



Biotechnology in Malaysia: A Current Perspective

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Introduction

How quickly time has passed! It is now two years since the launching of Malaysia's National Biotechnology Policy. At that time, the Malaysian economy has improved tremendously not only in assets and investments but also has gained confidence in the process to meet the challenges and opportunities of globalization. In fact, a prominent local newspaper, the New Sunday Times of Malaysia in its February 18th 2007 edition, reported that Malaysia was richer with investments totaling RM46 billion (US\$13.4 billion) RM20.2 billion (US\$5.9 billion) from foreign investments and RM25.8 billion (US\$7.54 billion) from local investment in 2005 and that Malaysia's

annual total trade broke the RM1 trillion mark in the last quarter of 2006. Per capita income rose more than 50% from RM12,079 (US\$3529) in 1998 to RM18,039 (US\$5271) in 2005 and the gross domestic product touched RM277.2 billion (US\$81 billion) in 2005 when compared to RM182.2 billion (US\$53.2 billion) in 1998. In addition, Malaysia's international reserves doubled to US\$70.486 billion in 2005 compared to US\$30.856 billion in 1998. Another plus for Malaysia is its booming stock market. As a result of mergers, acquisitions and restructuring within the banking, finance and public listed companies, the Kuala Lumpur Stock Exchange's composite index rose to an eleventh year high of almost 1300 as compared to the index of 262.7 in 1998. All these statistics augurs well for the Malaysian economy, of which biotechnology-related companies have played a small but significant role.

It was only in April 2005 that Malaysia declared her intention to become a serious player in biotechnology at the launching of the National Biotechnology Policy. This affirmative action was reinforced in 2006 by a significant allocation of RM2 billion (US\$0.58 billion) for biotechnology-related activities under the Ninth Malaysia Plan (2006–2010). There is no doubt that the creation of the Malaysian Biotechnology Corporation as a lead agency to guide biotechnology development in Malaysia has been a good catalyst for the growth of the nascent industry.

Malaysia has the potential of using recombinant DNA technology to develop biotechnology-enhanced products from its vast natural resources in the tropical rain forest. Malaysia also has the potential to increase food production and to ensure that the environment is sustainable through conservation and amelioration. Its rich flora and fauna of almost 15,000 species of flowering plants, 150,000 species of invertebrates, 4,000 marine fish species, numerous species of butterflies and moths, and many other life forms in equally diverse ecosystems has gained Malaysia a notable reputation as one of the 12 major centers of mega biodiversity in the world. In spite of this natural advantage, Malaysia is still highly dependent on foreign investments and technology transfer from developed nations in specific areas of advanced genetics, cell biology, genomics, proteomics and bioinformatics.

National Biotechnology Policy

Briefly, the highly comprehensive National Biotechnology Policy has been formulated to address vital aspects of biotechnology development in priority areas such as agriculture, healthcare industries and bioinformatics for further development. It also addressed issues of intellectual property rights, biosafety and financial infrastructure. To be completed over 15 years in three stages, the policy will initially see the establishment of advisory and implementation councils, biotechnology education and training of knowledge workers for research and manufacturing concerns, business development and industry creation. The second stage involves developing expertise in the discovery and the development of new drugs based on natural resources, and the home run will see Malaysian companies having a global presence. To achieve this objective, Malaysia has already set up a network of centers of excellence called Bionexus in research universities and research institutes in various parts of the country.

Biotechnology and the Ninth Malaysia Plan

Under the Ninth Malaysia Plan, biotechnology will be promoted even further, not only as a vehicle of wealth and job creation, but also to be applied in various sectors of the economy. It is well known that the biotechnology is not only the most heavily regulated industry in the world but it also has to meet the most stringent requirements for success and public acceptance. As such, there is a strong need for companies practicing biotechnology to emphasize on nurturing quality at every stage of the development in addition to enhancing its value using knowledge-intensive protocols developed from carefully conducted research and development activities. Towards this end, the strategic thrusts of biotechnology development in the Ninth Malaysia Plan have been formulated to include:

- transforming and enhancing value creation in the agricultural sector through biotechnology;
- capitalizing on the strengths of biodiversity to commercialize discoveries in health-related products and position Malaysia in the growing biogenetics market;
- nurturing growth opportunities in industrial bioprocessing and biomanufacturing;
- leveraging on the convergence of technologies to grow the nascent bioinformatics industry;
- promoting Bionexus as a unique brand to attract foreign and domestic investments in biotechnology;
- creating an enabling environment with supportive institutional, regulatory and financial framework to facilitate the build up of a strong and diversified biotechnology industry;
- enhancing human capital development to meet national needs; and
- establishing R&D centers of excellence and accelerating technology development, diffusion and commercialization.

The Ninth Malaysia Plan envisaged that by 2010, biotechnology and biotechnology-related companies would have doubled to 400; all of which will have to meet stringent requirements at every stage of production from designing and conducting trials to quality control and manufacturing.

Similar to the National Biotechnology Policy, the Ninth Malaysian Plan also identified four priority areas for concerted effort and investment, namely, agriculture biotechnology, healthcare biotechnology, industrial biotechnology and bioinformatics.

Agricultural Biotechnology

Malaysia excels in plantation technology and has accumulated a phenomenal amount of information on the biology, breeding and management of crops such as rubber, oil palm, coconuts, cocoa, pepper and rice. Using this information, biotechnology applications such as genetic engineering, functional genomics and proteomics could be utilized to improve not only the productivity of plants and livestock but also to discover

niche areas for increased agro-biotechnology products for use in healthcare and industrial biotechnologies. Towards this effort, the National Institute of Agro-biotechnology at MARDI has been selected to serve as the center of excellence for agro-biotechnology R&D, commercialization and diffusion. At this stage, it may be pertinent to mention that the recent concluded international exhibition held in November 2006 to showcase the country's agricultural business and products under the auspices of Malaysia's Agriculture, Horticulture and Agro-tourism (MAHA) was highly popular and had to be extended an additional day to accommodate the thousands who flocked to view the exhibits and to listen to talks.

