International Legal Challenges to Biotechnological Products

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Abstract

Biotechnologies have already improved and have taken a significant role in the sustainable development of human life in different aspects such as economy, medicine, education, nutrition, etc. Biotechnological products help farmers reduce the number of chemical pesticides, water, and fuel consumption for food production. They can also be used for environmental cleaning and food production at lower costs and reduce the use of harmful substances. However, biotechnologies have been criticized, for example, genetically modified organisms may not have fully investigated consequences, and unknown toxins may be produced by biotechnological products or reduce biodiversity, leading to genetic contamination and poisoning. This paper attempts to estimate the advantages and disadvantages of the current international law and various structures and bodies to solve possible problems. Issues of biotechnology at the international level and agreements and treaties related to each of them may include the following: patenting and intellectual property protection; transparency of export and import, labeling system, and establishment of international standards and procedures; possible damage caused by genetically modified imported products, international liability, compensation for harmful effects, and preventive measures; liability for transboundary, negative impact on the environment of neighboring countries, etc. After consideration, it can be concluded that there is no single "contractual regime" governing biotechnologies; we can find a disparate and contradictory "network" of agreements related to intellectual property, trade, and environment, as well as a number of general principles of law and rules.

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1 Introduction

Thanks to biotechnologies, advanced revolutionary solutions are already being successfully adopted in various areas of society. The international community should promptly cooperate to create legal mechanisms for regulating various aspects.

Scientists claim that the interaction between different genes will make it possible to treat such diseases as cancer, Alzheimer's disease, and many others. The developed microorganisms and products can make a beneficial impact, increasing the geographical range of crops. Also, biotechnological means can be used for animal husbandry to improve the quality and quantity of resources (e.g., milk, eggs, meat, or wool, or even produce "healthier" animals) (Greely, 2016).

It is possible to increase the supply and develop food products with higher nutritional value, the number of vitamins, and useful elements. Even though there are environmental concerns about the harmful effects caused by the manipulation of nature with the help of biotechnology, the positive application of biotechnology can be extremely diverse.

Meanwhile, various national and international problems have arisen with the development of genetic engineering. Many consumers, scientists, and environmentalists believe that genetically modified products should not be distributed until long-term tests are carried out. The negative factors

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include toxins, antibiotic resistance, counterfeit, genetic contamination, etc. There is no scientific evidence of any damage, but scientists should do more research on the risks. Moreover, scientists are concerned about the possibility of disrupting the balance of the ecosystem.

The international community should promptly respond to changes and challenges to introduce the necessary legal regulators. Currently, there are several mechanisms and documents regulating issues related to biotechnologies, including the following:

- The Convention on Biological Diversity (CBD) (United Nations, 1992);
- The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol) (United Nations, 2010a);
- The FAO Commission on Genetic Resources for Food and Agriculture;
- The UNESCO International Bioethics Committee;
- The WHO's Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing;
- The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (World Intellectual Property Organization (WIPO), 1977);
- The Cartagena Protocol on Biosafety (Secretariat of the Convention on Biological Diversity, 2000);
- The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (United Nations, 2010b).

2 Materials and Method

This study is based on general scientific methods and approaches, as well as special scientific methods of systemic and logical study. In other words, the authors applied the methods of deduction, induction, and dialectical analysis. Additionally, the authors applied other special methods such as systemic, structural, historical-legal, and comparative methods to investigate the subject and reach the following results.

3 Results

3.1 Intellectual Property Protection

There are various issues related to patents in the context of biotechnology in the field of agriculture and pharmaceuticals. Developed countries argue that intellectual property rights (IP) should be clearly regulated and protected. In turn, developing countries argue that protection, access, and distribution issues will be expensive or even inaccessible. Many developed countries have access to the genetic diversity available in developing countries as an essential resource for genetic engineering; meanwhile, developing countries insist on sharing benefits available in their countries (Dederer & Herdegen, 2017).

Issues arising in connection with patents and biotechnological inventions can be divided into several categories. The first category is related to legal regulations related to the scope of patent protection, issues about whether certain obtained substances are "inventions" or "discoveries" cause widespread debate, as well as inventive activity, industrial applicability, and disclosure requirements, the requirements that "support" the non-disclosure of the invention's "elements."

