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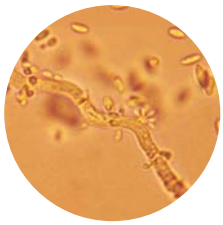
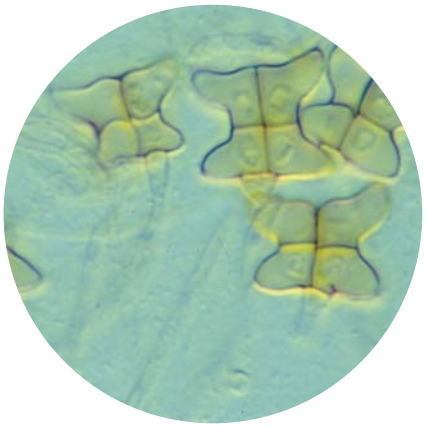
UNU-IAS/JBA Collaborative Work on ABS Case Studies





United Nations University
Institute of Advanced Studies (UNU-IAS)
And
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ABS Case Studies

Note

The views presented in this document are those of the authors and does not represent or reflect those of the institutions they belong to.

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Preface

United Nations University Institute of Advanced Studies (IAS) and Japan Bioindustry Association (JBA) have collaborated for the past several years to provide a platform to discuss and advance ideas on emerging issues of global importance, in the context of access to genetic resources and benefit sharing (ABS) under the Convention on Biological Diversity (CBD). This was primarily done through symposia and roundtable discussions involving various stakeholders such as governments, industry and NGOs.

In view of the forthcoming negotiations on international regime at the Conference of Parties (COP) in Bonn and subsequent meetings of the ABS Working Group, IAS and JBA have carried out collaborative work on case studies of experiences in Asia in the implementation of ABS measures. The case studies highlight different kinds of arrangements between countries in Asia that provide genetic resources and Japan. It also focuses on ABS implementation in Japan and challenges faced by bio-industry through the example of current global trends in natural product-based drug discovery (NPDD). Through the case studies, this document seeks to facilitate informed discussions within the CBD-ABS process. It is hoped that this document will help clarify some issues on challenges faced by ABS issues and how countries like Japan are dealing with these challenges – mostly using a bilateral approach.

1. Introduction: Access to Genetic Resources, Benefit Sharing and its Links to Traditional Knowledge and IPRs

The Convention on Biological Diversity

With the coming into force of CBD in December 1993, countries that are Parties to CBD recognized the sovereign rights of states over their genetic resources. CBD provides an opportunity for countries to address equity not only in accessing the genetic resources, but also in sharing the benefits arising out of their utilization. Of the three founding principles of CBD, i.e., conservation, sustainable use, and equitable sharing of benefits, the issue of access and benefit sharing has been the most challenging to develop and implement.

Outcomes from the World Summit on Sustainable Development (WSSD) in Johannesburg in 2002

Paragraph 42(o) of the Plan of Implementation of the WSSD recognised the need for countries to *"[...] negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources* ". Furthermore, paragraph 42 (j) of the Plan of Implementation calls for, subject to national legislation, the recognition of "*the rights of local and indigenous communities who are holders of traditional knowledge, innovations and practices, and, with the approval and involvement of the holders of such knowledge, innovations and practices, develop and implement benefit sharing mechanisms on mutually agreed terms for the use of such knowledge, innovations and practices*". Thus, countries now have a mandate to *negotiate* an international regime, bearing in mind the Bonn Guidelines that were adopted by the Parties to CBD in 2002.

These developments required countries to have a more clear understanding of the implications of such emerging processes, identify needed capacities, assess national and regional scenarios in deciding over ABS issues.

Evolution of debates

Access to Genetic Resources, Traditional Knowledge and Intellectual Property Rights (IPRs)

Article 15 of CBD calls for the Parties to establish systems and procedures for access to genetic resources and fair and equitable sharing of the benefits, arising out of the utilization of genetic resources. This provision gave rise to varied levels of understanding and interpretations of how access is to be provided and what is equitable sharing of benefits.

Historically, two distinct periods can be considered- a pre-CBD period, when genetic resource were largely considered to be part of the common heritage of mankind and deemed to belong to everyone and no one at the same time. This principle – recognised in an international instrument as part of the 1983 FAO *International Undertaking on Plant Genetic Resources* – helps explain the free, unregulated flows of genetic resources from continent to continent. Until 1992, the flow of and trade

in biological materials worldwide was generally governed by international trade rules and practices (including trade treaties); phytosanitary measures in some cases; CITES regulations and, at the national level, by scientific research, collection and export (import) permits.

