RIS
Research and Information System
for Developing Countries
www.ris.org.in/abdr.html

Asian Biotechnology and Development Review
Vol. 10 No. 3, pp 37-48

Printed in India

Bioindustry and the Convention on Biological Diversity: Japan's Experience

Seizo Sumida*

Abstract: In Japan, industry association and the government are working very closely to implement the ABS regime. This has yielded some very encouraging results which may provide guidelines for future policy options. The Japan Bio Industry Association, JBA, has been making efforts to build mutually beneficial relations with other countries as well that may provide genetic resources, by facilitating access to genetic resources and implementing fair and equitable sharing of benefits arising from the use of those resources.

Keywords: ABS, CBD, Japan.

Introduction

Since the Convention on Biological Diversity (CBD) entered into force in 1993, Japan Bioindustry Association[1] (JBA) has been steadily involved in the process of implementing CBD.

The Ministry of Economy, Trade and Industry (METI) is a competent national authorities on ABS in Japan. On behalf of METI, JBA has been implementing the access to genetic resources and benefit-sharing (ABS) provisions of the CBD, since 2002, in order to help the private sector and the scientific community to continue to build a win-win relationship with other countries. As part of this project, JBA has been participating in the meetings of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing (WG-ABS) as well as the Conference of Parties (COP) to CBD for discussion of ABS and other issues. JBA has also been making efforts to build mutually beneficial relations with countries that provide genetic resources, by facilitating access to genetic resources and promoting fair and equitable sharing of benefits arising from the use of genetic resources in an appropriate manner.

* Japan Bioindustry Association (JBA). Email: sumidasiz@jba.or.jp

Bioindustry and the Convention on Biological Diversity

Currently, the market size (domestic sales volume) of modern biotechnology products and services in Japan for 2006 was worth 1,847 billion Japanese Yen (JY) (approximately equivalent to US$ 18 billion) per year.[2] The market has shown steady growth since 1989. If products of both conventional and modern biotechnology are combined, the market size in 2005 was JY 7,692 billion (approx. US$ 77 billion). The size of the world pharmaceutical market in 2005 was US$ 601.4 billion. Japan's share was approx. US$ 66 billion (11 per cent of the world market), which is the second after the United States (44 per cent).[3]

Historically, Japan's pharmaceutical industry has strengths in microbial natural product-based drug discovery, as demonstrated by the world-wide blockbuster drugs such as pravastatin and tacrolimus. An example of more recent commercial success is micafungin. Some other compounds originating from Japanese natural products are currently being tested in the clinical phases.

There are several reasons for the Japan's strengths in microbial natural product-based drug discovery.[4] Japan has traditionally developed fermentation industries using *Aspergillus, Saccharomyces*, and other microbes. This tradition helped to nurture expertise in applied microbiology. For example, more than 100 years ago, Jokichi Takamine, a pioneer in biotechnology in both Japan and the United States, developed and patented microbial enzymes for the first time in the world. Modern fermentation processes for amino acids and nucleotides have bloomed in Japan since late 1950s. Discovery and development of natural product-based drugs require a wide diversity of researchers in different disciplines. Success depends on well-organized collaboration between these experts rather than one genius. This type of research collaboration seems compatible with Japanese culture.

However, the percentage of small-molecule drugs worldwide that include those of natural product origin are envisaged to decrease substantially in the coming decades. On one hand, modern biotechnology-based drug discovery (for large-molecule drugs such as antibody drugs) attracted considerable attention of the corporate management in Japan. On the other, CBD has negatively affected corporate management's incentives for investment in natural product-based drug discovery, because of uncertainty about the regulatory procedures of a number of developing countries that are

potential providers of genetic resources. Major Western pharmaceutical companies either withdrew or reduced their focus in natural product-based drug discovery. Japanese pharmaceutical companies have been affected by this trend, but a number of them still manage to keep the function of their natural product drug discovery on a smaller scale. Continuous efforts are needed to keep the natural product drug discovery alive. In this sense, CBD-based collaboration with developing countries, such as efforts by Nimura Genetic Solutions in Malaysia, Mercian Corp. in Indoensia and HyphaGenesis Inc. in Vietnam, will be essential. MET and JBA have been implementing ABS provisions of the CBD,in order to help the private sector and the scientific community to continue to build a win-win relationship with other countries. The evolution of CBD-ABS implementation in Japan is described later in the section on development of Japan's ABS guidelines for users.