Licensing issues and final innovations can be covered by a large-scale patent issued at the "beginning" of innovation; it is extremely important to strengthen partnerships between the public and private sectors and generate income and investment. One of the elements of biotechnological inventions is the facilitation of the transfer of technology from basic research to applied research and commercialization.

Considering the international structures and bodies that contribute to the protection of intellectual property, it is necessary to note the World Intellectual Property Organization (the WIPO). IP issues related to genetic resources discussed by the WIPO include the prevention of the illegal grant of patents, the "patentability" of inventions, and obtaining benefits (e.g., royalties).

The WIPO member countries consider the possibility of using a unified IP system and developing a new disclosure requirement that would oblige patent applicants to indicate the source or origin of patents, as well as evidence of prior informed consent and benefit-sharing agreements, if any. The WIPO has created and maintains a collection of agreements on genetic resources, licensing agreements, and related information.

The development of information tools and databases is one of the approaches to solving the problem of erroneous patents. Databases can help increase the degree of probability that information is localized and accessible when it is necessary during patent processing.

The WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore develops possible requirements, issues of disclosure of resources in patent applications, and issues of using genetic resources, as well as transformations during the "Fourth Industrial Revolution." Transformations during the "Fourth Industrial Revolution" are defined as a transformational change in technological capabilities and data processing capabilities combined with the fusion of digital, biological, and material aspects, in particular: genomics, gene

editing, synthetic biology, bioinformatics, the use of artificial intelligence in biological sciences, the application of digital technologies to genetic and genomic data, and the evolution of other technologies. This convergence of biological, digital, and material systems has the clearest consequences for biotechnology, food, agriculture, healthcare, and pharmaceuticals. The WIPO has been and is actively participating now in the discussion of issues in international forums related to biotechnology, including:

- The development of the CBD in 1992 (United Nations, 1992);
- The Nagoya Protocol (United Nations, 2010a);
- The FAO Commission on Genetic Resources for Food and Agriculture;
- The UNESCO International Bioethics Committee;
- The WHO's Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing;
- The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure in 1977 (World Intellectual Property Organization (WIPO), 1977), etc.

Biotechnologies and the creation of modified organisms were the subject of extensive discussions by the CBD, which led to the adoption in the early 2000s of the Cartagena Protocol on Biosafety (Secretariat of the Convention on Biological Diversity, 2000) and the subsequent Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Compensation (United Nations, 2010b).

The CBD tries to consider the problems associated with ensuring access to materials and genetic resources and promote the equitable distribution of materials and products derived from genetically modified organisms. The CBD is an important step toward the development of the international regime of biotechnology. Meanwhile, the criticism of the document is that the rules and regulations are very general and leave much unsaid. Official negotiations on the CBD began in 1991 and were completed by the Summit in Rio de Janeiro in 1992. The hasty pace has led to insufficient time for the exchange of countries' views. As a result, the text of the CBD is partly unclear, ambiguous, or even contradictory; the CBD does not consider the national and private actors in full (Schmid & Schmidt-Dannert, 2009).

Article 19 of the CBD also concerns the management of biotechnology and the distribution of its benefits. The access regime is also a part of the CBD regulation. However, it is worth considering a more detailed within analyzing the Nagoya Protocol.

3.2 Biotechnologies: Access, Import, Export, and Benefits Sharing

Another sensitive legal issue about biotechnologies is the appropriate level of transparency in the case of import and export. Countries may establish internal rules and national legislation for access to technologies, creation, development, and application of biotechnological products to assess the risks of modified products. Each country needs an effective system for identifying such products or for obtaining information from the importer or exporter. Information or declaration can be achieved through a labeling system. For example, in 1997, the EU adopted a law requiring labeling of genetically modified crops (Carroll & Charo, 2015).

Governments should set standards for determining genetic content. The Cartagena Protocol on Biosafety (Secretariat of the Convention on Biological Diversity, 2000) was adopted to promote transparency. It provides an international framework for addressing environmental risks and consequences of certain genetically modified crops. The Cartagena Protocol is intended to ensure an appropriate level of protection against harmful effects on the conservation and sustainable use of biodiversity (Abashidze et al., 2021) and consider the risks associated with these products for human health.

