access to information epitomizes their mission. Through this balance, WIPO navigates the fine line between innovation and protection—a tightrope that can only be walked with precision and purpose. With WIPO at the helm, the world of intellectual property becomes less daunting, guiding creators through a clearer, fairer path to recognition and reward in an otherwise tumultuous arena.

WIPO global IP protection encompasses a vast array of WIPO functions that are key to understanding its mandate. With international copyright and IP regulations varying widely, WIPO acts as a unifying force, much like a seasoned conductor leading a diverse orchestra. This harmonious approach enables the smooth operation of intellectual property systems worldwide. WIPO's objectives prioritize the establishment of a coherent, functioning ecosystem where intellectual property is safeguarded, and innovation is encouraged. By offering tools and resources to nations, it reduces barriers that often stymie creativity. Just as a gardener nurtures each plant to bloom, WIPO ensures that intellectual endeavors grow under their protective watch. The nuanced balance they achieve between strict protection and free idea exchange catalyzes global progress. In a world where boundaries blur and ideas flow freely, the role of WIPO is indispensable, securing an equitable stage where all creators can shine.

The strategic goals of WIPO include:

- The balanced evolution of the international normative IP framework;
- Facilitating the use of IP for development;
- Providing global IP services; building respect for IP;
- Developing global IP infrastructure;

- Becoming a world reference source for IP information; and
- Addressing IP in relation to global policy challenges such as climate change, public health and food security.

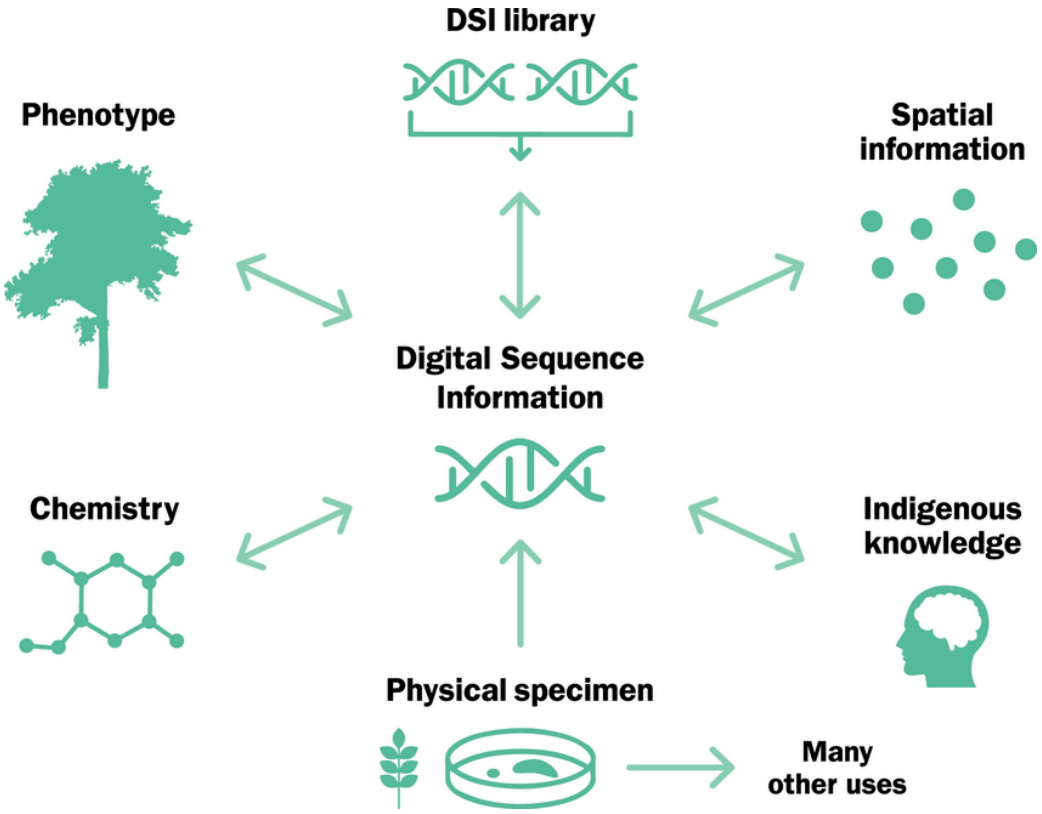
4.3. Scope of the Agenda

The World Intellectual Property Organization (WIPO) plays a central role in governing digital sequence information (DSI) and genomic data assets as it navigates the delicate intersection of biological innovation, indigenous rights, and modern patent law. Within WIPO's mandates, particularly under the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), this agenda addresses how to prevent the unauthorized patenting of naturally occurring genetic data while encouraging commercial biotechnology. Because digital sequence data can be shared instantly across borders without moving physical biological materials, WIPO focuses on establishing standardized mechanisms—such as mandatory disclosure requirements of origin in patent applications—to ensure transparency and prevent "biopiracy." Furthermore, the committee works to harmonize international IP frameworks so that copyright, database protections, and patent flexibilities do not conflict with emerging United Nations mechanisms for multilateral benefit-sharing, thereby safeguarding open-access scientific research while respecting the data sovereignty of biodiversity-rich nations. **Intellectual Property Guide for Genetic Resources and Genetic Sequence Data**

5. Conceptual Background

5.1. What is Digital Sequence Information (DSI)?

Digital Sequence Information (DSI) is a broad term accepted in international policy and scientific circles that refers to the digital use of biological resources and their derivatives. Unlike traditional methods, it allows scientists to work on the digitally transferred genetic structures of these organisms instead of physical biological materials. This concept encompasses genomic data such as DNA, RNA, and protein sequences, as well as all molecular information that determines the unique characteristics, evolutionary processes, and functional attributes of organisms. This digitalization of genetic resources, i.e., their



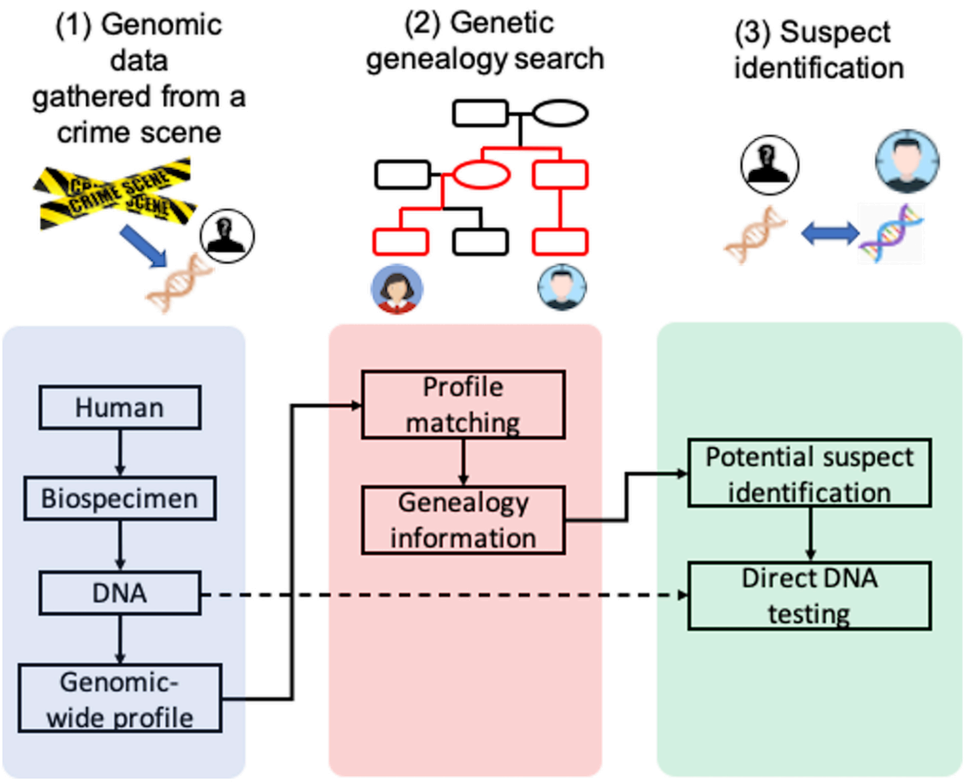
independence from physical samples, has facilitated international data sharing and created a radical transformation in the field of biotechnology. DSI technology has greatly increased the speed and scale of biomedical and pharmaceutical research by enabling the rapid analysis and comparison of genomic data. Scientists can identify pathogenic targets by scanning the digital genetic sequences of viruses or bacteria within minutes. Computer-based simulations (in silico) allow drug interactions to be tested virtually, reducing the need for preclinical laboratory work and animal experiments. Combined with synthetic biology tools, DSI enables researchers to develop new vaccines, treatments, and enzymes using only digital codes obtained over the internet, without needing a physical sample of a virus from the other side of the world. This massive data flow is sustained by open-access genetic databases that serve an international level and form a global network of collaboration. The GenBank, within the National Institutes of Health in the United States, houses all publicly available DNA and RNA sequences; the dbGaP database archives studies examining genotype and phenotype interactions in humans; and dbSNP, also affiliated with the same center, lists intraspecific genetic variations and common mutations. The European Bioinformatics Institute (EMBL-EBI) provides free bioinformatics services to the global scientific community, while the DNA Bank of Japan (DDBJ) ensures data synchronization based in Asia. These three major institutions work together under the umbrella of the International Nucleotide Sequence Database Cooperation (INSDC) to ensure that genetic data uploaded anywhere in the world is instantly accessible to all of humanity. The intensive use of DSI by pharmaceutical and biotechnology companies has brought about