Since the entry into force of CBD in 1993 that recognises the sovereign rights over genetic resources, countries began focussing on ways of securing the resources using the ABS principles as defined through Article 15. Implementation of Article 15 has to date mostly resulted in the restriction of access than the facilitation of access, causing concerns among scientists, business and others on issues of collaboration, research and commercialization. The period of early to late 1990's also saw the emergence of increased privatisation of knowledge and resources using intellectual property regimes, supported by the Trade Related Intellectual Property Rights (TRIPS) and the implementation of principles of World Trade Rules through the WTO process. Countries began discussing the need for access to genetic resources for sustainable development, and a contentious scheme emerged on pitting biodiversity-rich developing nations against technology-rich developed countries in taking forward the CBD principles.

Benefit sharing

The past two decades have seen rapid developments in biotechnology and other related fields. They have, at the same time, contributed to continued debates over the control of genetic resources and use of IPRs over biological and genetic materials and their derived products. A main challenge in implementing the ABS principles under CBD is to determine how the benefits, in terms of sharing research results, capacity building, monetary income, IPRs, etc., are to be effectively shared among users and providers of these resources.

Traditional knowledge

Discussions on ABS issues are often associated with knowledge of indigenous people and local communities. Such knowledge is generally called traditional knowledge (TK: "knowledge, innovations and practices" as Article 8(j) of CBD refers to it). However, these discussions have further implications in the context of IPR with the limitations of available tools to handle TK. The possibilities of effectively handling TK dominate certain political and legal agendas. The question of how TK should be handled is still far from being answered. Possible solutions range from an international regime on *sui generis* system on TK, including non- IPR based options, to adapting existing IPR tools, and a broad range of creative in-between options.

The Bonn Guidelines

The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (adopted by COP Decision VI/24) are a set of voluntary, non-binding guidelines targeted at assisting countries in the implementation of CBD provisions, particularly Articles 8(j), 10(c), 15, 16 and 19. The Guidelines are to serve as an input to national and international ABS policy, administrative or legislative processes.

The Bonn Guidelines cover most, if not all of the relevant ABS issues. They offer different alternatives which may be taken into account in national legislation. It is noteworthy that a substantial part of the Guidelines is based on existing ABS policy and legal instruments.

An International Regime on ABS

Discussions responding to the WSSD call for an international regime have to date taken place within the CBD, in particular, the Ad Hoc Working Group on Access and Benefit Sharing. So far these discussions have shown how complex the issue is and how varied the positions of different countries are. It is hoped that constructive discussions will lead to a consensus on a workable international regime that is balanced, effective and internally consistent within the framework of CBD. Achieving such an outcome will depend significantly on identifying best practices on ABS implementation across the world. In the following sections, we highlight some experiences of the Japanese Government and industry on the implementation and realization of ABS measures.

2. Japan's Measures to implement the CBD and the Bonn Guidelines

Japan has been actively participating in discussions on ABS at the meetings of COP of the CBD and ABS working group meetings. Japan has also been making efforts to build mutually beneficial relations with countries that provide genetic resources, by following carefully the national obligations under provider countries on access to genetic resources and implementing fair and equitable sharing of benefits arising from the use of genetic resources in an appropriate manner.

The Ministry of Economy, Trade and Industry (METI) is a competent national authority on ABS in Japan, and has been implementing CBD. On behalf of METI, Japan Bioindustry Association (JBA) has been implementing the Bonn Guidelines in order to help the private sector and the scientific community to continue to build a win-win relationship with other countries in compliance with the CBD principles.[1]

Dissemination of the Bonn Guidelines in Japan

Soon after the adoption of the Bonn Guidelines in February 2002, JBA translated them into Japanese. JBA disseminated the Bonn Guidelines (translated version) 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 (e.g. 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 users of genetic resources to cope with their practical needs. They emphasized a need for user-specific and user-friendly guidelines. Taking these requests and experiences into consideration, METI decided to develop user-specific guidelines on the basis of the Bonn Guidelines to be used as Japan's METI-

[1] SUMIDA S. 2008. The experience from Japan. *Business.2010*, vol. 3(1): 10-11

JBA ABS guidelines. In consultation with experts from industry and academia, METI started working on such guidelines in cooperation with JBA in 2004. In April 2005, "the Guidelines on Access to Genetic Resources for Users in Japan" (abbreviated as Japan's ABS Guidelines for Users) were completed and published.