The Protocol allows trading in case two conditions are fulfilled. The supplied products intended for food, feed, or processing must be accompanied by documentation stating that such goods "may contain changes" and are not intended for deliberate environment introduction. The supply of products intended for "autonomous use" (e.g., in a laboratory) or for deliberate introduction into the environment (e.g., microorganisms, seeds for planting, or live fish distribution in water spaces) must be accompanied by identifying documentation. The importing country must confirm receipt and then grant or refuse to issue a permit.

The Cartagena Protocol on Biosafety (Secretariat of the Convention on Biological Diversity, 2000) is a step in ensuring transparency of the export of biotechnologies (especially regarding the emissions into the environment) and addressing the issue of cross-border biotechnology. However, this Protocol contains significant gaps.

For instance, one of the gaps is labeling projects that cause contradictions due to free trade agreements and obligations arising from the WTO agreements (Matytsin, 2021). The provisions of the Protocol and the WTO agreements should be complementary and should not imply amendments: the General Agreement on Tariffs and Trade and related agreements, such as the Agreement on the Application of Sanitary and Phytosanitary Measures (World Trade Organization (WTO), 1995) and agreements on trade barriers, etc.

It is worth highlighting the Nagoya Protocol (United Nations, 2010a), which also regulates the regime of access and distribution of benefits from the use of genetic resources. The use of genetic resources means research and development in the field of genetic composition or biochemical composition of genetic resources, including the use of biotechnology. Biotechnology refers to any technological application using biological systems and living organisms or their derivatives to create or modify products or processes for specific purposes.

Countries should cooperate in technical and scientific research and development programs.

Annex 2 to the Nagoya Protocol includes biotechnologies in the list of benefits. The provisions of the Annex relate to issues of knowledge and technology, terms of delivery and provision of information and database, as well as biological diversity and biotechnology and its use (United Nations, 2010a).

3.3 Liability and Damages

Various modified foods can cause general harm. When such damage occurs, someone should be responsible for it; it should be determined who is responsible. There is an indefinable risk of harmful effects on ecosystems; for example, when spread to other natural species, the ability to manage these risks decreases when the genes of living organisms are exported around the world.

For many years, the parties of CBD intend to continue the process of developing international rules and procedures concerning liability and compensation for damage caused by the transboundary movement of modified products (Sears & Wolt, 2012).

According to the Cartagena Protocol on biosafety (Secretariat of the Convention on Biological Diversity, 2000), the process is limited to harmful effects caused by genetically modified products. Prospects for international liability treaties in this area will not have a positive effect (as practice shows for similar treaties in other fields of international law); they will not be supported by many importers and exporters of biotechnological products (governments and private companies).

Developing such a legal regime, the international community faces difficulties unrelated to biotechnology, covering procedural issues (e.g., which courts have jurisdiction over the claims, make claims, enforcement of decisions in the courts of another country, the burden of proof, and limitations of liability). If a developing country is entitled to shared benefits when a biotech company develops a product using genetic resources located in the country, the responsibility should probably be shared.

The issue of cross-border is becoming the most urgent. For example, tuna has been genetically modified in the laboratory to have a larger size than normal tuna; once it is approved for widespread breeding in one country, there may be an adverse effect on tuna, affecting all parties involved in fishing.

There are general principles of international law that recognize the national rights of countries to exploit their natural resources and, simultaneously, instruct governments not to allow the use of land for activities that harm the environment of other countries (e.g., Article 21 of the Stockholm Declaration (United Nations, 1972)), but it is not enough until the issues of countries' responsibility for transboundary damage caused by their biotechnological applications are settled and regulated.

Some multilateral legal regimes, such as the Cartagena and Nagoya Protocols, have established specialized bodies, such as compliance or implementation committees, tasked with stimulating compliance, encouraging compliance, and reviewing cases of non-compliance. Under the Nagoya Protocol, the members of the implementation or compliance committees, although elected by the governing bodies of the treaty instruments, are technical experts acting in their personal capacity and not as representatives of the parties, which allows for independent expert consideration of technical issues (United Nations, 2010a).

4 Conclusion

With the growing awareness of various fields of the application of biotechnology, it became clear that governments and private companies are currently investing huge sums of money in this area, including at the international level. However, the risks related to the application of biotechnology and legal gaps are being gradually identified, including the following:

- IP protection: it is necessary to impose a legal regime that assumes the rights of developing countries or concentrates the most advanced biotechnologies and protects the "inventor."
- Transparency regarding the access, import, and export of biotechnological products: notification of the parties and labeling.
- Liability for damage by genetically modified goods: there is an uncertain risk of harmful effects on ecosystems, issues of procedural and substantive law, distribution of responsibility, etc.