significant socio-economic and environmental debates centered on the conservation of biodiversity and the equitable sharing of benefits. International agreements such as the Convention on Biological Diversity and the Nagoya Protocol mandate that companies using a country's physical genetic resources share their commercial profits with that resource country. However, the fact that companies develop drugs using digital codes downloaded from open-source databases without touching the physical sample creates a legal loophole. Developing countries, which are mostly rich in biodiversity, describe this situation as biopiracy and demand that the profits from digital data also be shared fairly with them for the protection of ecosystems, advocating for the establishment of global funding mechanisms for this purpose. These legal and ethical debates have become a critical risk and opportunity factor for sustainability-focused Environmental, Social, and Governance (ESG) investors. Investors who prioritize ESG criteria closely examine the DSI (Digital Data Integration) usage policies of the pharmaceutical and biotechnology companies they fund. In the environmental dimension, companies contributing to global benefit-sharing funds directly support the protection of ecosystems. In the social dimension, respect for the rights of local peoples and indigenous communities, who are the original owners of genetic resources, and the fair use of traditional knowledge are emphasized. In terms of governance, with the tightening of international DSI regulations, companies that can legally and transparently trace the source of data protect themselves from future legal sanctions, high fines, and reputational damage, thus ensuring long-term financial security.

5.2. Genomic Data Assets

Genomic Data Assets are essentially the transfer of the genetic codes of living organisms into a computer environment, transforming them into invaluable digital treasures. Today, with the rapid advancements in biotechnology and artificial intelligence, these genetic maps are no longer just dry scientific information; they have become as valuable as a new generation of oil or minerals for companies and governments. These digital assets are not only used in medicine; they serve as raw materials in a wide range of fields, from producing more resilient crops in agriculture to developing specialized yeasts used in industry.

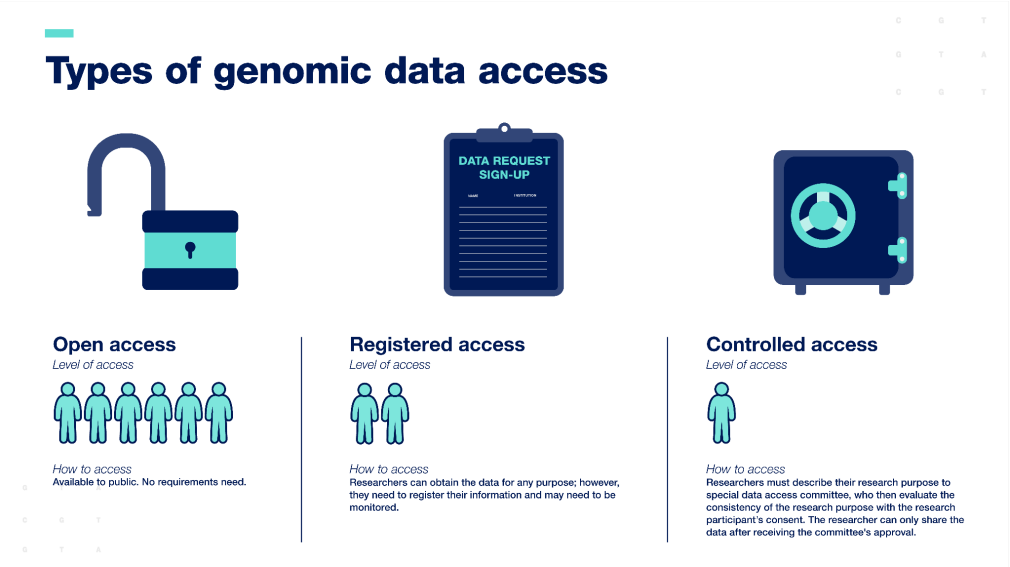
Therefore, how to store, protect, and monetize this genetic data is one of the most important topics in today's world. In the pharmaceutical and medical fields, the systematic use of this data paves the way for what we call personalized treatment, making the production of directly targeted drugs much easier. Artificial



Intelligence systems can scan these massive data pools to instantly identify the genetic causes of rare diseases and predict in advance which drug will be beneficial for which patient. Thanks to this genetic data collected from all over the world, pharmaceutical companies can complete research that would take years in the lab much faster and at a much lower cost. Moreover, because the data is digital, a laboratory at one end of the world and a research team at the other end can work on the same data simultaneously via the internet without having to physically transport any samples. Of course, to securely store such a large and valuable digital archive and make it available to everyone, massive databases have been established worldwide. Giant libraries like GenBank store millions of genetic data uploaded by researchers from all over the world in a standard format that everyone can understand, paving the way for the scientific world. Specialized systems such as dbGaP and dbSNP, which focus on human health, appearance, and genetic differences, transform this raw data into useful resources. Large bioinformatics centers in Europe and Japan constantly monitor the accuracy and quality of this data. In this way, genetic information is not locked away in the hands of a single company, but becomes a pool of information that the whole world can use together.

On the other hand, as the commercial value of this data increases, serious debates about justice and rights arise. Developing countries, often with rich natural environments and biodiversity, rightly watch with concern as genetic codes taken from plants or local populations in their territories are transformed into billions of dollars worth of commercial products by technology giants in developed countries. Since old international rules only covered the physical

removal of a plant or sample, legal loopholes emerged when the process completely shifted to downloading digital data from a computer. The buying and selling of this data without the knowledge or consent of local populations is creating discussions about digital biocolonialism worldwide and forcing legal professionals to take urgent action. This is precisely why large investors who are sensitive to nature and society (ESG investors) are very closely examining how the biotechnology companies will invest in obtaining this genetic data. On the environmental side, preserving the genetic maps of endangered species means digitally protecting nature. On the social side, investors check whether the companies respect the rights of local populations. Finally, data security stands out in the management aspect of the business; because protecting this genetic data from cyberattacks, preventing theft, and managing it in accordance with the law directly affects both the reputation and the future of companies.



5.3. Intellectual Property and Biotechnology

Biotechnology is a multidisciplinary field that studies the transformation of living organisms or their components through technical processes, profoundly shaking the classical doctrines of traditional industrial property law. The patent system, designed to protect inanimate mechanical inventions, has undergone a radical transformation with the debate over patenting living material. The US Supreme Court's decision in Diamond v. Chakrabarty, ruling that "everything made by human hands is patentable, paved the way for the inclusion of living microorganisms under patent protection, creating a new legal paradigm at the global level. Within the European Union, according to the Biotechnology Directive 98/44/EC, new, inventive, and industrially applicable biological inventions are considered patentable, even if they occur naturally in nature, provided they are isolated through a technical process. However, the human body, germ cells, gene sequences of only discovery value, and plant or animal production methods that are essentially biological are excluded from patent

protection. Patent protection provided for biological material is extended to include subsequent generations derived from that material and possessing the same characteristics. The fact that this expansion is not explicitly regulated in Türkiye's Industrial Property Law (IPL) is a significant shortcoming.

In Türkiye, intellectual and industrial property rights are protected under the provisions of the Industrial Property Law No. 6769 (IPL). Under the IPL, for an invention to be patentable, the conditions of absolute novelty, inventive step, and industrial applicability must all be met simultaneously. Utility model protection is prohibited by law for biotechnological and chemical inventions and their methods of acquisition; these inventions can only be subject to patent registration, which provides protection for 20 years. While discoveries, theories, mental methods, and computer programs themselves cannot be patented, algorithms that combine technical elements with programs can be protected. Inventions in the health and biomedical fields are predominantly grouped under the A61 main class in the International Patent Classification (IPC). In this hierarchy, while diagnostic, therapeutic, and surgical methods themselves cannot be registered as procedural steps, medical devices, implants, stents, or biotechnological materials to which these methods are applied can be patented. Therefore, the wording of claims defining the scope of protection in patent applications is of vital importance.

The most prominent tension in the global regime of biotechnology patents is between developed countries that produce technology and developing countries rich in obiological resources. Developing countries refer to the unauthorized patenting of their local biological resources and traditional knowledge by foreign companies as biopiracy. This geopolitical conflict is embodied in the legal incompatibility between the TRIPS Treaty, which advocates strong industrial property standards, and the Convention on Biological Diversity (CBD), which envisages the sovereignty of states over resources and the equitable sharing of benefits. Although Article 27.3(b) of TRIPS grants member states the right to exempt plants and animals from patents, it mandates the patenting of microorganisms. In the discussions on harmonizing TRIPS and the CBD within the framework of the Doha Ministerial Declaration, countries such as India and Brazil advocate for the addition of Article 29 bis to TRIPS, making it mandatory to disclose the origin of genetic resources, obtain prior informed consent (PIC), and submit profit-sharing agreements in patent applications. Fundamental platform technologies, which affect the entire industry rather than specific products, are the areas where the biggest legal battles take place. The multi-year global patent battle between the University of California and the Broad Institute over the CRISPR/Cas9 gene editing system patent demonstrated how blurred the boundaries of ownership can be between those who make fundamental scientific discoveries and those who implement them. Similarly, periods of global crisis test the delicate balance between patent protection and

public health. While the development of mRNA vaccines during the COVID-19 pandemic was presented as a major R&D success, the inequalities in access to vaccines for developing countries led to global calls for a temporary waiver of patent protection (TRIPS waiver). While the pharmaceutical industry defends patent protection to offset high R&D costs, public health advocates emphasize that loosening intellectual property monopolies is a humanitarian necessity in global emergencies.