Development of 'Japan's ABS Guidelines for Users'

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.[2]

Chronology of the implementation leading to the Japan's ABS Guidelines for Users is given below.

2002	The Bonn Guidelines were adopted at COP6 in February. In September, Japanese translation of the Bonn Guidelines was completed.
2003 – 2004	The Bonn Guidelines were disseminated at a series of public seminars and international symposia in major cities across Japan. In parallel with those promotional activities of the Bonn Guidelines, Japan started developing user-specific guidelines.
2005	"The Guidelines on Access to Genetic Resources for Users in Japan" were completed in March, and published on April 1. Six public seminars were organized in major cities across Japan to disseminate the Japan's Guidelines.
2006	In February, the English translation of the Japan's Guidelines was completed for distribution. Four public seminars were organized in major cities across Japan to disseminate the Japan's Guidelines.
2007- 2008	Public seminars were organized in Japan, including the one in cooperation with the Japan Society for Bioscience, Biotechnology and Agro-chemistry, and the one with the Japan Institute of Intellectual Property, to disseminate the Japan's Guidelines. More are scheduled to take place .

Support for users of genetic resources

On the basis of the Japan's 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 and METI invited CBD officials (or experts) from provider countries to Japan for information exchange at public workshops or meetings. They presented information to the

[2] www.mabs.jp

audience on their national policy, laws and regulatory systems relevant to ABS implementation. In some cases, experts from JBA traveled to provider countries for information exchange and learn about their national rules and procedures on ABS. 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 in Japan.[3]

- *JBA's 'Help Desk'*:

JBA has been involved in the CBD matters since 1993. Based on this experience, JBA gives advice on ABS matters to those potential users in Japan who have questions or problems, free of charge and on a confidential basis. Since 2005, JBA has conducted more than 90 cases of such individual consultation.

Group Training Courses in Bioindustries for Capacity Building

Japan International Cooperation Agency (JICA), supported by JBA, has been implementing "Group Training Courses in Bioindustries" for officials and researchers from developing countries. Annually about ten trainees are invited to Japan for the two months course. The training course includes lectures and field trips including hands-on experiences in a microbial taxonomy laboratory. As an example, the program for 2007 is outlined below.

The topics covered during the training include:

- Conservation and sustainable use of biological resources:

Japan's national policy on bioindustry, current status and future prospect of bioindustry, CBD, risk assessment of biotechnology products, patents related to biotechnology, public understanding

- Evaluation of biological resources:

Applied microbiology, plant engineering, bio-active substances from biological origin, recombinant DNA technology, bioreactors, biotechnology-supporting technologies

- Application of biological resources to industries:

Fermentation industry, biopharmaceuticals and diagnostics, new applications and potentialities of industrial enzymes, biotechnology for food industries, marine biotechnology, protein engineering, bioinformatics

Field trips included visits to the following institutions:

- Universities:

Hokkaido University, Kitasato University, Kyoto University, Nagahama Institute of Bio-science and Technology, Nagoya University, Nara Institute of Science and Technology, Tsukuba University, University of Tokyo

[3] www.mabs.jp

- Public research institutes:

Japan Biological Information Research Center, National Food Research Institute, National Institute of Advanced Industrial Science and Technology, National Institute of Agrobiological Resources, National Institute of Technology and Evaluation, RIKEN Yokohama Institute

- Private companies:

Ajinomoto Co.,Inc., Amano Enzyme Inc., Astellas Pharma Inc., Kyowa Hakko Kogyo Co., Ltd., Meiji Seika Kaisha, Ltd., Mitsukan Group Corp., Shimadzu Corp., Suntory Research Center, Toyota Motor Corp., Yotsuba Milk Products Co., Ltd.

To contribute to the development of human resources in bioindustries and to the promotion of mutual understanding and friendship, since 1989 a total of 180 officials and researchers have been invited to take the course in Japan from 30 countries as follows:

(Asia) Bangladesh, China, Indonesia, Kazakhstan, Laos, Malaysia, Nepal, Pakistan, Philippines, Thailand, Sri Lanka, Syria, Turkey, Vietnam,

(Central and South America) Argentina, Brazil, Chile, Colombia, Costa Rica, Cuba, Mexico, Nicaragua, Peru, Uruguay,

(Africa) Egypt, Senegal, Tunisia, and

(Countries in Economic Transition) Bulgaria, Estonia, Hungary.