However, certain successes in the international legal regulation of issues related to biotechnologies have been achieved thanks to numerous international forums. A number of documents in this area have been developed and signed, in particular:

- The Convention on Biological Diversity (United Nations, 1992);

- The Nagoya Protocol (United Nations, 2010a);
- The FAO Commission on Genetic Resources for Food and Agriculture;
- The UNESCO International Bioethics Committee;
- The WHO's Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing;
- The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (World Intellectual Property Organization (WIPO), 1977);
- The Cartagena Protocol on Biosafety (Secretariat of the Convention on Biological Diversity, 2000);
- The Nagoya-Kuala Lumpur Additional Protocol on Liability and Compensation (United Nations, 2010b).

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References

Abashidze, A. K., Inshakova, A. O., Solntsev, A. M., & Gugunskiy, D. A. (2021). Socio-economic inequality as a barrier on the path of sustainable development: "Institutional traps" and perspectives of overcoming them. *International Journal of Sociology and Social Policy, 41*(1–2), 62–75. https://doi.org/10.1108/IJSSP-03-2020-0069

Carroll, D., & Charo, R. A. (2015). The societal opportunities and challenges of genome editing. *Genome Biology, 16*, 242. https://doi.org/10.1186/s13059-015-0812-0

Dederer, H. G., & Herdegen, M. (2017). *Internationales Biotechnologierecht*. C.F. Müller Verlag.

Greely, H. T. (2016, January 19). Are we ready for genetically modified animals? World Economic Forum. Accessed January 15, 2022, from https://www.weforum.org/agenda/2016/01/are-we-ready-for-genetically-modified-animals/.

Matytsin, D. E. (2021). Retail investment financing via remote digital computer algorithm. *Legal Concept, 20*(2), 150–158. https://doi.org/10.15688/lc.jvolsu.2021.2.20

Schmid, R., & Schmidt-Dannert, C. (2009). *Biotechnology: An illustrated primer*. Wiley-VCH.

Sears, M., & Wolt, J. D. (2012). Ecological considerations in biotechnology: Ecological concerns and environmental risks of transgenic crops. In J. S. Popp, M. M. Jahn, M. D. Matlock, & N. P. Kemper (Eds.), *The role of biotechnology in a sustainable food supply* (pp. 142–143). Cambridge University Press. https://doi.org/10.1017/CBO9781139026710.009

Secretariat of the Convention on Biological Diversity. (2000). Cartagena protocol on biosafety to the convention on biological diversity: Text and annexes, Montreal, Canada. Accessed January 15, 2022, from https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf.

United Nations. (1972). Stockholm declaration (adopted by the United Nations conference on the human environment, June 16, 1972). Stockholm, Sweden. Accessed January 15, 2022, from https://wedocs.unep.org/bitstream/handle/20.500.11822/29567/ELGP1StockD.pdf?sequence=1&isAllowed=y.

United Nations. (1992). Convention on biological diversity (treaty series) (June 5, 1992). Rio De Janeiro, Brazil. Accessed January 15, 2022, from https://treaties.un.org/doc/Publication/CN/1996/CN.29.1996-Eng.pdf.

United Nations. (2010a). The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (adopted October 10, 2010), Nagoya, Japan. Accessed January 15, 2022, from https://treaties.un.org/doc/source/docs/UNEP_CBD_COP_DEC_X_1-E.pdf.

United Nations. (2010b). The Nagoya-Kuala Lumpur supplementary protocol on liability and redress to the Cartagena protocol on biosafety (adopted October 15, 2010), Nagoya, Japan. Accessed January 15, 2022, from https://treaties.un.org/doc/source/docs/UNEP_CBD_BS_COP_MOP_5_17-E.pdf.

World Intellectual Property Organization (WIPO). (1977). The Budapest treaty on the international recognition of the deposit of microorganisms for the purposes of patent procedure (signed April 28, 1977). Budapest, Hungary. Accessed January 15, 2022, from https://www.wipo.int/treaties/en/registration/budapest/.

World Trade Organization (WTO). (1995). *The agreement on the application of sanitary and phytosanitary measures*. Accessed January 15, 2022, from https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.