# Challenges and Opportunities for Biotechnology Development: the Korean Experiences

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#### Background

Up to 1979, Korea had made a ditch effort to revitalize from the ruins of the Korean War and established the minimal basis for industrialization. In the early 1980s when genetic engineering and new biotechnology was emerging worldwide, the Korean economy was also turning its basis from traditional manufacturing to forefront high technologies. In 1982, the Ministry of Science and Technology included biotechnology in the government projects and the Korea Biotechnology Research Association (KOBRA) was established by the industrial sector. This organization is a consortium of companies with active interests in biotechnology.

In 1983, the Biotechnology Promotion Law was enacted by the government. Under this law, the Korea Research Institute of Bioscience and Biotechnology (KRIBB) was established in 1985 as one of the spin-off institutes out of the Korea Institute of Science and Technology. KRIBB has become the key player in the national biotechnology promotion and development programmes. Entering the 1990s, national and local universities opened new departments related to biotechnology, and established biotechnology research centers. As the world's biotechnology market grew

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bigger, the need to cultivate the domestic bio-industrial environment led the birth of the Bioindustry Association of Korea (BAK) in 1991.

The Ministry of Science and Technology (MOST) launched the first national programme which was called Highly Advanced National (HAN) Project with a top priority. The programme included two biotechnology-related programmes: the development of new functional biomaterials and the development of new pharmaceuticals and agrochemicals.

In 1994, the most ambitious national initiative for the promotion of biotechnology, called Biotech 2000 Programme, was launched. In the same year, the government declared "the Year of Biotechnology" to draw the public and industrial awareness of biotechnology. With the dawn of the 21<sup>st</sup> Century, the Korean government kicked off a new initiative, called the 21st Century Frontier Research Programme. The programme comprises of two research areas of biotechnology and robotics. Each programme will be funded to the extent of a total of US\$ 100 million for 10 years.

# The National Drive

In the early 1980s, Korea recognized that biotechnology would emerge as a key discipline for the nation's economic growth in the 21st century. Making a lot of success stories in information technology and Korea becoming one of the world's superpowers in microchips, software development and high speed internet business, its policy makers support biotechnology with the highest priority for the R&D investment in order to level up the nation's technological as well as industrial competitiveness.

The Highly Advanced National (HAN) Project, begun in 1992, was supposed to be a springboard for Korea to catch up with advanced nations. (Its nickname is the "G7 project," after the group of seven countries that meet annually to discuss global economic and trade issues.) It funded 18 teams conducting researches on every area from agrochemicals to nuclear fusion. Although the results have helped Korean companies to commercialize such products as high-definition television sets and 256-megabyte DRAM chips, the project fell short in other areas, including fusion and high-speed rail transportation.

#### **Biotech 2000 Programme**

Biotech 2000 Programme was set up by the Korean government in 1994 as an offshoot programme of the HAN Project . It aims specifically to place Korea's biotechnological capability at the competitive levels with those of world's leading countries by 2007. Under the programme, the government plans to invest about US\$ 15 billion in 14 years (1994-2007). Inter-ministrial Commission was formed to support the programme with the participation of seven governmental ministries. The role of the commission is to review the whole projects and to avoid the duplication of the investment to the similar projects. The commission was coordinated by the Ministry of Science and Technology (MOST) and other participating agencies are the Ministry of Commerce, Industry and Energy (MOCIE), the Ministry of Education and Human Resources Development (MOEH), the Ministry of Environment (MOE), the Ministry of Agriculture and Forestry (MOAF), the Ministry of Health and Welfare (MOHW), and the Ministry of Marine Affairs and Fisheries (MOMAF).

The governmental agencies provide industries, government research institutions, and universities with funding. Main actors in the programme include the Korea Biotechnology Research Association, the Bioindustry Association of Korea, the Korea Research Institute of Bioscience and Biotechnology, and universities across the country. In order to encourage the active participation of private sector in the programme, the government introduced the incentive policy for the participating companies such as research funding, tax deduction for the R&D expenditure and provided the companies with the governmental loans for the construction of the R&D facilities.

The project has the three phases with their own strategic objectives. The Phase I (duration:1994-1997) successfully attained its goal to establish a scientific foundation for the development of novel biotechnology. In the Phase II (duration:1998-2002), currently in progress, the aim is to develop the platform technology and improve the nation's R&D capability. The Korean government hopes to extend the nation's commercializing capability and expand the world market share for the domestic bio-products in the Phase III (duration 2003-2007).