3. Global Trends of Natural Product-based Discovery in the Pharmaceutical Industry

Since 1990s, a number of major multi-national pharmaceutical companies have abandoned or drastically reduced their activities world-wide in natural product-based drug discovery (NPDD). In Japan for example, Pfizer in Nagoya, Bristol Myers Squibb in Tokyo, and Hoffmann-La Roche in Kamakura closed their respective NPDD facilities in 1990s for one reason or another. Some of Japan's pharmaceutical companies also withdrew from NPDD during the same period, but others have sustained their NPDD capabilities on a reduced scale. Major reasons given for these closures are that there have been fewer commercial successes in NPDD in recent decades, and that new technologies other than NPDD have continued to emerge for curing diseases. For example, antibody drug technologies have attracted the interest of some Japanese pharmaceutical companies for investment. Furthermore, slow progress in national implementations worldwide of the ABS provisions under the CBD has negatively affected the management's incentives for investment in NPDD, because of uncertainty about the regulatory procedures of a number of developing countries that are potential providers of genetic resources.

The size of the world pharmaceutical market in 2005 was approx. US$ 600 billion. Japan's share was 11% of the world market, which was the second after the United States (44%). Traditionally, Japan has strengths in microbial product-based drug discovery, as typically

demonstrated by a case of pravastatin, a blockbuster drug to cure hyperlipidemia.[4, 5, 6] (see Box 1) There is a background for it. Japan has a long tradition of fermentation industries (e.g. production of sake, soy sauce, soybean paste, etc) using *Aspergillus, Saccharomyces* and other microbes. This helped to nurture applied microbiology in modern centuries. For example, 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, more than 100 years ago. Modern fermentation processes for amino acids and nucleotides have bloomed in Japan since late 1950s. During the period when research and development in antibiotics prevailed, Hamao Umezawa and his group were world leaders. 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 the Japanese culture.

Box 1

Case study on the discovery and development of pravastatin

In 1971, researchers of Sankyo (currently, Daiichi-Sankyo, a leading pharmaceutical company in Japan) started a screening program in search of a drug to cure hyperlipidemia (excess of lipids in the blood) by specifically inhibiting mevalonic acid biosynthesis. They devised a cell-free system from rat liver tissues with HMG-CoA reductase (a rate-limiting enzyme in cholesterol biosynthesis) as the target enzyme. After screening extracts from a numerous number of microbes by using the cell-free system, they found an inhibitor of HMG-CoA reductase from the extract of *Penicillium citrinum* that was isolated from rice produced in Kyoto, Japan in 1967. This (coded as ML-236B) was a specific inhibitor of HMG-CoA reductase that was discovered for the first time in the world. The discovery made a historic contribution to the basic research in anti-hyperlipidemia, even though ML-236B did not proceed to a commercialization stage, as described below.

Sankyo researchers looked for compounds better than ML-236B from the standpoints of tissue selectivity and the inhibitory potency. Luckily, they obtained a hydroxylated metabolite of ML-236B in a minute amount from urinary excretions of a dog administered with ML-236B. This compound had properties that they were looking for. This hydroxylated ML-236B was named as 'pravastatin'. However, because of its structural complexity, it was not practicable to synthesize pravastatin by organic chemistry. The researchers thus faced another difficulty in preparing a sufficient amount of sample to take the research forward for more detailed pharmacological and toxicological studies.

The researchers decided to try microbial transformation for hydroxylation of ML-236B into pravastatin. After extensive screening, they found that a fungus *Mucor hiemalis* had an activity to enable the preparation of a sufficient amount of pravastatin samples to continue further studies. With the samples prepared, the research proceeded with promising results. However, when it advanced to a stage of manufacturing process development, they found that *Mucor hiemalis* could not give

[4] Guidebook for Access to Genetic Resources, June 1999, p. 40, Japan Bioindustry Association, Tokyo, Japan (in Japanese)

[5] ENDO A. et al. 1976. ML-236A, ML-236B, and ML-236C, new inhibitors of cholesterogenesis produced by *Penicillium citrinum*. *J. Antibiotics* vol. 29: 1346-1348.