Experiences in Research Cooperation Projects on Conservation and Sustainable Use of Tropical Biodiversity between Japan and Southeast Asian Countries

Mutual understanding and trust are the basis to develop a good human relationship. Anticipating the advent of CBD-era, METI and JBA started planning bilateral research cooperation projects with Southeast Asian countries in early 1990s. We had a long-term objective to continue to develop good relationships with other countries. ABS was not an immediate target. The objective was to get to know each other in the upcoming CBD context.

The Bilateral Research Cooperation Projects between Japan and each of Thailand, Indonesia and Malaysia started in April 1993 and continued for six years until March 1999. The projects exchanged a total of 591 Japanese and Southeast Asian scientists, installed the most-needed equipment and instruments in the local research facilities, and sponsored domestic research programs. The Japan Bioindustry Association (JBA) carried out these projects entrusted by the New Energy and Industrial Technology Development Organization (NEDO) under the guidance of Ministry of International Trade and Industry (currently called METI).[5]

The research activities were mostly conducted by the scientists from universities and public research institutes. A total of 389 Japanese scientists were dispatched to the three Southeastern countries for on-

site collaborative research, whereas a total of 202 scientists from those three countries were invited to Japan for joint research or training for technology transfer. A variety of interesting results were gained in the research projects.[6] The projects' cumulative budget was approximately 1 billion yen (approximately US$ 10 million) over 6 years on Japan's side, including costs for personnel, equipment and instruments, research and training, and traveling. The JBA secretariat, in cooperation with its counterparts, worked out mutually acceptable, transparent and practical procedures for handling biological resources, including Material Transfer Agreements for scientific research purposes. The Bilateral Research Cooperation Projects helped all the participating countries to develop mutual understanding and confidence which became the foundation for the subsequent developments, including those described in the Section on Experiences of Japan's National Institute of Technology and Evaluation (NITE) in Research Cooperation in Microbial Taxonomy with Other Countries.

As policy relevant lessons, JBA learned that biological resource centers, as repository of biological materials and related information, have become an essential part of the scientific and technological infrastructure for each country in the era of Convention on Biological Diversity, and that they should therefore be strengthened. JBA also learned that involvement of industries would be essential in future cooperation projects on biological diversity, because industries have the actual capabilities to create benefits from utilization of biological resources.

In fact, after several years of preparation, some Japanese companies established its laboratories in these countries and have since been conducting research activities in compliance with the CBD and their national laws. In retrospect, the mutual understanding and trust that had been developed through the Research Cooperation Projects in 1990s were foundations for these developments

Objectives of the Arrangements

The primary objectives of the projects were;

(1) To assist the participating countries in their own efforts to conserve and use biodiversity in a sustainable manner;

(2) To train the participating scientists and help further develop their scientific skills through collaborative research with installment of state-of-the-art equipment and instruments in their countries.

Content and Implementation of the Arrangements

Japan-Thailand Project

As the basic agreement, Memorandum of Understanding (MOU) was concluded between NEDO, Japan and The National Science and Technology Development Agency (NASTDA), Thailand. Scientists and researchers from a number of national research institutes and universities of both countries participated in the joint research activities. The subjects of the cooperation projects were as follows:

A. Taxonomic analysis, ecosystem evaluation and monitoring
   - 1.1 Feeding strategies of primates
   - 1.2 Improvement of microbial culture collection systems: Use of classification/identification methods based on DNA

B. Conservation of biodiversity through man-made ecosystems
   - 2.1 Interactions among different organisms within a man-made ecosystem
   - 2.2 Genetic diversity analysis of artificial ecosystems
   - 2.3 Socio-economic and ethnological analysis of an artificial ecosystem

C. Use of bioresources
   - 3.1 Use of bioresources: Screening of new bioactive substances found in plants and their applications
   - 3.2 Study of traditional use of plant resources

Japan-Indonesia Project

The MOU was concluded between NEDO, Japan and The Agency for the Assessment and Application of Technology (BPPT), Indonesia. Scientists and researchers from a number of national research institutes and universities of both countries participated in the joint research activities. The subjects of the joint research were:

A. Taxonomic analysis, ecosystem evaluation and monitoring
   - 1.1 Microbial culture collection systems
   - 1.2 Plant conservation techniques:
     - (1) Conservation of plant diversity
     - (2) Tissue and cell cultures of tropical plant species
     - (3) Development of DNA techniques for the evaluation of biological diversity

B. Utilization of tropical bioresources
   - 2.1 Utilization of microbial resources

2.2 Utilization of plant resources
2.3 Elucidation of symbiosis between plant and microorganism and its utilization

C. Promoting the establishment of "Tropical Bioresources Industrial Development Center" in Indonesia

Japan-Malaysia Project

The MOU was concluded between NEDO, Japan and The Standards and Industrial Research Institute of Malaysia (SIRIM). Implementation of the cooperation project on Malaysian side was conducted by National Biotechnology Directorate (NBD), The Ministry of Science, Technology and the Environment (MOSTE) Malaysia. Scientists and researchers from a number of national research institutes and universities of both countries participated in the joint research activities. The subjects of the research cooperation were:

A. Ecosystems and monitoring
   1.1 Biodiversity databases and gene banks
   1.2 Evaluation and monitoring of marine ecosystems
   1.3 Ecosystem evaluation and inventory development based on advanced technologies

B. Utilization of tropical bioresources
   2.1 Screening and separation of bioactive compounds produced by microorganisms and plants
   2.2 Evaluation of therapeutic and toxic potentials of natural products

Experiences of Japan's National Institute of Technology and Evaluation (NITE) in Research Cooperation in Microbial Taxonomy with Other Countries

Microbial resource centers are fundamental to preserving and harnessing microbial biodiversity and genetic resources. The availability of precisely identified and validated microbial resources is essential for scientific research and industrial and other applications. In many cases, microbial resource centers are centers of excellence for preserving microbial biodiversity and training microbial taxonomists. In recent decades, academia in Japan has experienced a conspicuous decline in number of taxonomic experts trained to discover, identify, describe and classify microbial biodiversity. For example, when professors in microbial taxonomy retire, the universities often suppress the posts, and recruit

researchers with disciplines more 'glamorous' than taxonomy. This trend has led to drastic reduction in graduate training in microbial biodiversity research. Becoming increasingly concerned about the situation, Japan's academia and industry together made a recommendation to the government that a national microbial resource center be established the function of which is to be adapted to the principles of the Convention on Biological Diversity (CBD) and the genomic era. In response to this recommendation, the Japan's government, in 2002, created a microbial resource center within the National Institute of Technology and Evaluation (hereafter referred to as NITE-BRC).

Organization of NITE-BRC

Within NITE-BRC, the functions of the microbial culture collection and genomic research are integrated to promote synergy and to add value to the microbial resources and associated data. The functional organization of NITE-BRC is as follows:

- Preservation and distribution of microbial resources as references
  NITE-BRC collects, identifies, preserves and distributes potentially useful microorganisms and cloned genes to users to promote basic research as well as industrial and other applications. These strains serve as references for diversified purposes. As a separate entity, NITE-BRC also has a patent microorganism depositary in accordance with the Budapest Treaty.
- Microbial genome analysis
  The function of microbial genome analysis group is integrated within NITE-BRC. Once genome analysis of a microorganism is completed, the results are released for public use in the "Database of the Genomes Analyzed at NITE" (DOGAN).[7]

Concept of International Collaboration and "Tsukuba Statement"

The concept of international collaboration that has been leading NITE-BRC is consistent with the 'Tsukuba Statement' issued by the Global Taxonomy Initiative (GTI) Programme of Work in Microbiology that took place in Tsukuba, Japan in October, 2003[8] (see the box below). The GTI is a cross cutting issue of the CBD. In the Tsukuba meeting, delegates from Asian and Oceania countries participated.

Key points are excerpted from the Tsukuba Statement as follows:

1) Strategic inventory of microbial diversity should be developed in each country.