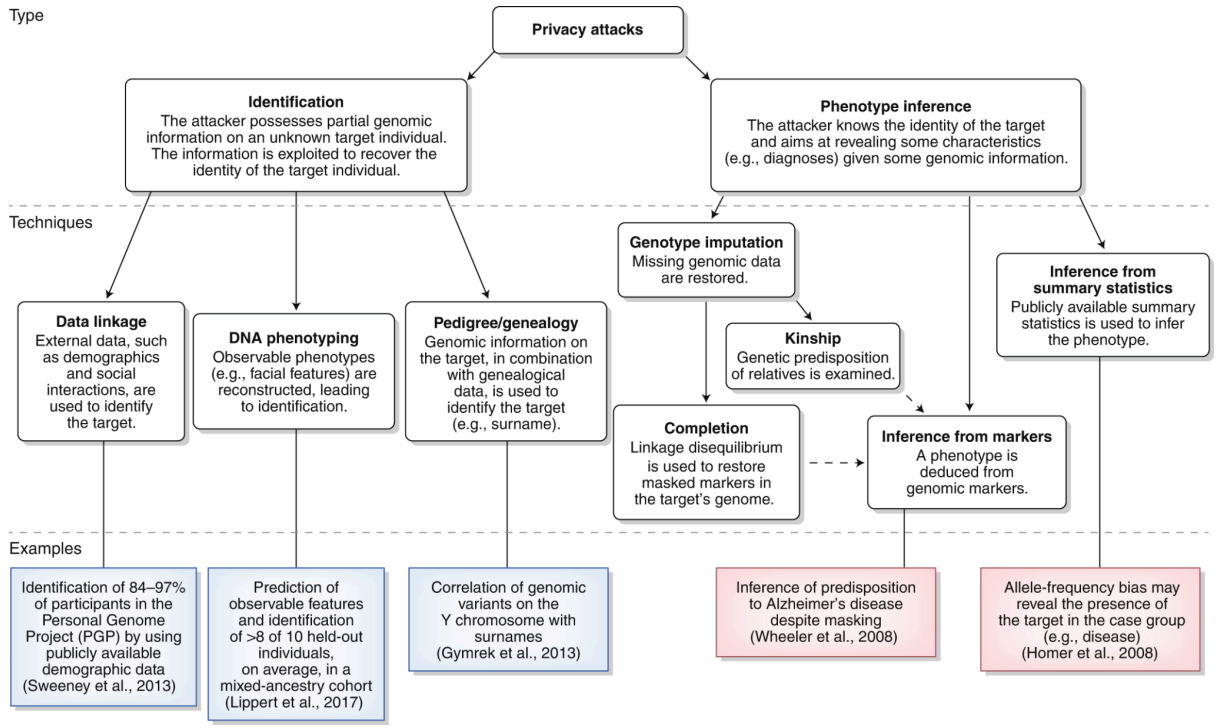
The modern world of R&D, where artificial intelligence (AI) can autonomously design new molecules and predict protein folding, is fundamentally shaking the human inventor doctrine of patent law. Applications by Dr. Stephen Thaler for inventions developed by his autonomous AI system DABUS have been rejected by the US, EPO, and Japanese patent offices. The U.S. Federal Court of Appeals has ruled that inventors can only be natural persons. The European Patent Office (EPO), meanwhile, rejected Thaler's split applications due to a contradiction between the human inventor's claim and DABUS's autonomous contribution. To resolve this legal confusion, the U.S. Patent and Trademark Office (USPTO), in its Guidelines for Invention of AI-Powered Inventions, updated in November 2025, reverted to the traditional human design standard. According to the new guidelines, each claim must demonstrate the lasting and definitive intellectual contribution of at least one human; AI is merely a research tool and cannot legally be the sole or co-inventor. This approach, consistent with international AIPPI decisions, mandates rigorous documentation of human contribution in R&D processes and design phases for patentability of AI outputs under the global intellectual property regime.

6. Legal-Ethic and Historical Structure

6.1. Development of Intellectual Property in Biotechnology

The development of intellectual property protection in biotechnology began with the application of traditional patent principles to inventions involving living or biologically active material. Early patent systems were designed mainly for mechanical, chemical, and industrial inventions. Advances in molecular biology, genetic engineering, microbiology, and DNA analysis therefore required patent offices and lawmakers to determine how established concepts such as novelty, inventive step, industrial applicability, and sufficient disclosure should apply to biological inventions. Biotechnology created a difficult distinction between a discovery, which identifies something already existing in nature, and an invention, which involves human technical intervention or produces a new practical application. This distinction remains central to debates over isolated biological materials, genetically modified organisms, gene-related inventions, and biotechnological processes.

The expansion of biotechnology during the 1970s and 1980s also created practical problems for patent disclosure. A patent application must explain an invention clearly enough for a qualified person to reproduce it, but some microorganisms and biological materials cannot be described fully through written text alone. The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, adopted in 1977, responded to this problem by allowing a microorganism deposited with a recognized international depositary authority to be accepted for patent procedures in all contracting states. This removed the need to deposit the same



biological material separately in every country where protection was sought and helped create a more workable international patent system for microbiological inventions.

The international legal framework became broader with the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights, commonly known as the TRIPS Agreement. TRIPS requires patents to be available for inventions in all fields of technology when they are new, involve an inventive step, and are capable of industrial application. However, it also permits states to exclude certain subject matter, including diagnostic, therapeutic, and surgical methods, as well as plants and animals other than microorganisms and essentially biological processes for producing them. At the same time, members must provide protection for plant varieties through patents, an effective *sui generis* system, or a combination of both. These provisions established common minimum standards, while leaving states considerable freedom to define the boundaries of biotechnology patent protection within their national systems.

As biotechnology developed, intellectual property protection expanded beyond the invention itself to include licensing, research use, plant breeders' rights, confidential know-how, regulatory data, and technology transfer. Biological material presents special legal problems because it can reproduce itself and pass its characteristics to later generations. Patent systems must therefore determine whether protection extends to reproduced material, how exhaustion rules apply after an authorized sale, and whether special exceptions should exist for researchers, breeders, or farmers. Biotechnology may also create overlap between patents and plant-variety protection, since a genetically engineered trait may be patented even where the plant variety containing it is governed by a separate legal system. These overlapping rights can encourage investment and commercialization, but they can also increase licensing complexity and restrict access to research tools or genetic material.

The rise of biodiversity governance added another dimension to the relationship between biotechnology and intellectual property. The Nagoya Protocol, adopted in 2010 as a supplementary agreement to the Convention on Biological Diversity, created a legal framework for access to genetic resources and for the fair and equitable sharing of benefits arising from their use. It places importance on prior informed consent, mutually agreed terms, compliance measures, and recognition of traditional knowledge associated with genetic resources. This changed the debate from a narrow question of who invented a biotechnological product to a broader question of where the genetic resource originated, who provided it, and whether the country or community connected to that resource should share in the resulting scientific or commercial benefits.

WIPO's work in this area reached an important stage with the adoption of the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge on 24 May 2024. The Treaty establishes a patent disclosure requirement for claimed inventions based on genetic resources or associated traditional knowledge. Patent applicants are required to disclose the country of origin of the genetic resources or identify the Indigenous Peoples or local community that provided the relevant traditional knowledge. This development reflects growing concern that the patent system should not grant rights over inventions derived from genetic resources without sufficient transparency concerning their source. It also represents an effort to improve patent quality and respond to long-standing concerns about misappropriation and biopiracy.

The digitalization of biotechnology has created a further shift from physical biological samples to digital sequence information and genomic data assets. Genomic sequences can now be stored, copied, analysed, and transferred across borders without the physical movement of the organism from which they originated. Intellectual property law does not provide one single form of

ownership over all genomic data. A patent may protect a new technical application, engineered product, diagnostic method, or industrial process that satisfies patentability requirements, but it does not automatically grant ownership over every underlying biological fact. Similarly, international copyright rules may protect a database when the selection or arrangement of its contents is sufficiently original, while not extending that protection to the underlying data merely because they appear in the database. Confidential genomic datasets, research methods, and commercially valuable analytical systems may also be protected as undisclosed information when they remain secret, have commercial value because of that secrecy, and are subject to reasonable protective measures.

6.2. Existing International Legal Frameworks

Global Policy Agencies

- *FAO (Food and Agriculture Organization):* Coordinates the multilateral sharing of agricultural plant genes. Its importance to the agenda is preventing corporate monopolies on crop DNA, ensuring that gene-edited seeds remain accessible for global food security.