[6] OKAZAKI T. et al. 1989. *Annual Report Sankyo Res. Lab.* vol. 41: 123-133.

yields satisfactory for an industrial-scale production. The researchers decided to conduct an extensive 'targeted' search for better microbes, and they finally isolated a new species from an Australian desert, named *Streptomyces carbophilus,* that was suitable for the industrial-scale hydroxylation step.

In 1981, a preclinical trial started, followed by a series of clinical trials which were completed in 1987. In March 1989, pravastatin was approved by the Japanese health authorities as a new drug, and Sankyo launched it commercially with the trade name of 'mevalotin'. Pravastatin has since been used in more than 70 countries by over 4 million patients (as of 1999) to cure hyperlipidemia. It took Sankyo 18 years and a half from the initiation of the screening program in 1971 to the commercial launch in 1989, and consumed ingenuities and careers of a numerous researchers to reach that goal.

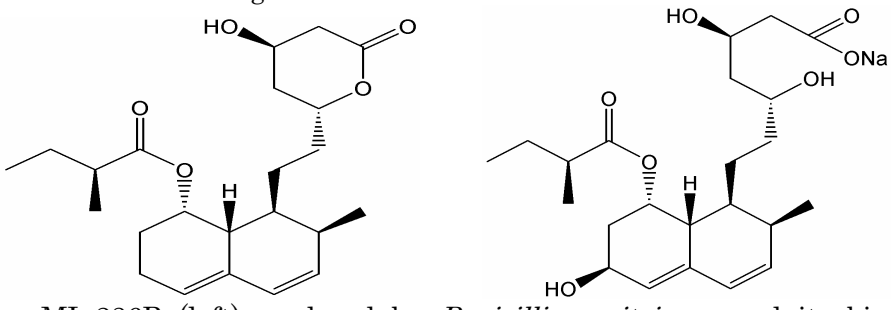

Fig. 1. ML-236B (left) produced by *Penicillium citrinum* and its bioconversion product by *Streptomyces carbophilus*, pravastatin (right)

Challenges to NPDD researchers

As the case study on pravastatin indicates, natural products have a potential to play an important role in drug discovery on a long-term basis. It can provide unique pharmaceutical leads. However, the corporate climate world-wide has not been favorable for NPDD researchers in recent years. When a pharmaceutical company terminated its NPDD activities, the researchers of the NPDD group either got reassigned to completely different jobs within the company, or they had to leave the company to join or create other organizations (often small biotech companies) where they could continue to use their expertise. In the former case, the NPDD expertise and know-how that had accumulated in the company may have been permanently lost. In the latter case, the NPDD researchers could survive for the time being, but their future may be uncertain because small biotech companies are often financially unstable. This situation means that natural product researchers are 'endangered species'. Since the potential of NPDD can be sustained by a sufficient number of competent NPDD researchers, this situation also means that NPDD is an endangered field. This, in turn, means that the value of biological diversity for drug discovery may be endangered.

What is of great concern on a long term basis is that microbial taxonomy is not being actively taken up by both universities and students in recent decades. NPDD has been supported by these taxonomists who isolate, select and identify a large number of microbial strains from nature. It is these isolates that are to be subjected to screening assays. Nothing promising can reasonably be expected from samples selected by untrained persons.

Scientific, technical, corporate and perhaps governmental approaches should continue to be attempted to improve and re-invigorate NPDD. But, as far as the matter in the CBD context is concerned, the stakeholders cannot afford to be adversarial to one another in handling ABS issues.

Rather, it is to the benefit of all the stakeholders to promote NPDD, because NPDD can create benefits for them by utilizing the value of biological diversity, and because, through this process, it can contribute significantly to the improvement of human health. It is wiser for both providers and users of genetic resources to cooperate in promoting and facilitating NPDD research for mutual benefits.

4. Case Study 1: Nimura Genetic Solutions: Collaborative Experience of a Japanese Company in Malaysia

The case study highlights the experiences that Nimura Genetic Solutions (NGS)[7], a private company from Japan, has had with the Forest Research Institute Malaysia (FRIM) [8] and Sarawak Biodiversity Centre (SBC) in Malaysia.