2) Taxonomists themselves should recognize the importance of their role for solving biodiversity problems. National governments should establish laboratories and institutes for applied microbial taxonomy.
3) Developed countries are requested to draw up and implement a plan for the advancement of microbiology in collaboration with developing countries.
4) Providers and users of microbial resources must respect and follow the CBD and the Bonn Guidelines. National governments should

Tsukuba Statement
Tsukuba, Ibaraki, Japan, 9 October 2003
Global Taxonomy Initiative (GTI) and Microbial Taxonomy[9]

1. For the purpose of accumulating knowledge on and the full understanding of microbial diversity, predicting its change, and assessing the impact of any change, and for the purpose of developing the technology and measures for sustainable use and the fair and equitable sharing of benefit, a strategic inventory of microbial diversity should be implemented in each country.
2. Taxonomists themselves should recognize the importance of their role for solving biodiversity problems. In order to sustain and advance microbial taxonomy and to prevent the loss of and increase the number of microbial taxonomists, national governments should establish laboratories and institutes for applied microbial taxonomy. Microbial taxonomists must exert all their powers to advance microbiology.
3. Recognizing the importance of microbial taxonomy for the strategic inventory of microbial diversity, developed countries are requested to draw up a plan for the advancement of microbiology in collaboration with developing countries and the plan should be implemented.
4. Providers and users of microbial resources must respect and follow the CBD and the Bonn Guideline. National governments should pay attention so that the CBD does not hinder strategic inventory of microbial diversity. Providers must accelerate acquisition of strains and specimens used for taxonomy. In particular, national governments should not excessively restrict the academic use of biological resources, especially type strains of bacteria and reference strains of fungi and algae. As much as possible of the information associated with these strains should be made available to the public.
5. In addition to the strains referred to above, the data from the inventory work in each country should be managed within database systems which support global networking, and which are effective for supporting the clearing house mechanism of transfer of microbes and guarantees continuity between generations.

pay attention so that the CBD does not hinder development of strategic inventorying of microbial diversity.

5) The data from the inventory work in each country should be managed within database systems which support global networking.

As stated at the beginning of this section, the availability of precisely identified and validated microbial resources is essential for scientific research and industrial and other applications. On a long term basis, microbial taxonomy is an essential tool to implement the three objectives of CBD, including ABS.

Experiences of NITE-BRC in Collaborative Research with Other Countries

NITE-BRC signed memorandums with governmental organizations in Asian countries; with Indonesia, Mongolia and Vietnam for collaborative research for the conservation and sustainable use of microbial resources, and with China and Thailand for collaboration between culture collections. The framework and content of the joint projects vary, on a case by case basis. The following is an example of collaborative research:

— Sharing of research results
— Installation of equipments for capacity building
— Collaboration in sampling, isolation and taxonomical characterization
— On-site workshops for technology transfer
— Hosting of researchers at NITE-BRC facilities for joint research and/or technology transfer

Note that, since this is a collaboration project between government institutes, the form of benefit sharing is non-monetary.

The Asian Consortium for the Conservation and Sustainable Use of Microbial Resources (ACM)

NITE contributed to the establishment of the Asian Consortium for the Conservation and Sustainable Use of Microbial Resources (ACM) with 12 Asian countries. The ACM is aimed mainly at the following activities:

— Human resource development and capacity building to manage culture collections of microbial resources for ex-situ conservation in each member country
— Establishment of the network of biological resource centers and

the database of culture collections of microbial resources with a common interface

— Development of the material transfer system to facilitate international collaborative research among the member countries in compliance with the CBD

These activities in the region have been useful for the streamlined and effective implementation of access to microbial genetic resources, benefit-sharing and capacity-building on the basis of mutual understanding and goodwill, consistent with the principles of CBD and the Bonn Guidelines.

Development of 'Japan's ABS Guidelines for Users'[10]

Soon after the adoption of the Bonn Guidelines in February 2002, JBA translated them into Japanese. Using the Japanese translation, JBA disseminated the Bonn Guidelines by organizing more than 8 public seminars in major cities across the country during 2003 and 2004. This helped to enhance the awareness of genetic resources users, i.e. companies and researchers, about the Bonn Guidelines.