- *UNEP (United Nations Environment Programme)*: Hosts the secretariats for global biodiversity treaties like the Convention on Biological Diversity. Its importance to the agenda is legally managing the Cali Fund, which forces multi-billion dollar corporations to pay for utilizing digital genetic resources.

- *WHO (World Health Organization):* Manages pathogen sharing networks for dangerous viruses and bacteria. Its importance to the agenda is ensuring that when a virus genome is uploaded digitally, developing nations get guaranteed, equitable access to the resulting vaccines and diagnostics.

- *WIPO (World Intellectual Property Organization):* Set international patent laws. Its importance to the agenda is introducing strict rules that force companies to disclose exactly which country's digital genetic sequences were used to develop a patented biotech invention.

- *WTO (World Trade Organization):* Governs global market and trade barriers. Its importance to the agenda is preventing national DSI regulations from creating trade blockades or unfair economic penalties against biotech and generic drug manufacturers.

Scientific Partnerships

- *DReAM (Data Rights and Access Management):* Designs ethical protocols for genetic research data. Its importance to the agenda is protecting indigenous groups from exploitation, preventing researchers from publishing indigenous genomic sequences without explicit consent.

- *GA4GH (Global Alliance for Genomics and Health):* Sets the technical frameworks for human medical data. Its importance to the agenda is establishing international encryption and privacy standards so clinics can securely share human genomic assets to cure rare diseases.

- *GISAID (Global Initiative on Sharing All Influenza Data):* Main public tracking platform for respiratory viruses. Its importance to the agenda is keeping viral mutations open and free to download for global public health tracking while preventing countries from hiding pandemic data.

- *INSDC (International Nucleotide Sequence Database Collaboration):* The structural backbone of all global public DNA databases. Its importance to the agenda is keeping biological data completely open-access, serving as the central baseline platform where DSI benefit-sharing rules are directly applied.

Non-Governmental Entities

- *IPCB (Indigenous People's Council on Biocolonialism):* An advocacy group protecting native rights. Its importance to the agenda is fighting "biocolonialism" by ensuring native tribes retain intellectual ownership of their traditional biological resources and data.

- *IUCN (International Union for Conservation of Nature):* A scientific advisory network for governments. Its importance to the agenda is providing the hard ecological data needed to determine which conservation projects should receive money collected by global DSI funds.

- *TWAS (The World Academy of Sciences):* Supports scientific capacity building in the Global South. Its importance to the agenda is funding labs and training scientists in developing countries, ensuring they can actually process and benefit from digital genomic sequence technologies themselves.

6.3. Misuse and Commercial Exploitation of Genomic Data

Genomic data has significant scientific and economic value because it can support medical research, drug development, disease prediction, personalized

treatment, agricultural biotechnology, and population studies. However, the same information can also be misused when it is collected, transferred, analysed, or commercialized without clear consent, adequate security, or fair legal safeguards. Unlike many other forms of personal data, genomic information may reveal inherited characteristics, possible health risks, biological relationships, and information relevant not only to one individual but also to relatives and, in some cases, wider communities. This makes genomic data especially sensitive and difficult to treat as an ordinary commercial asset.

Commercial exploitation may occur when genomic datasets are licensed, sold, incorporated into private research systems, or used to develop profitable products without adequately informing the people or communities from whom the data originated. Commercial use is not automatically unlawful or unethical, since partnerships between research institutions and biotechnology companies can contribute to medical innovation. The main concern arises when those providing the data have little control over secondary uses, receive no meaningful benefit, or are unable to withdraw their consent after their information has entered a wider research or commercial network. WHO principles therefore emphasize informed consent, transparency, privacy, responsible data management, and equitable access to the benefits of genomic research.

Another risk is the use of genomic information for discrimination or unequal treatment. Genetic information may be used to estimate possible health conditions or inherited predispositions, creating concerns that employers, insurers, educational institutions, or other third parties could make decisions based on biological risk rather than actual ability or present health. UNESCO's International Declaration on Human Genetic Data states that identifiable genetic information should be protected as confidential and should not be made available to third parties such as employers or insurance companies without a strong legal basis or the free and informed consent of the person concerned.

Data security is also a major concern. A genomic sequence cannot be replaced in the same way as a password or identification number. Once exposed, copied, or transferred, it may remain useful for future analysis even if its original significance was not understood when it was collected. Advances in data analysis may also make it possible to draw new conclusions from old datasets. This means that consent given for one research purpose may not fully cover later commercial uses, especially where new technologies allow the data to be combined with health, family, geographic, or demographic information.

The commercial value of genomic data also creates questions about intellectual property ownership. Genetic resources themselves are generally not directly protected as intellectual property merely because they exist in nature, but inventions developed from them may qualify for patent protection. In addition, genomic databases, analytical software, research methods, engineered

sequences, and biotechnology products may be protected through patents, copyright, contractual licenses, or trade-secret rules. This can result in a situation where individuals or communities do not legally own the commercial tools created from their biological information, even though their data contributed to the innovation.

The problem is particularly serious when genomic research involves Indigenous Peoples, local communities, or genetic resources from developing countries. Data or biological material may be collected in one country, processed in another, and later used to create patents or commercial products elsewhere. Without transparency and benefit-sharing mechanisms, this can lead to biopiracy, unfair extraction, or the concentration of scientific and economic benefits in a small number of companies and research institutions. The WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, adopted in 2024, responds to part of this problem by requiring patent applicants, once the Treaty enters into force for contracting parties, to disclose the origin or source of genetic resources and the providers of associated traditional knowledge when a claimed invention is based on them.

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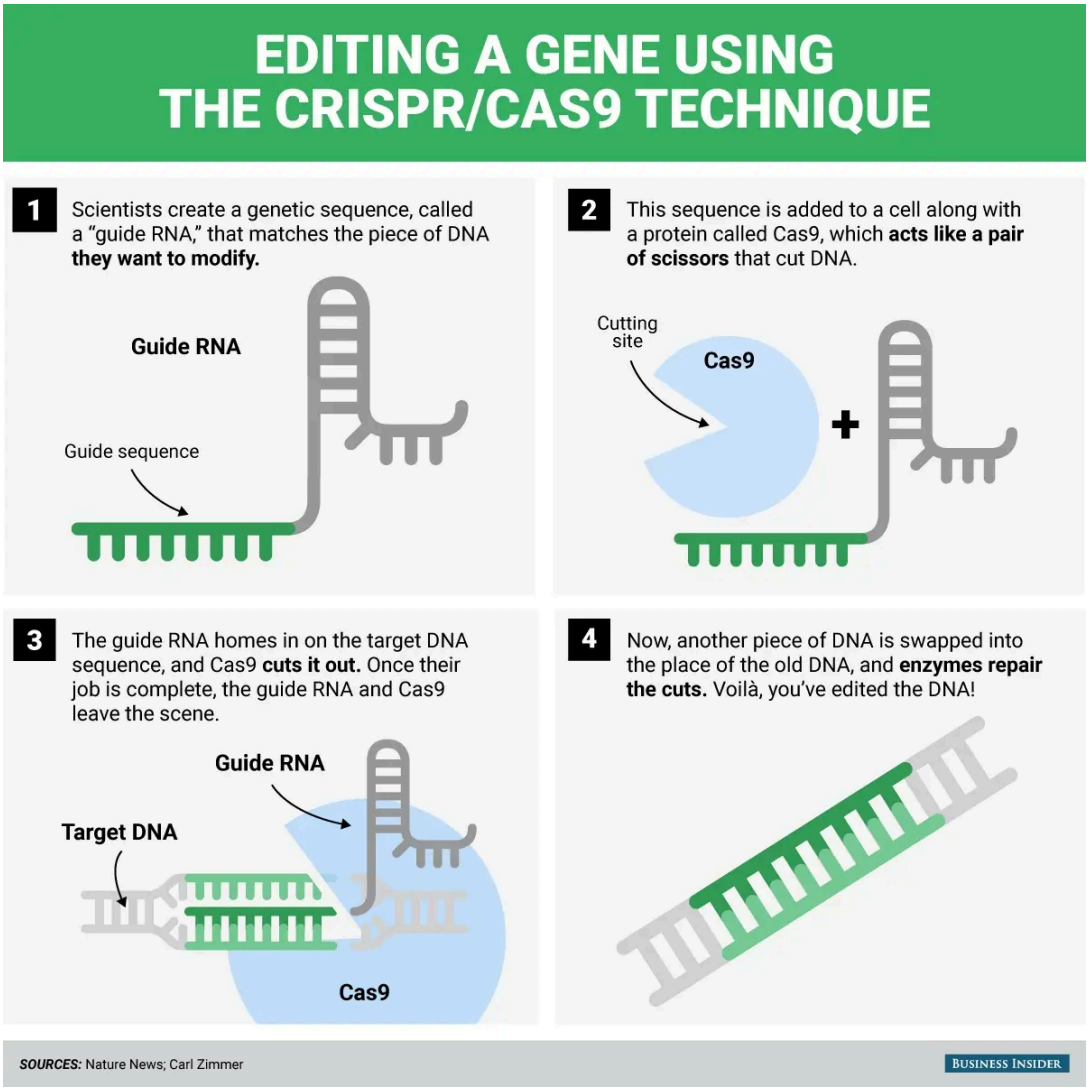
7. Case Studies and International Debates

7.1. Patent Disputes Involving Genetic Material

The question of whether genetic materials, DNA and genes, the most fundamental building blocks of living organisms, can be patented is one of the biggest debates that has pitted the scientific community against the legal system for many years. Traditionally, patents were designed for inanimate machines or chemical formulas invented by humans. However, with modern biotechnology enabling researchers to decipher the genomes of living organisms, the question of whether a gene already existing in nature can be granted a monopoly by a single company through patent rights has created a major ethical crisis. These debates have not remained confined to laboratories; they have turned into multi-million dollar lawsuits in international courts and have affected a very wide range of areas worldwide, from access to healthcare to the rights of indigenous populations. The biggest turning point regarding the patentability of living materials was the famous Diamond v. Chakrabarty case, decided by the United States Supreme Court in 1980. In this case, the patent application of scientist Ananda Chakrabarty, who developed an artificial bacterium capable of breaking down petroleum waste, was examined. The court ruled that a living microorganism produced by human hands could be patented, declaring that everything produced by humans under the sun could benefit from patent protection, thus completely removing legal obstacles to biotechnology patents.