Despite the economic crisis which devastated the nation's economy in 1997, the government even increased its total R&D expenditure in the following years. Korea still plans almost to double its investment for the development of biotechnological capabilities under the Biotech 2000 Programme by 2010. In real terms, almost US\$ 500 million was invested by the government in the first four years of the programme, matched by about \$1 billion from industry. The Ministry of Science and Technology is the main investor and about 20 per cent of R&D funding made by MOST was invested into biotechnology-related research projects in 1998. Recently, the investment by the Ministry of Commerce, Industry, and Energy is significantly increasing. It plans to invest about US\$ 100 million for 5 years from 2002 to boost bioindustry of Korea.

The main research areas of focus are as follows:

- High throughput screening of lead compounds
- Development of bioprocesses for commercialization
- Biosensors, BIOMEMS, Biomimics
- DNA microarrays and protein chips
- Bioinformatics
- Nanobiotechnology
- Antibody engineering and vaccine development
- Anti-aging and anti-cancer drug development
- Neurobiology and brain research
- Drug delivery system
- Gene therapy
- Carbohydrate engineering
- Genomics and breeding technology for transgenic animals and plants
- Biosafety issues on GMOs

#### 21st Frontier Research Programme

One of the major stumbling blocks of Biotech 2000 Programme is the shortage of homegrown talents. That's why the 21st Century Frontier Research Programme will include much more foreign collaboration. One big difference between Biotech 2000 Programme and the newly launched 21<sup>st</sup> Frontier Research Programme is that a single leader will be firmly in control of each project and be given a relatively free hand to allocate

resources. That's a big departure from the Biotech 2000 Program's piecemeal system, in which the central government selected and managed subprojects directly but did not hold anyone accountable for the overall direction of the research. To keep focused on their research, project leaders must sever ties with other institutions. Another big difference is that 21<sup>st</sup> Frontier Research Programme will be evaluated every three years, rather than annually to reduce paperwork.

The main research areas of focus are as follows:

- Functional analysis of human, microbial and crop genomes
- Biodiversity of indigenous plants
- Stem cell biology and therapeutic applications
- Proteomics research
- High throughput screening of novel compounds for bioregulators using structural biology and pharmacogenomics

#### **Bioindustry**

Korea has a traditionally sound basis for biotechnology and its related technologies. In particular, fermentation technology, antibiotics, diagnostics, and Hepatitis B vaccines are at the internationally competitive level. Generally speaking, however, the current status of biotechnology in Korea is mainly at the stage of improving the imported technologies and efforts are being made to develop its own innovative products. From 1986 to 1995, Korea imported 43 biotechnology-related technologies mainly from advanced countries and exported 11 technologies in the same period mostly to developing countries. Despite the financial crisis from late 1997 through 1999, the bioindustry keeps increasing its investment into biotechnology areas.

As of the end of 1998, Korea's biotechnology market size amounts to US\$ 510 million. Since 1994, the volume of market size has increased every year by 25 per cent. In particular, the biopharmaceutical market showed the biggest increase. It has increased by 56 per cent during the last 5 years.

There are a few examples of domestic products with international competitiveness:

- Amino acids captured the world market share of 20 per cent and Rifamycin took about 10 per cent in 1998.
- Developed by the Korea Green Cross Corp. in 1987, Hepatitis B Vaccine's world market share was 40 per cent in 1999.
- KRIBB developed Bioinsecticide (Bt) in 1990 and filed patents in 27 countries.
- Recombinant human growth hormone was developed by LG Chemical Ltd. in 1990. The technology was transferred to SmithKline Beecham of U.K.
- SK Chemical Ltd. developed first domestic new drug (anticancer medicine) in 1999. The technology was sold to the Johnson & Johnson Co. of the U.S.A.
- Currently, about 300 new drugs are under development in Korea. Among them, 23 new drugs are in progress or in completion of clinical trials.

#### **Bioventure Creation**

Korea is pushing forward with various programmes to establish favourable environment conductive to market-driven innovative bioventures. After the financial crisis from late 1997 to early 1999, the number of venture companies has been dramatically increased. The Korea Securities Dealers Association opened "KOSDAQ" market to support capital to small and medium-sized companies. There are 94 venture-incubating centers and 93 venture capaital companies as of 1999. In 2002, there are about 500 bioventure companies registered in Korea.

