

The Nagoya Protocol and the Biotechnology Industry

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Abstract—After the Convention on Biological Diversity (CBD) introduced a new legal framework covering the sovereign rights of states over resources that are considered to be a common heritage and freely accessible, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization came into force in 2014. While the Nagoya Protocol will affect the biotechnology industry, industry awareness of the protocol is still fairly low. In this paper, we introduce the Nagoya Protocol, investigate the levels of awareness about the protocol, and analyze its expected impact on the biotechnology industry. The results show that companies in the biopharmaceutical field and the health functional food field are likely to be relatively highly impacted. Although the Nagoya Protocol may increase legal certainty and transparency, participants in companies have voiced concerns that it will negatively affect firms' innovation performance by leading to increased costs and complexity of obtaining genetic resources. This study suggests that procedures for accessing genetic resources should be clearly and transparently certified.

Index Terms—nagoya protocol, convention on biological diversity, access to genetic resources, procedures of benefit sharing, biotechnology industry

I. INTRODUCTION

Historically, genetic resources have been considered to be a common heritage of humankind that is freely accessible [1]. With rapid development of modern biotechnology over the past decades, the roles of genetic resources have gained prominence. There are significant potential benefits associated with the use of genetic resources [2]. The resources act as a crucial source of information to better understand the natural world and can be used to develop a wide range of products and services for human benefit, such as pharmaceuticals and cosmetics [2].

With the increasing instances of commercial use of genetic resources, the emphasis on intellectual property rights and private ownership of products derived from genetic resources has steadily increased. There were also growing instances of bio-piracy, and hence, a demand for an international regime emerged. This resulted in the Convention on Biological Diversity (CBD), the International Treaty on Plant Genetic Resources for Food

and Agriculture (ITPGRFA), and the Inter-Governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) of the World Intellectual Property Office (WIPO), which deals with ownership and intellectual property rights issues related to genetic resources [3].

The CBD introduced a new legal framework covering the sovereign rights of states over resources that are considered to be a common heritage and freely accessible [1]. Articles 8, 15, and 19 of the CBD address the concept of benefit sharing [3]. The Food and Agriculture Organization's ITPGRFA presents an internationally agreed framework for the conservation and sustainable use of crop diversity, and the equitable sharing of benefits, consistent with the CBD [3]. The IGC works closely with the CBD for the protection of genetic resources and associated traditional knowledge (TK) in the context of access and benefit sharing [3].

Furthermore, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, commonly known as the Nagoya Protocol, entered into force on October 12, 2014, following its ratification by 51 parties to the Convention on Biological Diversity (CBD) [4].

In this paper, we introduce the Nagoya Protocol, investigate the levels of awareness, and analyze its expected impact on the biotechnology industry.

II. THE NAGOYA PROTOCOL

The CBD, which was adopted at the Earth Summit in Rio de Janeiro in 1992, has three objectives, which are in accordance with Article 1. These are the conservation of biological diversity, the sustainable use of components, and the fair and equitable sharing of the benefits arising from the utilization of genetic resources [5]. According to Article 2, "genetic resources" refers to genetic material of actual or potential value, while "genetic material" means any material of plant, animal, microbial, or other origin that contains functional units of heredity.

The Nagoya Protocol aims to conserve biological diversity through the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including through appropriate access to genetic resources and appropriate transfer of relevant technologies, taking into account all rights over those resources and technologies (see Appendix). It also aims to do so

through appropriate funding, so as to contribute to the conservation of biological diversity and the sustainable use of components [6]. In Article 2 of the Protocol, the same conceptual terms are used as in the CBD, with the addition of the following definitions of terms [6]:

(c) “Utilization of genetic resources” means the conducting of research and development into the genetic or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the CBD.

(d) “Biotechnology” includes any technological application that uses biological systems, living organisms, or derivatives thereof to make or modify products or processes for specific uses.

(e) “Derivative” refers to a naturally-occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

These terms are important because they are key concepts related to bio-trade [7].

When a user of genetic resources wants to access genetic resources, the user has to obtain the providing party’s prior informed consent (PIC). In Article 6 of the Nagoya Protocol, it is stated that “access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party” [6].

According to Article 5.1 of the Nagoya Protocol, “benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms (MAT) [6].

The Nagoya Protocol may provide legal certainty and transparency for both providers and users of genetic resources, creating a PIC/MAT framework [4].

III. EXPECTED IMPACT OF THE PROTOCOL

While the Nagoya Protocol will affect the biotechnology industry, industry awareness of the protocol is still fairly low. We investigate the levels of awareness about the protocol, and analyze its expected impact on the biotechnology industry.

A. Data

The primary source of the data in this study data was a firm survey that we conducted from October to December of 2013. The sample that was surveyed comprised companies in the biotechnology industry that were listed with the Korea Bio Association, Korea Cosmetic Association, and Korea Health Supplement Association. In the survey, we asked about awareness of the protocol and the expected impacts of the Nagoya protocol on

firms’ performance. Missing data were addressed through list-wise deletion, leading to 106 useable responses.

B. The Levels of Awareness

In the survey, we asked the participants how much they knew about the Nagoya Protocol, to investigate their level of awareness. The results showed that about a third of the participants (29.2%) knew nothing and more than half of the respondents (55.7%) had a rough idea about it, as presented in Fig. 1.