However, this decision became much more controversial in subsequent years with the beginning of patenting natural genes in the human body. The most concrete and shocking example of this is the patent battle over the BRCA1 and BRCA2 genes by Myriad Genetics, a company working in collaboration with the University of Utah. These two genes are vital genetic sequences that directly determine the risk of breast and ovarian cancer in women. In the 1990s, Myriad Genetics claimed to have been the first in the world to sequence these genes and obtained patents from the U.S. Patent Office (USPTO) for isolated gene sequences and diagnostic methods based on them. Based on these patent rights, the company monopolized genetic tests that measure women's cancer risk and began demanding exorbitant fees for these tests. Furthermore, it did not allow any other independent laboratory, university, or doctor to examine these genes, develop tests, or conduct scientific research without its permission. This situation not only prevented researchers from making progress in cancer treatment but also made it impossible for thousands of women to access life-saving tests. Myriad's rigid and profit-driven approach sparked widespread outrage in the medical community, patient associations, and scientific circles. Eventually, a broad coalition, led by the American Civil Liberties Union (ACLU) and the Public Patent Foundation, and including medical associations, researchers, genetic counselors, and patients, filed a historic cancellation lawsuit against the company. The plaintiffs argued that human genes are part of nature and that no one can appropriate a part of the human body, while Myriad Genetics claimed that isolating genes from the body and cleaning them in a laboratory was a technical invention and that they chemically differed from their natural state. This lawsuit, which lasted for years and kept the future of the biotechnology industry on the edge, was concluded in 2013 with a unanimous decision by the US Supreme Court. The court ruled that human genes, which already exist in nature, cannot be patented, even if they are isolated from the body in a laboratory. Chief Justice Clarence Thomas stated that isolating genes is a legal trick and that discovering a product of nature does not mean inventing it. However, the court left an important loophole, ruling that artificial genetic chains (cDNA) produced entirely from scratch in a laboratory can be patented because they do not occur naturally in nature. This decision paved the way for clinical laboratories, rapidly lowering the cost of genetic testing and redefining the boundaries of gene patenting worldwide. A similar struggle took place on the European front. The European Patent Office (EPO) received objections from several reputable institutions, such as the Institut Curie in France and the Belgian Society for Human Genetics, on ethical and technical grounds against Myriad's patents. The objectors argued that these patents hindered access to treatment and undermined scientific research. After lengthy reviews, the EPO canceled or severely restricted many of Myriad's patents related to diagnostic methods. This process has shown the world that biotechnological developments must be regulated not only from legal and commercial perspectives, but also within the framework of universal ethical values such as human dignity, public

health, and scientific freedom. Patent wars over genetic materials have not been limited to human genes, but have also affected the agricultural and livestock sectors. This has continued through groundbreaking technologies. The most recent and striking example of this is the CRISPR/Cas9 gene editing tool, which has revolutionized genetic engineering. This technology makes it possible to cut, copy, and rearrange the genetic codes of living organisms, just like a computer program. The fundamental discovery of the technology was made by Jennifer Doudna and her partner Emmanuelle Charpentier from the University of California, and a patent application was filed. However, immediately afterward, the Broad Institute (a partnership between MIT and Harvard) filed a more specific application demonstrating how this technology could be applied to



human and mammalian cells (eukaryotic cells) and, by requesting expedited review, managed to obtain the patent first. This situation sparked a global patent war between those who discovered the basis of the technology and those who first adapted it to the most commercially valuable area. The debates over who would own these patents, which directly control multi-billion dollar agricultural,

livestock, and medical markets, have once again highlighted how intellectual property law can create injustice while rewarding scientific innovation. On an international level, genetic patent disputes have transformed into a deep geopolitical conflict between wealthy countries and developing countries rich in biodiversity. At the heart of this conflict are the TRIPS Agreement of the World Trade Organization, which advocates for strong patent protections and the globalization of intellectual property rights, and the United Nations Convention on Biological Diversity (CBD), which aims to protect nature, equitable distribution, and the rights of indigenous peoples. Multinational pharmaceutical and agricultural companies in developed countries collect plants and microorganisms from the forests, rivers, or indigenous tribes of developing countries, take them to their laboratories, map their genes, and obtain patents on them. This prevents the local communities, who are the true owners of that genetic resource, from claiming any rights or sharing in the profits; this is referred to as biopiracy in international literature. To break this colonial approach and ensure global justice, biodiverse countries such as India, Brazil, and Peru are demanding a radical reform of international patent rules. The amendment proposal submitted by these countries to the TRIPS Council, called Article 29 bis, envisages revolutionary rules in the patent system. According to the proposal, companies applying for patents for any invention containing genetic material must clearly state the origin and source of the material they used, prove that they have obtained official consent from the country and local population from which they obtained the material, and commit to fairly sharing the commercial profits generated. Although developed countries argue that these rules will slow down innovation and overload patent offices, drawing these ethical boundaries is now unavoidable for the protection of biological resources, which are the common heritage of humanity, and for bridging the deep divide between the global South and the global North. The patent wars over genetic materials show that the future of medicine and agriculture will be shaped not only by the power of inventions made in the laboratory, but also by how fairly, morally, and humanely these inventions are shared with all of humanity.

7.2. Public Health and Vaccine Research

Strategic advancements in biotechnology and modern medicine are directly dependent on the rapid, secure, and open sharing of genomic data on a global scale. Digital Sequence Information, or DSI as it is commonly known, which defines genomic sequence data and other related digital information, is a highly broad policy term that underlies much of current research in the life sciences. Vital for both basic and applied research in the public and private sectors, this data is a shared heritage of the global scientific community. In this context, the effective use of digital sequence information to respond to global pandemics, and particularly to design a next-generation vaccine for COVID-19, has

constituted one of the most dynamic intersections of global health diplomacy, patent regimes, and international legal systems.

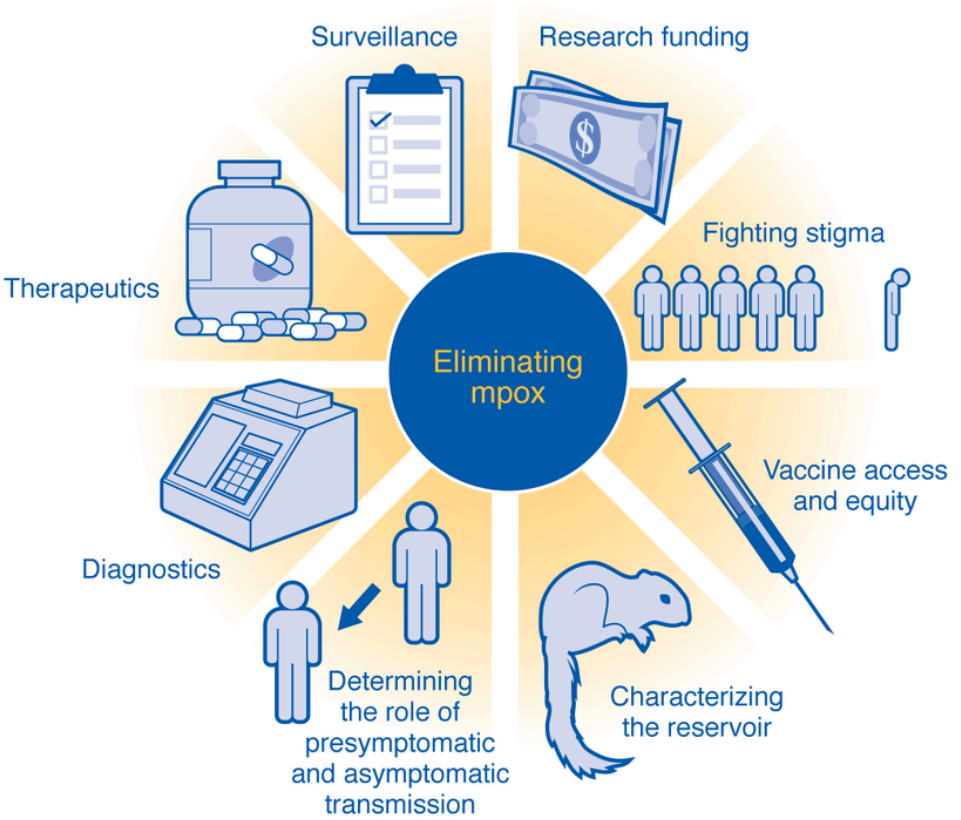
The advancements in nucleic acid technologies during the pandemic represent humanity's most sophisticated line of defense against global threats. mRNA vaccines against COVID-19, produced by Moderna and Pfizer/BioNTech, were among the first approved and most widely used effective vaccines in the United States and Europe. The high clinical success rates of these vaccines have clearly demonstrated that they offer a much more flexible and adaptable biodesign platform compared to traditional vaccination methods. These platforms, which form the basis of next-generation vaccination technologies, are based on artificial nucleic acid structures synthesized through extracellular (in vitro) transcription methods. mRNA vaccines introduce mRNA molecules into human cells, which then use this mRNA to create a harmless viral protein specific to the SARS-CoV-2 coronavirus. This foreign antigen produced by the cells acts as a trigger, simultaneously activating the humoral and cellular arms of the immune system, training the system to recognize the protein and produce antibodies against it; this provides protection against serious infection.

