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Opinion on Access and Benefit Sharing of Digital Sequence Information

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At present, one of the major issues discussed in the framework of the Convention on Biological Diversity (hereinafter, CBD) and the Nagoya Protocol to the CBD is access and benefit sharing (hereinafter, ABS) of digital sequence information (hereinafter, DSI), and discussions on policy options for ABS of DSI are currently ongoing.

In view of the status of discussions at the 15th Conference of Parties (COP15) on the Convention on Biological Diversity to be held this year, our opinions on ABS of DSI are expressed here.

[Conclusion]

● ABS of DSI should not be made mandatory.

[Reasons]

1. DSI is not considered to be subject to the Nagoya Protocol nor the CBD.

Genetic resources are defined as follows at CBD and it is clear that DSI is not subject to the Nagoya Protocol to the CBD.

- "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.
- "Genetic resources" means genetic material of actual or potential value.

According to the Nagoya Protocol, benefit sharing is to be handled based on the mutually agreed terms (MAT) between the provider and the user of the genetic resource, and is to be left to the autonomy of the parties concerned. ABS of DSI can be handled based on the MAT if both parties concerned agree. Since DSI is not a genetic resource, it is considered even more obvious that it should be left to the autonomy of the parties concerned.

2. Legal certainty of the system may be compromised.

It is essential to ensure legal certainty and predictability to achieve the objectives of the Nagoya Protocol. Transparency of the framework of the system and clarity and effectiveness of the basic procedures are required.

Expansion of the targets of the Nagoya Protocol to include DSI will make the procedure more complicated and unclear, which will compromise the certainty, predictability, and transparency of the framework of the system.

In addition, the domestic system and operations based on the Nagoya Protocol differ in each country. If the targets of the Nagoya Protocol are expanded to include DSI under such circumstances, tremendous works will be generated, legal certainty will be impaired, and

access to the information may be inhibited.

In the first place, there is no consensus on the definition of DSI and the definition of open access in relation to access. Under such circumstances, legal certainty cannot be guaranteed.

3. Negative effects on advancement of science and technology and research and development of pharmaceutical products

DSI on public databases should be freely accessible. Advancement of science and technology is based on free access to scientific information, research results, etc. Placing regulations and burdens on the use of such DSI will inhibit research and development, and will end up with crucial inhibition of advancement of science and technology.

Free access to DSI also contributes significantly to the research and development for conservation and sustainable use of biodiversity in individual countries, including developing countries, and is essential to the intent of Article 12 (Research and Training) of CBD.

In the current research and development of pharmaceutical products, not only human DSI but also non-human biological DSI are used in most cases. If complex procedural and financial burdens are placed on the use of non-human biological DSI, research and development of most pharmaceutical products will be impeded.

Even the current framework of the Nagoya Protocol on genetic resources is impairing timely sharing of samples for seasonal influenza, etc. Under such circumstances, it is obvious that placement of further regulations will interfere with timely sharing of samples and timely development of pharmaceutical products and vaccines. Such a system that may have a fatal impact on public health must not be introduced.

4. Reliability of DSI database may be compromised.

If ABS is linked to DSI, there is a concern that a large number of copies of DSI or falsified information, which are expected to yield high monetary benefits, may be created. Dissemination of scientific information which is intentionally manipulated in an illegal manner may compromise the reliability and utility of the database as well as the entire scientific infrastructure. Free and unrestricted access to DSI and the reliability of its databases are an important basis for implementation of research and development and must be strictly adhered to.

5. Cost effectiveness and feasibility of the system

If DSI is subject to benefit sharing, the system itself is not realistic. In the pharmaceutical industry, DSI may be accessed in diverse stages from the stage of research to the stage of transition from research to development stage and the stage of actual production, etc. However, the success rate of research and development of pharmaceutical products is very low, and a long period research and development and enormous costs are required. Under such basic framework of the pharmaceutical industry, the level of contribution of individual DSI to individual drugs is extremely low. Even if a system for benefit sharing for that purpose is established, the cost for construction and operation of the complex system is expected

to be higher than the benefit sharing, and it is not realistic to create such a system. The traceability of DSI, etc. required for the benefit sharing currently discussed is expected to be extremely difficult to realize, and even if it can be realized, it is expected to become a complex and expensive system. It is also expected that substantial effort and cost will be required to eliminate the above-mentioned false information and to ensure the reliability of the database.

In addition, unclear obligations based on unclear access to DSI and benefit sharing may impose tremendous burdens on the user countries for checking and monitoring, or it may be virtually impossible. We have to say that the framework including DSI in ABS becomes unfeasible in the end.

6. Policy options

Several policy options for ABS of DSI have been proposed and evaluated using criteria such as efficacy, feasibility, compliance, legal certainty, inhibition of R&D, maintenance of open access to public databases, etc. It is completely unknown at present how the significance of these criteria is determined and what consensus will be reached regarding ABS of DSI. However, as described above, it is greatly concerned that imposing an obligation on ABS of DSI may prevent access to DSI, which is the basis of research and development, may affect the reliability of the database, and may bring threat to the research and development and the advancement of science and technology.

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