

Report

An Opinion for Benefit-sharing of Synthetic Biology

Ad-Hoc Group
ABS Japan

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1. Introduction

In Japan, synthetic biology has not been well implemented yet but is looked as promising technology for biotechnology industry. Advanced molecular technologies have been applied for manufacturing processes in many Japanese biotechnology companies and are still rapidly growing. Some of these technologies are closely related to synthetic biology.

However, an issue relating to synthetic biology, which has been raised in the Convention on Biological Diversity, has affected Japanese biotechnology companies which are concerned for its development in the future.

Representatives concerning an issue relating to synthetic biology have formed an ad-hoc group and have discussed the issue by considering a future industry prospect in Japan. They consist of R&D and intellectual property management directors in pharmaceutical, cosmetic, and advanced biotechnology companies, who are very knowledgeable for synthetic biology. Also the ad-hoc group has consultation from academic researchers who are now dealing with advanced genetic biology and bioinformatics.

Here are our opinions regarding to the document of the subsidiary body on scientific, technical and technological advice (SBSTTA) issued on 2 May 2016 (UNEP/CBD/SBSTTA/REC/XX/8). We have mainly discussed and concluded our opinions on (c) the working definition and (o) the use of digital sequence information in the section of Recommendation to the Conference of Parties. Our views and opinions are follows:

2. Working definition

We believe that the working definition will serve as a basis for determining regulations only within the Convention on Biological Diversity but not for synthetic biology in biological science society. Therefore, it must consider within a view of the Convention but not from science itself.

A proposed working definition seems to be written mainly from a view of the Cartagena Protocol but not from the Nagoya Protocol. It is difficult to understand that the definition describes biotechnology and information but does not suggest any materials or products. We could not therefore accept a concept that the information is subject for benefit-sharing. We consider to make a separate definition of synthetic biology for the Cartagena and Nagoya Protocols. Or a definition should include clear clauses for benefit-sharing in the scope of materials.

We have discussed the proposed working definition:

“Synthetic biology is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems”
UNEP/CBD/SBSTTA/REC/XX/8, May 2, 2016.

Our opinions for two paragraphs of the working definition are follows.

2.1 “Biological systems”

If “biological systems” means ecological systems in nature, it should be mentioned clearly as “ecological systems”. But academic researchers and industries dealing with synthetic biology understand that “biological systems” include not only genetic systems but also metabolic systems in living organisms.

From a viewpoint of synthetic biology, genetic and metabolic systems are usually analyzed by bioinformatics technologies such as systems biology and metabolomics which are essential to construct synthetic organisms.

Design of biological systems using devices and modules with understanding of metabolic networks will be done by computer simulations. Molecular static and dynamic analyses to adapt suitable biological systems usually need vast data analysis by super-computer system and programs.

These analyses are done *in vitro* and *in silico* without any functional units of heredity and within human intellectual activities. Newly created pathways or networks do not usually exist in nature. We therefore conclude that these new technologies and analysis methods done *in vitro* or *in silico* should be excluded from the working definition.

Our proposal for “biological systems” in the working definition is:

- Following the word of “biological systems”, a phrase such as “, containing functional units of heredity” is added. Genetic materials, living organisms and biological systems must contain functional units of heredity.

2.2 “design, redesign”

We believe that the meaning of “design, redesign” is different from the “modification” when the three words line up in a sentence. Modification usually means spontaneous mutation in genetic sequences of genetic resources and creates a wide range of variety. But we understand that “design, redesign” are intentional modification and construction not only of genetic sequences but also metabolic pathways within natural occurring organisms. “redesign” means that we try to design again and again “designed” sequences or pathways to adapt them in different organisms by

using computing systems.

Synthetic biology does not directly use genetic sequence obtained from genetic resources but uses naturally occurring sequences and metabolic pathways to create a new artificial organism. For creation of a new organism, a lot of simulations and try-and-error developments using innovative minds are applied to construct an optimized sequence and metabolisms for synthetic organisms. These newly constructed sequences are not related anymore to naturally occurring sequences and metabolic pathways derived from genetic resources.

For example, an enzyme sequence which derived from animal genetic resources is designed to adapt to express in yeast. For expression of the animal gene in yeast, the sequence must be designed to be expressed efficiently in yeast and changed largely. This creates new sequence information which is neither animal nor yeast. Question is whether this newly created sequence is a derivative of the sequence of original genetic resources. We need further analysis of similarities and difference between original and newly created sequences.

The creative efforts are considered as human innovation. Outcomes should be protected by intellectual property rights. We believe that without this recognition, we would not progress and expand synthetic biology in the future.

Our proposal for “design, redesign” in the working definition is:

- Exclusion and inclusion criteria should be added on the working definition.
- In the exclusion criteria, “design, redesign” should be specified as creation and recreation of new information of sequences and metabolisms by human intellectual activity.

3. Digital sequence information and benefit-sharing

We believe that digital sequence information is not a product of nature but is created by human being. Digital sequence data dramatically accumulated in the era of the human genome project starting in the middle of 1990. In such period, digital sequence data were assumed valuable and tended to be monopolized by patenting the sequence data. But many genetic scientists discussed the monopolization issue and reached a consensus that the digital sequence data should be open to the public. After the decision, it become scientific norm that digital sequence data after decoding immediately come into public domain and everybody can access the data. Digital sequence data accumulate in petabyte scale day by day.

Digital sequence data possess no meanings by themselves and are just accumulation of simple four letters. They are just products of nature, therefore not patentable. Scientists' knowledge and experience create new technologies and analyze such meaningless data resulting in meaningful information. These technologies are called bioinformatics. And we can use bioinformatics for analysis of digital sequence data only within the computer.

Digital sequence information is only created by human intellectual activities. We consider there are two types of digital sequence information. The first digital sequence information is directly derived from digital sequence data by human intellectual activities. The second digital sequence information is created by designing and redesigning the first digital sequence information by simulation technology within computer. For example, a new artificial gene can be produced by combining parts of animal, plant and bacterial genes for creating the maximum activity and efficacy.

Our opinions for benefit-sharing of digital sequence information are as followed:

- The object of benefit-sharing does not include information under the Convention on Biological Diversity.
- Digital sequence information is different from digital sequence data. It is not a product of nature and created by human intellectual activities.
- Digital sequence information are designed and redesigned to create new advanced information which may produce materials not naturally occurring but useful for human being.
- Benefit-sharing for digital sequence information is not reasonable.

4. Ad-Hoc Group for Synthetic Biology in Japan

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