The enormous scientific, industrial, and logistical effort behind vaccine development processes has redefined the boundaries of global collaboration. While incredibly fast by historical standards, the COVID-19 vaccine development process was an extremely long and complex one, dependent on global scientific collaboration and open access to DSI. In the early days of the pandemic, the rapid sharing of the virus's genome map online enabled laboratories worldwide to begin R&D simultaneously. This process, involving a large number of people and enormous resources working across multiple phases of research, development, and testing, required a high level of coordination at every step, from preclinical design to phase trials, industrial scaling, and the establishment of global distribution chains.

The fair sharing of intellectual and commercial rights derived from the use of genetic resources is one of the areas where international policymakers currently expend the most energy. To understand the complexity of working with DSI and some of the challenges scientists and policymakers may face in sharing the benefits of DSI, it is necessary to focus on a specific part of the work done by Moderna, specifically the US-10702600-B1 patent application titled "betacoronavirus mRNA vaccine," filed in February 2020, just two months after the start of the pandemic. This patent describes the molecular components and manufacturing methodologies of coronavirus vaccines that are subject to patent protection. The early filing date reflects the company's long history and priority rights in developing an mRNA platform infrastructure against respiratory pathogens. Upon examination of the patent, it is evident that it targets a much broader group of pathogens than a specific virus strain, describing a general method for producing an mRNA vaccine for respiratory viruses, particularly betacoronaviruses. Sovereignty rights over physical biological materials and their digital data are debated in international law along two main axes. The

United Nations Convention on Biological Diversity (CBD), adopted in 1992, aims to protect and sustainably utilize biological diversity and ensure the equitable sharing of benefits derived from the use of genetic resources. However, the lack of a concrete mechanism to implement these goals led to the preparation of the Nagoya Protocol, adopted in 2010 and entering into force on October 12, 2014. Currently, 142 countries are parties to the Nagoya Protocol, and more than 100 national access and benefit sharing (ABS) laws are implemented worldwide. The Nagoya Protocol is built on a bilateral model, recognizing that each country has sovereign rights over biological resources within its own borders.However, this model faces serious operational crises in the modern age of biotechnology, where digital sequence data can be copied and shared over the internet in seconds.

The tension between the intellectual property claims of biotechnology companies and the demands for fair sharing from resource-supplying countries is particularly evident in vaccine development processes. The question of how the benefits of a vaccine should be shared tends to rely on legal documents in the international arena. A benefit-sharing system that needs to know which DSI was used in the development of a particular product, and thus aims to determine which countries are entitled to benefit from the sale and/or use of that product, would likely rely on publicly available documents such as patent applications. However, for mRNA vaccines, the final product is essentially a single and relatively short nucleotide sequence. At first glance, it might be thought that there should be a one-to-one relationship between the natural sequence and the vaccine sequence, which would facilitate the assignment of benefits to a country of origin. However, an examination of Moderna's US-10702600-B1 patent



clearly shows why this is not the case. This Moderna patent does not utilize any SARS-CoV-2 sequences; therefore, countries sharing information related to COVID-19 will not be entitled to any benefit sharing arising from this patent. The patent is based on generic platform designs synthesized in a laboratory setting prior to the start of the pandemic. Instead, the patent draws on publicly available DSIs and refers to 176 genetic sequences from several different respiratory viruses obtained from a wide range of countries, including Saudi Arabia, the United Kingdom, the UAE, Jordan, France, the United States, Qatar, Thailand, Oman, and China. This demonstrates that a commercial biotechnology product cannot be reduced to a single country's biological resource.
Furthermore, the patent discloses 96 novel sequences submitted to publicly available DSI databases along with the patent application. While some of these are similar to or identical to existing publicly available sequences, others represent engineered or modified versions of sequences already referenced elsewhere in the patent document. As a result of these advanced manipulations carried out by scientists, the natural origin link of nucleic acids is broken, and many are simply labeled as Artificial Sequences, lacking a traceable country of origin.

It is clear that a system based on tracking and tracing the origin and use of individual sequences would provide negligible benefit sharing, and none of the countries providing SARS-CoV-2 DSI would necessarily benefit. The wide variety of sequences used and the exclusion of SARS-CoV-2 sequences demonstrate that Moderna is free to decide which sequences to include in its patent document, and that not a single sequence is vital to its work. Therefore, if such a legal tracking system is adopted by only some countries and not all, companies like Moderna can easily avoid using sequences from countries that mandate benefit sharing, a phenomenon known as forum shopping.
Focusing solely on the final sequence in the vaccine, rather than just the patent stage, does not resolve the traceability crisis, as it is impossible to correlate this sequence with any specific natural sequence. The final result is an artificial sequence that does not match any sample that could have been collected in the natural environment and therefore could not be traced back to a country of origin. Indeed, the actual sequence used in the Moderna vaccine was initially protected by trade secret (a legal protection that is very difficult to enforce through benefit-sharing laws) and shared only about 70% similarity with naturally occurring SARS-CoV-2 strains. The final sequence is the culmination of a long research process that defines which proteins are good vaccine targets, how they change, how they are structured, and how they can be engineered for higher stability, and all this research requires a wide variety of sequences beyond the virus of interest. Moreover, since some of this research takes place in the field of academic research, it may not be fully reflected in institutional documents or patents. This 70% similarity difference between the final sequence and the natural SARS-CoV-2 genome is a biochemical necessity for codon

optimization and structural engineering. Naturally occurring viral sequences have suboptimal nucleotide combinations that limit protein expression rate and antigen stability in human host cells. In the codon optimization process, while the amino acid sequence of the protein to be expressed is fully preserved, nucleotide codons are redesigned to best suit the tRNA pool of human cells. For example, uracil bases are modified to fit 1-methylpseudouridine.

7.3. Biodiversity and Genetic Resource Governance

Protecting the global ecological balance, defending the rights of indigenous communities, and ensuring biotechnological innovation within a fair framework constitute the fundamental pillars of biodiversity and genetic resource governance. Historically, the Earth's rich biological resources have long been considered humanity's common heritage, and this approach has allowed multinational corporations and research institutions in industrialized countries to freely exploit the rich biological ecosystems of the Global South without any financial compensation. These activities, known as bioprospecting, which aim to transform genetic resources in nature into commercial products, are largely based on the traditional knowledge accumulated by local communities over centuries. However, the exclusion of local populations, the true protectors and possessors of this knowledge, from the enormous pharmaceutical, agricultural, and cosmetic revenues generated by these processes has led to a serious ethical and legal debate internationally, known as biopiracy. Biopiracy, a socio-political concept referring to the monopolization of traditional knowledge for commercial gain without consent or compensation, disregarding the collective rights of indigenous communities, has become central to governance debates. The first institutional challenge to this asymmetrical exploitation in international law was embodied in the Convention on Biological Diversity, adopted in 1992. The Convention established the absolute sovereignty of states over biological and genetic resources within their borders, thus ending the doctrine of common heritage. The principle of fair and balanced sharing of benefits derived from the use of genetic resources, one of the three pillars of the Convention on Biological Diversity, has been legally established through the mechanisms of Prior Notification and Mutually Agreed Conditions. To make these principles more binding and enforceable, the Nagoya Protocol, adopted in 2010, provided a transparent bilateral legal framework at the global level for access to and benefit sharing of genetic resources. However, global regimes such as the World Trade Organization’s Agreement on Trade-Related Intellectual Property Rights (TRIPS), while protecting modern patent laws that reward individual inventions and define novelty criteria with strict rules, have been insufficient in protecting the oral and collective traditional knowledge of local communities. This legal inconsistency remains a source of unending tension between industrialized countries and biodiverse developing countries.