As the Bonn Guidelines became better understood in Japan, a number of users expressed their views that descriptions of the Bonn Guidelines were often too general to be helpful for them to cope with their practical needs. They emphasized a need for user-specific and user-friendly guidelines. Taking these experiences into consideration, METI decided to develop user-specific guidelines on the basis of the Bonn Guidelines and the CBD. In consultation with experts from industry and academia, METI started working on such guidelines in cooperation with JBA in 2004. The Guidelines on Access to Genetic Resources for Users in Japan ("Japan's ABS Guidelines for Users" for short) were completed and published in Japan in March 2005.

The Japan's ABS Guidelines for Users aim to help both providers and users of genetic resources to build win-win relationships, and to minimize the risk of getting involved in problems, while ensuring business flexibility. To promote their dissemination, JBA held since 2005 more than 12 public seminars in 6 major cities across the country. Its English translation was completed in February 2006.

Governmental Support for Users of Genetic Resources

On the basis of the Japan ABS Guidelines for Users, METI and JBA have developed a number of tools to support users of genetic resources.

- Bilateral workshops and meetings with CBD officials of providing countries:
  In order to promote development of partnership between users of genetic resources and providing countries, JBA, supported by METI, invited CBD officials (or experts) to Japan for information exchange at public workshops or meetings. They were requested to present information to the audience on their national policy, laws and regulatory systems relevant to ABS implementation. In some cases, JBA went to providing countries for information exchange. So far, JBA and METI have held such bilateral workshops or meetings with the following countries; Australia, Brazil, Bhutan, China, India, Indonesia, Malaysia, Mongolia, Myanmar, Nepal, New Zealand, Singapore, Thailand and Vietnam.
- JBA's specialized website for ABS-related information on providing countries:
  JBA created a Japanese-language website specialized for disseminating information on ABS-related policy, laws and regulation of different countries, for users of genetic resources.
- JBA's Help Desk:
  JBA has been involved in the CBD matters since 1993. Based on this experience, JBA gives, to users of genetic resources, advice on ABS matters to those who have questions or problems, free of charge and on a confidential basis. Since 2005, JBA has handled more than 90 cases of such consultation, as of April 2008.

Concluding Remarks

Our approach is based on mutual understanding and trust. We choose partners when both sides feel confortable with each other from that perspective. So far, we feel that this approach has been working. The following statement is my personal view.

Social and economic situation is different in different countries. Therefore, domestic needs are different, national policy is different, and, in turn, laws and regulatory systems are different. However, even under these circumstances, different peoples can successfully collaborate if they identify a point of mutual interest. Key to success is mutual understanding. Steps for win-win partnership development would be as follows:

1) Understand each other's national situation.
2) Set a mutually agreed target, and jointly develop practical and

effective procedure for collaboration based on the national laws of the providing country, or the principles of CBD and the Bonn Guidelines if there is no such law.

3) Help each other to overcome risks, achieve the target and generate benefits.

4) Share the benefits in a fair and equitable manner based on the agreement made in 2.

Endnotes

1 JBA is a non-profit organization dedicated to the promotion of bioscience, biotechnology and bioindustry. JBA was established in 1942 through the support of industry, academia and government. Today, JBA functions as a think tank and a platform for cooperation among scientists, technologists, corporate managers and policymakers.

2 Nenkan (2007).

3 Sumida. and Okuda (2008).

4 ibid

5 The Tokyo International Forum on Conservation and Sustainable Use of Tropical Bio-resources, Results of the Bilateral Research Cooperation Projects Between Japan and Each of Thailand, Indonesia and Malaysia from 1993 to 1999, NEDO and JBA, November 9-10, 1998, Tokyo, Japan

6 ibid

7 Dogan (http://www.bio.nite.go.jp/dogan/Top)

8 WFCC Newsletter, No. 38, Global Taxonomy Initiative (GTI) and Taxonomy, January 2004, p.50 (http://www.wfcc.info/NEWSLETTER/newsletter38/index.html)

9 ibid

10 Sumida (2008).

References

Nikkei BP (2007). *NikkeiBio Nenkan (Year Book)*, Tokyo: Nikkei BP (in Japanese)

Sumida, S. and T. Okuda (2008). 'Current Status and Trends of Japan's bioindustry' *Microbiology Australia*, 29 (1) 11-14, March.

Sumida, S. (2008). 'The Experience from Japan'. *Business* 2010, 3(1): 10-11, January.