Under the protocol, the commercial development of genetic resources can be more time consuming and expensive [8]. It might involve several steps of negotiation between the prospective user and the provider of genetic resources [8]. If the entities do not understand the protocol, they cannot make well-informed decisions about the genetic resources they need to use [8]. Organizations active in the field of biotechnology are therefore encouraged to raise awareness of the Nagoya Protocol provisions, which are related to access to genetic resources and the fair and equitable sharing of benefits arising from their utilization.

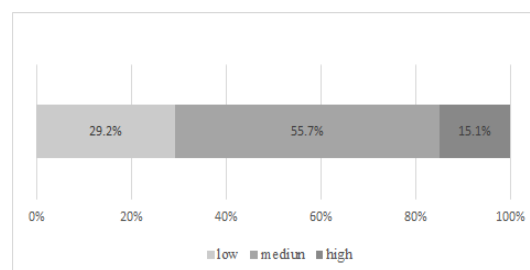


Figure 1. The levels of awareness about the Nagoya protocol.

C. Expected Impacts of the Nagoya Protocol

Genetic resources can be used to develop a wide range of products and services for human benefit [2]. In the pharmaceutical industry, chemical compounds and biochemical substances produced by living organisms often provide good leads for the development of new medicines [2]. Genetic resources can improve performance and farming efficiency in the agricultural biotechnology industry [2]. Enzymes and several biochemicals are often used in the detergent, food, feed, and other industries to improve product efficiency and quality [2].

We analyze its expected impact on the biotechnology industry by using survey data. Impacts of the Nagoya protocol are likely to differ according to the sub-field in question. The results of this study showed that companies in the biopharmaceutical field and the health functional food field are the most likely to be relatively highly impacted by the protocol, followed by biochemical and other fields, as driven by the PIC/MAT framework as presented in Fig. 2.

Study participants voiced concerns that the Nagoya protocol would negatively affect firm innovation performance by leading to higher costs for R&D and production, and increased complexity of obtaining genetic resources as presented in Fig. 3. In the absence of

clear guidance on the ownership of resources and procedures of benefit sharing, there is always scope for confusion over the use of genetic resources [3].

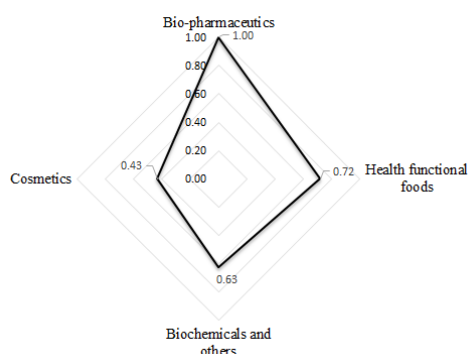


Figure 2. Relative impact of the Nagoya protocol on the biotechnology industry.

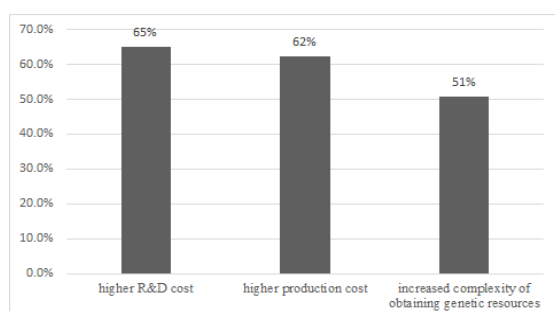


Figure 3. Expected impacts of Nagoya protocol.

IV. DISCUSSION

When the Nagoya Protocol came into force, companies using genetic resources should acquire the resources that they need in accordance with the procedures of donor countries and share the benefits arising from the utilization of such resources with donors based on mutually agreed-upon terms [9].

The Nagoya Protocol will affect the biotechnology industry, particularly companies in the biopharmaceutical and health functional food fields [10]. While the Nagoya Protocol will affect the biotechnology industry, results of our study showed that industry awareness of the protocol is still fairly low. Organizations active in the field of biotechnology are therefore encouraged to raise awareness of the Nagoya Protocol provisions [11].

Although the Protocol may increase legal certainty and transparency, participants in companies have voiced concerns. If procedures for accessing genetic resources are not clearly and transparently certified, the Nagoya Protocol will negatively affect firms' innovation performance in the biotechnology industry.

APPENDIX. RELATED ARTICLES OF THE NAGOYA PROTOCOL [6]

Article 1. Objective

The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of

genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

Article 2. Use of terms

The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Convention" means the Convention on Biological Diversity;

(c) "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;

(d) "Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

(e) "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

Article 3. Scope

This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

Article 4. Fair and equitable benefit-sharing

1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.

2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.

3. To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.

4. Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex.

5. Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

Article 5. Access to genetic resources

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.

2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:

(a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;

(b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;

(c) Provide information on how to apply for prior informed consent;

(d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;

(e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit sharing Clearing-House accordingly;

(f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and

(g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, inter alia:

(i) A dispute settlement clause;

(ii) Terms on benefit-sharing, including in relation to intellectual property rights;

(iii) Terms on subsequent third-party use, if any; and

(iv) Terms on changes of intent, where applicable.

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