One of the most iconic and shocking examples in the history of biopiracy is the case of the Algerian violet (Catharanthus roseus), a plant endemic to Madagascar. The indigenous Malagasy people of Madagascar had used this flower for centuries as a traditional medicine, particularly in the treatment of diabetes, suppressing hunger, and alleviating various physical ailments. The spread of the plant to Europe by French colonialists from the 1600s onwards and the establishment of global bioprospecting networks paved the way for the American pharmaceutical company Eli Lilly to conduct systemic research on the plant in the 1950s. Inspired by the indigenous people's experience with the plant's use in diabetes treatment, Eli Lilly researchers discovered in their laboratory studies that the alkaloids vinblastin and vincristine, isolated from the plant, suppress white blood cells and halt tumor development. Following this discovery, the company patented the process of isolating the alkaloids and launched the groundbreaking cancer drugs Oncovin, used in the treatment of childhood leukemia, and Velban, developed against Hodgkin's disease. While Eli Lilly earned enormous profits ranging from $90 million to $400 million annually from these two cancer drugs in the 1980s, the Madagascar government and the indigenous Malagasy people, the true owners of the traditional knowledge and genetic resource, received not a single penny of financial benefit from this commercial success. This situation is considered the clearest historical example of the gratuitous appropriation of biological resources by the Global North and the disregard of the rights of the Global South. The company and some Western scientists have attempted to weaken the proprietary claims by arguing that the local people used the plant for diabetes, not cancer, and therefore its effectiveness against cancer was entirely a product of modern scientific endeavors. However, this argument has been criticized as a neoliberal approach aimed at covering up the fact that this genetic resource would never have been discovered without the guidance and protection of the local communities. Furthermore, the subsequent production of the raw material in US states such as Texas led to Madagascar's complete exclusion from the supply chain and its economic marginalization.

Another landmark case highlighting the conflict between the two is India's struggle over the neem tree (Azadirachta indica). For over a thousand years, the leaves, bark, and seeds of the neem tree have been used in the Indian subcontinent as an antiseptic toothbrush, soap, toothpaste, and, most importantly, a natural pesticide against agricultural pests. In the early 1970s, US lumber importer Robert Larson observed this use in India, brought the seeds to his company in Wisconsin, developed a pesticide extract called Margosan-O, and received approval from the US Environmental Protection Agency (EPA) in 1985. Three years later, Larson sold this patent to the multinational chemical company W. R. Grace. In 1994, W. R. Grace and the US Department of Agriculture (USDA) obtained a patent (Patent No. 436257) from the European Patent Office (EPO) for a fungicide using neem oil. The company argued that

Neem seeds deteriorate very quickly under traditional use, and that their formulation, which they developed, made the product storable and stable, claiming it was a genuine invention. Following W. R. Grace's patent acquisition, local farmers and businesses in India faced the threat of being prevented from producing pesticides using traditional methods, Neem seed prices skyrocketed, and local agricultural communities suffered significant economic losses. In response, the Indian government, local NGOs, and the renowned environmental activist Vandana Shiva launched a global legal battle. The Indian side proved that the antifungal properties of the Neem tree were already detailed in ancient Ayurvedic medical texts written in Sanskrit and in scientific articles from 1953. They argued that the stabilization method claimed by the company was merely a simple modification of traditional Indian practices and therefore did not meet the criteria of novelty and inventive step. After a lengthy legal process, the EPO ruled the patent invalid in 2000, canceling W. R. Grace's patent. Supported by Articles 25 and 64 of the Indian Patent Act (1970), which protect traditional knowledge, this victory became the most important precedent for the official recognition of traditional knowledge as prior art by international patent offices.

The generations-long traditional knowledge of the indigenous San people living in the harsh climate of the Kalahari Desert was once again brought to the global agenda by the biopiracy case involving the Hoodia gordonii plant. San hunters chewed this succulent plant to suppress hunger and thirst during their hunting expeditions across the long deserts. In the 1960s, the South African Scientific and Industrial Research Council (CSIR) tested this property of the plant in a laboratory setting by examining ethnobotanical records and isolated an active appetite-suppressing molecule called P57 from the plant. After patenting this molecule in 1996, CSIR, seeing the enormous commercial potential in the global obesity market, sold the licensing rights to the British company Phytopharm, which in turn transferred them to giant pharmaceutical and food companies such as Pfizer and Unilever. Throughout this process, the San people, the original owners of the knowledge, were completely excluded from the system and only became aware of their rights through excessive media attention. CSIR officials initially tried to rationalize biopiracy by claiming that the tribes using this traditional knowledge had become extinct, which led to widespread outrage that colonial approaches continued in modern science. As a result of pressure from civil society organizations and human rights advocates, the San community established its own council, initiated legal proceedings, and signed a historic benefit-sharing agreement with CSIR in 2003. Under the agreement, the San Hoodia Benefit-Sharing Foundation was established, and it was decided that the San people would receive certain milestone payments and royalties from future commercial sales. However, the sale of Hoodia in unregulated gray markets, imitations, illegal cultivation activities, and the failure of clinical trials to yield the expected commercial success have resulted in income for the local community falling far short of the promised level. This case clearly

demonstrates that simply having benefit-sharing agreements on paper is insufficient; strict market controls and international protection shields are necessary to safeguard the rights of indigenous peoples.

In the high plateaus of the Andes Mountains, particularly around Lake Junin, Maca root (Lepidium meyenii), cultivated for thousands of years by Quechua and Aymara indigenous communities, forms a vital part of the local culture and economy due to its high nutritional value as well as its energizing, hormonally balancing, and fertility-enhancing medicinal properties. In the early 2000s, the US-based PureWorld Botanicals company began developing compounds derived from Maca root and The company has obtained numerous international patents relating to the use of these compounds in the treatment of sexual dysfunction. It has also patented traditional extraction techniques for the plant, disregarding Peru's rights as a country of origin and threatening to prevent local producers from exporting their Maca products to international markets. In response proactively, the Peruvian government established the National Commission Against Biopiracy (CNB) in 2004 under Law No. 28216, a world first. The commission is tasked with systematically monitoring and challenging international patent applications related to biological resources originating in Peru, and as of 2024, has successfully canceled 149 patents, at least two of which were based on Maca root. Although the French company Naturex, which acquired PureWorld, has opened up the patents to the Peruvian public, the threats to Maca have not been limited to Western patents. In 2014, it was determined that Chinese buyers had smuggled tons of unprocessed maca roots and seeds from farmers in the central Andes Mountains of Peru, paying cash far above market value, through Bolivia to Yunnan province in China. Despite Peruvian law strictly prohibiting the export of unprocessed maca, these networks, exploiting weak state oversight, smuggled the seeds and initiated illegal cultivation activities in China. This was recorded as a modern case of biopiracy, clearly violating the principles of sovereignty and benefit sharing of the country of origin under the Nagoya Protocol, and once again highlighting the weaknesses in global governance oversight.

The rapid transformation in biotechnology has ushered in a new era shaped by the wave of digitalization, making genetic resource governance completely independent of physical raw material transfer. Digital Sequence Information (DSI) refers to the process of digitizing DNA and RNA sequencing data obtained from genetic resources and storing and sharing them in global open databases. This technological revolution has accelerated the production of innovative solutions across a wide range of fields, from agricultural research and development to the pharmaceutical industry. Scientists can now design new vaccines, resistant seeds, or industrial enzymes by downloading only digital sequencing information from a plant or microbe on the other side of the world, without needing a physical sample. However, this situation threatens to render

the traditional Access and Benefit Sharing (EFP) mechanism of the Nagoya Protocol, which relies on physical access and requires bilateral agreements with the country of origin, completely ineffective. While organizations such as the Global Biodiversity Information Facility (GBIF) advocate for the non-monetary benefits of open-access data, such as scientific progress and capacity building, countries in the Global South have labeled this as digital biopiracy, characterizing it as a new avenue for unfair profit. This long-standing tension between developed and biodiversity-rich countries has given rise to the demand that digital data should also be subject to international rules of fair sharing.

Following years of challenging global negotiations, the historic Resolution 16/2, which envisages the sharing of benefits arising from the use of DSI through a multilateral mechanism, was adopted at the COP16 Biodiversity summit held in Cali, Colombia in November 2024. Established in accordance with this resolution and managed by the United Nations Multilateral Trust Fund Office (MPTFO), in partnership with the United Nations Development Programme (UNDP) and the United Nations Environment Programme (UNEP), the Cali Fund was officially launched on February 25, 2025. The Cali Fund is financed by contributions from large-scale private sector actors who directly or indirectly use DSI data in their commercial activities. In this context, large companies with total assets exceeding $20 million, annual sales exceeding $50 million, and profits exceeding $5 million, and operating in sectors directly dependent on DSI such as pharmaceuticals, cosmetics, agricultural chemicals, food, and seed breeding, are required to contribute 0.1% of their revenue or 1% of their profits to the fund as an indicative contribution. Public databases, academic institutions, and non-profit public research organizations are exempt from these financial obligations in order to protect open science. Companies contributing to the fund are considered to have fulfilled their obligations under the multilateral mechanism thanks to the official certification they receive, and are exempt from individual compensation claims from other countries.