Malaysia's national policy on biodiversity

Malaysia is recognized as one of 12 mega-biodiversity countries, holding approximately 10 % of living species of the world, e.g., with 15,500 species of higher plants, 300 species of mammals and 189 species of amphibians. Malaysia launched the national policy on biological diversity in 1998. The policy provides direction for the country to implement strategies, action plan and programs on biological diversity for conservation and sustainable utilization of its biological resources. To provide a legal framework to the policy, three measures are either in place or a draft status, i.e. the Biosafety Act (in place), Access to Genetic Resources Act (draft) and the National Biodiversity Council Act (draft).

The Malaysian Government is actively promoting biotechnology industry in the areas of food and agro-biotechnology, bio-pharmaceuticals, nutraceuticals, bio-diagnostics, industrial enzymes, and bioactive compounds for healthcare. Malaysia still needs more expertise to exploit these resources for wealth creation. Smart partnership with companies from developed countries is a way to overcome these shortcomings. Malaysia welcomes collaboration with foreign institutions in order to build the foundation for sustainable biotechnology industries in the country.

The business activities of NGS in Malaysia

NGS was established in 2000 with its head office in Japan and its major research institute in Malaysia, with the objective of exploring bio-resources in tropical rainforests for new bio-active compounds, in compliance with the CBD. The above-mentioned policy of Malaysian government was one of the key reasons for NGS to start its activities in Malaysia. Research collaboration was negotiated between FRIM and NGS. In 2002, NGS was granted the research and development right

[7] http://www.ngs-lab.com

[8] Krishnapillay B, M.A.A. Razak and S. Nimura 2004. JBA/UNU-IAS Symposium on "Access and benefit-sharing of genetic resources – experiences, lessons learned and future vision" , Proceedings –Update, Japan Bioindustry Association and United Nations University Institute of Advanced Studies

for commercial use of Malaysia's bio-resources from the Government of Malaysia through FRIM. One of the NGS research facilities in Malaysia was established inside the FRIM campus in Kuala Lumpur. The collaboration includes the utilization of microorganisms as well as plants as resources for finding bio-active substances with medical and/or environmental potentials.

In 2004, NGS was granted the right to conduct similar activities by Sarawak Biodiversity Centre in the State of Sarawak in Northern Borneo. Furthermore in 2005, NGS was granted full access rights to all species inhabiting the Perak State primary forest near the Northern Malaysia-Thailand border, through the collaboration between NGS and BioPERAK, a partially Perak state-owned company.

The NGS laboratory located inside the premises of the FRIM has a space of approx. 460 square meters. The laboratory is well equipped for drug discovery research utilizing bio-resources. Twenty four people were recruited locally and young researchers trained on technologies for research in drug discovery. A few Japanese expert researchers are attached to the laboratory at all times, and other researchers visit on a monthly basis from Japan to provide guidance to the staff on technical and other matters. NGS also invites prominent researchers from Malaysia or from other countries for periodical forums and workshops organized by NGS for the purpose of technology transfer.

NGS's business rationale and outcomes

To conduct drug discovery research utilizing bio-resources in tropical rain forests, the following parameters generally need to be taken into consideration: understanding of the CBD policy and regulatory systems of the country, negotiation with the government authorities (it may take 1-2 years if started from scratch), setting-up of research facilities, recruiting of researchers and experts for operation in the jungles, management of research team and facilities under the local conditions of different languages, religions, and cultures.

If a pharmaceutical company in Japan or elsewhere is interested in drug discovery research utilizing bio-resources in tropical rain forests, there may be two options. One is to do it for themselves. The other is to collaborate with an appropriate company which has expertise to do it for them. Generally speaking, the second option seems more practical for Japanese companies, if the cost is justifiable. Since users want to keep as much business flexibility as possible, NGS has various business arrangements available to fit each client's need.

Outcomes of NGS' activities

NGS has a number of non-Malaysian clients from fields such as pharmaceutical and chemical companies. NGS has started paying royalty from its revenues gained through research collaboration with these clients. Moreover, NGS filed two patent applications for novel antibiotics together with FRIM in 2006.

Experiences and lessons learned

- *Confusion between legitimate bioprospecting and biopiracy is observed at grass roots level*:

There is widely held view that foreigners and commercial people indulge in biopiracy. Rumors

of biopiracy can have a dramatic impact on even well managed companies. The efforts of both government and companies are essential to prevent negative rumors and misuse of the word 'biopiracy'. NGS has so far been able to solve this problem by having opportunities for direct information exchange, as a locally based company.