#### **Human Resources Development**

Entering the 21st century, there is a consensus in Korea that the human resource development in higher learning and industrial skills should be an urgent national priority. The High Quality Human Resources Development Project (Brain Korea 21) has been established by the Ministry of Education and Human Resources Development to reform the higher education programmes and upgrade the graduate research infrastructure in various fields including biotechnology. As of the end of 2000, the total number of scientists in biotechnology area is 9,584. Among them, those who work in universities account for more than 50 per cent, and the rest is shared by those in the government research institutions and industries.

# **Intellectual Property Rights**

The number of biotechnology patents registered by Korean inventors has increased by 73.5 per cent from 1995 to 1998. Patents in biopharmaceutical area takes lion's share, accounting for about 57 per cent in 1998. The total of the publications increased three-fold from 1995 to 1998. The percentage of overseas publications to domestic publications was about 25 per cent in 1998.

#### **Biosafety Issues**

The Ministry of Foreign Affairs and Trade (MOFAT) is the focal point of Biosafety issues on GMOs. The Ministry of Science and Technology (MOST) included biosafety in a recently proposed Biotechnology Promotion Law reform bill. It is also funding for the risk assessment in biosafety from 2001. The Ministry of Agriculture and Forestry (MOAF) is preparing the regulatory guidelines to oversee recombinant DNA plants while the Ministry of Health and Welfare (MOHW) has already made the guidelines for recombinant DNA experimental research. In 2000, the Ministry of Environment (MOE) proposed to the National Assembly a law regulating research with an environmental impact as well as industrial application. The Ministry of Commerce, Industry, and Energy (MOCIE) is preparing a law to supervise the biosafety management and the import and export of LMOs.

#### **International Cooperation**

The Ministry of Science and Technology supported 32 projects by funding about US\$ 1.2 million. In biotechnology area, there are two international cooperation centers: one established in the People's Republic of China and the other in the United Kingdom. That is, the Korea-China Bioscience and Biotechnology Cooperation Center (KCBBCC) in the campus of Shanghai Research Center for Life Sciences, the Korea-UK Bioscience and Biotechnology Cooperation Center (KCBBCC) in the Institute of Biotechnology of the Cambridge University. The Korea Research Institute of Bioscience and Biotechnology is the coordinating institution for these centers and plans to set up its third overseas R&D center in the Weizmann Institute of Science in Israel in June 2002.

### ASEAN-Korea Biotechnology Information Network (AKBIN)

The "ASEAN-Korea Workshop on the Formulation of a Biotechnology Atlas" was held in Korea for the period of August 30-September 4, 2000 under the auspices of the ASEAN COST and the Ministry of Foreign Affairs and Trade (MOFAT) of Korea. During the workshop, the ASEAN Biotechnology Sub-committee of COST and KRIBB agreed to set up "ASEAN-Korea Biotechnology Information Network" and its homepage was constructed on internet (<u>http://asean.kribb.re.kr</u>). AKBIN is expected to serve as a communication link among researchers, broadening mutual understanding and contributing to taking a step forward to closer regional collaboration in the field of biotechnology.

To establish the network, the following information is to be input by 10 participating countries:

- National S&T policies
- National policies for biotechnology promotion
- R&D activities in biotechnology
- Bioindustries
- Natural resources (Bioresources)
- Biosafety protocol
- Manpower training in biotechnology
- International cooperation in biotechnology
- Bilateral collaboration with ASEAN member countries (or Korea)
- Biotechnology infrastructure
- Budget for R&D expenditure for biotechnology
- Key indicators

# Vision and Conclusion

Biotechnology is expected to become a major integral part of the 21st century global economy and also is a key platform to accelerate the national economic growth in Korea. With the government's strong commitment to the promotion of biotechnology R&D, Korea has a national ambition to become one of the top developed countries in biotechnology, once a successful follow-up of the national programmes is made by the early years of the 21st century. To achieve this goal, however, Korea has to set up a solid strategy to keep

the international competitiveness by leveraging the existing capability and creating new strength and by implementing the selection and convergence policy on the areas with high international competitiveness.

Korea will contribute to the progress of the world's life sciences, human health care, and global environmental protection through the development of environmentally sound and sustainable technology.