7.4. Recent International Negotiations on DSI

In the digitalized world, the governance of genetic resources has evolved into a new dimension encompassing the global circulation of biotechnological data, transcending physical boundaries. At the heart of this transformation is Digital Sequence Information (DSI), which defines the DNA and RNA sequence data of living organisms. Traditionally, the 1992 Convention on Biological Diversity (CBD) and the 2010 Nagoya Protocol regulated access to genetic resources and the sharing of benefits derived from them within the framework of bilateral agreements established between the country of origin and the user. However, advances in biotechnology and synthetic biology have made it possible for researchers to develop new products by downloading digital sequence information from open-access global databases without the need for physical

transfer of raw materials. This technological leap has fueled discussions of digital biopiracy on the international stage, threatening to undermine the sovereign rights of Global South countries and mechanisms for equitable benefit sharing, and has become one of the most challenging negotiating topics in global biodiversity diplomacy. The search for a multilateral solution to DSI governance was first formally raised at the COP13 summit in 2016 and, following technical discussions, reached a concrete framework at the COP15 summit in 2022. The Kunming-Montreal Global Biodiversity Framework (KGBFF), adopted in Montreal, decided on the establishment of a multilateral benefit-sharing mechanism and a global fund to share the benefits arising from DSI use. However, critical issues such as operational details, who will contribute, how the fund will be managed, and under what circumstances payment obligations will arise, could not be resolved due to deep disagreements and were deferred to the COP16 summit held in Cali, Colombia in 2024. During this process, developing countries demanded that access to databases be subject to a legally binding payment system that would not infringe on the rights of countries of origin; while industrialized countries advocated for the principle of open science to prevent disruptions to scientific research, proposing a voluntary model. The DSI negotiations at the COP16 Cali summit constitute a historic case study revealing the power asymmetry and struggle for dominance between the Global South and the Global North in international diplomacy. In these negotiations, the G77 group, representing biodiversity-rich developing countries, and especially the African Negotiators Group (AGN), led by countries such as South Africa, Egypt, Uganda, Namibia, Kenya, and the Democratic Republic of Congo, demonstrated a highly resolute and unified stance. The African Group's core argument was that the sovereign rights of states over their own resources, guaranteed in Article 15 of the CBD, should apply equally to DSI, the digitized version of these resources. Developing countries advocated for an end to this asymmetrical system where multinational pharmaceutical, agricultural, and cosmetics companies earn billions of dollars by freely extracting data from global open databases, and for the use of DSI as leverage to close the urgently needed annual $200 billion funding gap for biodiversity conservation. Opposing this alliance was a powerful bloc of industrialized and biotechnology-leading countries such as the European Union, Japan, Switzerland, Norway, the United Kingdom, Canada, and Australia. This group of developed countries argued that the principles of open science and the free flow of data were vital for global innovation and public health. They maintained that legal or administrative barriers to accessing DSI databases would slow down new drug and vaccine discoveries, hinder agricultural R&D, and impede data sharing, particularly during urgent global health crises. Therefore, the industrialized countries insisted that the databases themselves should be free from any paywalls or licensing requirements, and that contributions from commercial companies should be based on voluntarism and corporate social responsibility rather than legal obligation. On the final day of negotiations in Cali, tensions between the

two blocs reached their peak, and the closing plenary session became a continuous diplomatic battle that lasted until dawn. In the final hours before the official deadline of the summit, the President's Text, presented by the COP16 Presidency and aimed at reaching a consensus, caused a major uproar among developing countries. This draft text largely reflected the positions of developed countries such as the European Union and Japan, and contained flexible formulas that would bypass states' sovereign rights over publicly accessible DSI (Digital Information System) databases. If the text were adopted in this form, it would lead to increased biopiracy.

The African Group countries, arguing that DSI would be legitimized in the digital realm, along with biodiversity giants such as India, Brazil, Argentina, Colombia, the Philippines, and Bolivia, demonstrated extraordinary resistance and jointly opposed the text. This resolute stance forced industrialized countries to back down and ensured the inclusion of last-minute amendments protecting their sovereign rights. As a result of this resistance shown by the African Group and its allies, just before the general assembly was suspended due to a lack of members, the historic Resolution 16/2, considered a milestone in global environmental diplomacy and establishing the multilateral sharing rules for DSI, was adopted. The global mechanism established by this historic consensus, called the Cali Fund, provides a concrete and fair financial formula for companies using DSI in the biotechnology sector. According to the agreed guidelines, large-scale commercial organizations operating in sectors directly dependent on DSI, such as pharmaceuticals, cosmetics, agricultural chemicals, food, and seed breeding, are expected to contribute to the fund. According to the established benchmark thresholds, companies with total assets exceeding $20 million, annual sales exceeding $50 million, and net profits exceeding $5 million are required to contribute 0.1% of their annual revenue or 1% of their net profit to the Cali Fund. Academic institutions, public research organizations, and non-profit databases are completely exempt from these financial obligations in the name of protecting open science. The most delicate diplomatic balance of the negotiations was based on the legal nature and enforceability of these financial contributions. Since the COP decision taken at the international level does not have direct supranational enforcement power, payments to the Cali Fund could not be legally mandated globally. Instead, it was decided that national governments would encourage or compel companies to make payments to this fund through their domestic laws and administrative regulations. This created a unique voluntary-mandatory hybrid model in international law. To encourage companies to comply with this system, it is envisioned that actors contributing to the fund will be given an official certificate documenting that they have fulfilled their obligations under the multilateral mechanism, and that this certificate will exempt them from potential future bilateral compensation claims from countries of origin. Thus, it is aimed to increase the participation rate in the system by providing legal certainty for multinational companies

operating in the global market. The establishment of the Cali Fund symbolizes not only a financial settlement but also global justice in terms of recognizing the rights of indigenous peoples who have been historically excluded by colonial approaches. According to the historic decision, at least 50% of the resources collected in the Cali Fund will be transferred directly to indigenous peoples and local communities, who are the true guardians of global biodiversity and the holders of traditional knowledge, according to their own needs. This financial entitlement is crowned by the decision taken at COP16 to establish a permanent Article 8(j) Subsidiary Body to institutionalize the full and effective participation of indigenous communities in CBD processes. Thus, indigenous populations have succeeded in directly receiving a share from global funds to protect biodiversity in their habitats, without being dependent on state initiatives, and in gaining a lasting voice in international environmental decisions. On the other hand, the operational structure of the Cali Fund has also brought with it serious concerns and points of resistance in the global business world. Powerful umbrella organizations representing the global industry, such as the Japan Business Federation Keidanren, have warned that making payments to the fund mandatory at the national level will undermine biotechnology investments. Industry representatives have expressed their discomfort with the emergence of duplicate payments at different stages of complex supply chains and the ambiguity of the concepts of DSI use and indirect benefit. Industry circles argue that this financial burden will slow down the global biotechnology economy by shrinking R&D budgets and that governments should implement facilitating mechanisms such as tax breaks, corporate reputation logos, or state-backed innovation incentives to encourage these payments. This situation demonstrates that the practical extent to which the Cali Fund can raise revenue depends on the success of local policies implemented by national governments. Following the historic steps taken at the COP16 summit, the process of effectively implementing the Cali Fund gained significant momentum, and the fund was officially established on February 25, 2025. Managed by the United Nations Multilateral Trust Fund Office (MPTFO) in partnership with UNDP and UNEP, this new financial structure began accepting its first institutional payments by the end of 2025, thus theoretically marking the beginning of negotiations. The DSI has evolved from a mere title to a tangible global financial instrument. However, critical issues such as database auditing, verification of company statements, harmonization of national legislation, and mobilization of financial resources, which could not be completed in Cali due to time constraints, require an intensive technical work schedule that must be completed by the COP17 summit in 2026. The aim is to ensure a regular and sustainable flow of resources to the fund by COP17, thus beginning to finance conservation projects in the Global South. Ultimately, the international negotiations on DSI and the establishment of the Cali Fund offer a universal template not only for environmental law but also for global data governance and data justice in the digital age. The struggle for the fair sharing of profits from the

commercialization of genetic data serves as a precedent for a wide range of digital rights discussions, from AI training data to climate technologies. The diplomatic resistance shown by the Global South in Cali has proven to the world that physical sovereignty rights can be transferred to the digital cloud, and that the international system must abandon its colonial habits of extracting raw materials and adapt to a multilateral, fair, and sustainable model of coexistence.

8. Questions to be Addressed (QTBA)

1. How should intellectual property frameworks address artificial intelligence systems trained on genomic datasets or used to develop biotechnology-related inventions?
2. How can intellectual property protection be balanced with open scientific research, public-health needs and access to genomic databases?
3. How can non-develop and developing countries gain fair access to genomic technologies and databases?
4. What international rules should WIPO create and upgrade to manage disputes involving genomic data and digital sequence information?
5. How can WIPO and the international community prevent wealthy private actors, powerful families, and government officials from using exclusive access to genomic data and human cloning technologies to create hereditary privilege and gain excessive economic or political power?

9. Bibliography and Further Reading

DSI – Simply Explained

What is Digital Sequence Information?

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