- *Need for communication between providers and users:*

The R&D process for pharmaceuticals requires a long-term commitment and involves a huge amount of investment. Therefore, it is crucial to maintain communication and mutual understanding between both parties throughout the R&D process, starting from the contract negotiation. NGS does not have difficulty in this respect, because the company is locally based.

- *Government support in the resource-providing country:*

Venture capital-based start-ups are generally operating on a financially uncertain basis, while the viability of natural product drug discovery ultimately depends upon commercial success. In view of this reality, it seems highly desirable for the government in the providing country to assist companies for commercial success for the sake of mutual benefits. Malaysian government agencies have played a significant role in promoting a good investment climate for NGS.

5. Case Study 2: National Institute of Technology and Evaluation (NITE): Collaborative Research Experience in Microbial Taxonomy with Other Countries

Background for the establishment of NITE Biological Resource Center (NITE-BRC)

Microbiological 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 decline 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 which is to be adapted to the principles of the CBD and the genomic era. In response to this recommendation, the Japanese government, in 2002, created a microbiological resource center within the National Institute of Technology and Evaluation (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 also has a patent microorganism depositary in accordance with the Budapest Treaty.

- Microbial genome analysis

The function of microbial genome analysis 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)[9].

- International collaboration in microbial taxonomy

Based on the principles of the CBD, NITE-BRC has been conducting collaborative research with a number of Asian countries in microbial taxonomy. NITE-BRC contributed to the creation of the Asian Consortium for the Conservation and Sustainable Use of Microbial Resources (ACM) for regional collaboration as described below.

Concept of international collaboration and "Tsukuba Statement"

The concept of international collaboration that has been leading NITE-BRC is described in the 'Tsukuba Statement' issued by the Global Taxonomy Initiative (GTI) Programme of Work in Microbiology that took place in Tsukuba, Japan in October, 2003 (see Box 2).[10, 11]

Key points from the Tsukuba Statement include:

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 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.

[9] DOGAN (http://www.bio.nite.go.jp/dogan/Top)

[10] ANDO K. and M. WATANABE 2004. Global Taxonomy Initiative (GTI) and Taxonomy. *WFCC Newsletter* No. 38: 50

[11] http://www.wfcc.info/newsletters/newsletter38.pdf

Box 2

Tsukuba Statement

Tsukuba, Ibaraki, Japan, 9 October 2003
Global Taxonomy Initiative (GTI) and Microbial Taxonomy:

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 Guidelines. 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.

NITE-BRC in collaborative research with other countries: Experiences

NITE-BRC signed memorandums of understanding 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 varied, on a case by case basis. The following is a typical example of terms of partnership for collaborative research conducted:

- Sharing of research results
- Installation of equipment 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

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 a 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.

Conclusions

These case studies are indicative of certain trends in user and provider perceptions on the ABS process for genetic resources. It is apparent that users, whether in scientific research or commercial R&D, are conscious of the principles of the CBD, and have developed their practices, in cooperation with their partners, that are in line with CBD obligations and equity considerations.

The study highlights that commitments of countries to the principles of the ABS and equity of CBD, can be translated into industry best practices if guidelines are effectively communicated and implemented. The case studies also indicate that users enter into benefit sharing arrangements based on a case by case approach in terms of needs of the collaborators. For example, NGS, a company, is keen on ethical research and honest practices, and the benefits shared were chiefly monetary in nature, with transfer of expertise to host country researchers to enable the research collaboration. On the other hand, NITE, being a government organization, has been transferring technology for institutional capacity building in partner countries, and the benefits shared were non-monetary. JICA-JBA has been promoting human capacity building through training courses for bio-industry development in compliance with CBD and other international rules.

Additionally, the case studies present the current trends in pharmaceutical industry that are not favorable for the use of natural products in drug discovery research, citing reasons of constantly emerging competing technologies on one hand, and, on the other, lack of clarity on national regulatory procedure on ABS in some provider countries. This trend is worrisome to the very basis of ABS debates that presupposes the use of biodiversity for development purposes.

The case studies indicate that ABS partnerships between users and providers through bilateral arrangements could provide instances of ABS best practices. These could feed into multilateral negotiations to culminate in a meaningful ABS regime. It is noteworthy that while examples of partnerships have their merits, they cannot ensure general applicability in implementation across different regions. It is therefore important to ensure multilateral consensus- building, that guarantees all parties agree to adhere to a set of principles.

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