Healthcare Biotechnology

Another priority area for biotechnology development is the healthcare industry. Pharmaceutical and nutraceutical industries will be encouraged to focus on leveraging the country's extensive biodiversity and local knowledge in traditional or complementary medicine to develop new products for use in medicine and cosmetics. Additional niche areas for development will include contract R&D of biogenerics, diagnostics and vaccines for epidemiological diseases.

Industrial Biotechnology

Malaysia's industrial strength has developed significantly under its Industrial Master Plans with the help of foreign investments and technology transfers. In a number of industries such as semiconductors, there has been a conscious migration towards value added products and higher margin activities over time. The country hopes to exploit this innovative tendency to develop biocatalysts such as enzymes for food and feed preparations, cleaning products, textile processing and other industrial processes.

Bioprocessing is another growth area, which can be applied in the production of biomaterials such as bioplastics, biofuel, speciality chemicals and ingredients for cosmetics and electronic chemicals. Contract biomanufacturing, as exemplified by Inno Biologics Sdn Bhd, is a potential area for increased growth.

Biofuel

In the current situation of high crude oil prices at US\$60.00 and above per barrel, it makes good sense to embark on biofuel processing from palm oil. The Ninth Malaysia Plan estimates that the demand for biodegradable biofuel including palm diesel by developed countries is expected to reach 10.5 million tonnes by 2007.

Malaysia with 3.9 million hectares of oil palm plantations and more than 360 palm oil mills will be able to meet the projected demands for biofuel. The National Biofuel Policy announced by the Malaysian government in August 2005 has outlined various strategies to increase the use of biofuel as an alternative to petroleum-based diesel and has begun drafting a bill to make the use of biofuel compulsory by 2008. Negotiations with petroleum companies are currently ongoing to persuade them to produce fuel using both mineral and vegetable oils, with 19 parts diesel to one part palm oil.

In a recent development, Malaysia has entered into a memorandum of understanding with China's Ministry of Science and Technology to further develop biofuel and biomass production technologies. The fact that Malaysia was able to launch the first Malaysian Palm Oil Board initiated biodiesel plant in Pasir Gudang in Malaysia and its first shipment of 60,000 tonnes of biofuel to Europe on August 15 of 2006 speaks well for its biofuel venture. It may be mentioned here that the Indonesian government is also pushing ahead with its biofuel program as an alternative to fossil fuels and that it has also plans to do this in an environmentally and socially friendly way.

Bioinformatics

In the area of bioinformatics, grid computing will be adopted as a means of reducing the cost of investment in R&D through the sharing of facilities. It will do so through the enhancement of the Malaysian Research and Education Network (MyREN) to ensure connectivity among various universities and research institutes. The extension of this network to industrial partners will further encourage effective collaborative efforts in research activities such as the gathering, storing, classifying, analyzing and distribution of information derived from gene sequencing and functional analysis of research projects.

Financial Infrastructure

It is a well known fact that biotechnology projects are not only risky with long incubation periods, they also have to comply with stringent regulatory requirements for public acceptance. All these constraints will translate to a requirement for a substantial amount of long-term investment. To address these issues, a comprehensive funding structure and financial incentives to the tune of RM2 billion has been allocated under the Ninth Malaysia Plan for R&D and commercialization, strategic technology acquisition, business and entrepreneurship development as well as the building of the requisite infrastructure.

The funding for R&D in biotechnology is currently provided under existing sources such as the e-Science research funds and the Malaysian Technology Development Corporation's (MTDC) R&D commercialization schemes and TechnoFund. Early stage financing could also be accessed through the MTDC's newly established Malaysian Life Sciences Fund. These funds are essential for the development of ideas and applications from biotechnology research activities. It may be good to hear that in the Biotechnology Asia 2006 Conference, a total of 15 gold, 18 silver and 23 bronze medals were awarded to researchers and innovators from local universities and research institutes for their research findings which could be further developed for commercialization. In some cases, patents are pending.

Current Status of the Biotechnology Industry

In general, the biotechnology industry in Malaysia is dominated by small-to-medium-sized companies with a handful of large plantation companies which have developed strong R&D activities for their respective crops. A census of Establishments and Enterprises conducted by the Malaysia Government in 2005 showed that there were a total of 117 biotechnology-related companies in 2003. They generated

value added products of RM1.4 billion (US\$408 million) and created 10,200 jobs. Companies in the services sector comprised 68.4 per cent of the total, followed by manufacturing and agriculture at 23.9 and 7.7 per cent, respectively. The biotechnology-related services companies generated 65.7 per cent of the total value added in biotechnology and were involved in activities such as repackaging, distribution and marketing of biotechnology-related products as well as consultancy services for regulatory and standards compliance. Agro-biotechnology companies were mainly involved in the application of tissue culture and advanced reproductive techniques for the production of improved crops and livestock.

Since its inception, the Ninth Malaysia Plan has approved a total investment of RM715.5 million (US\$209 million) involving 30 manufacturing projects in areas of agriculture biotech, healthcare biotech and industrial biotech with potential employment of 1441 jobs. Of the approved projects, 10 companies commenced operations with a total investment of RM110 million (US\$32 million) generating 364 jobs. These projects included the production of nutritional immunology supplements based on plant materials, monoclonal antibodies, polypeptide and formulations as well as diagnostic kits.

Inno Biologics Sdn Bhd is one example of a government funded company which has ventured into biopharmaceuticals. It is a globally operating contract manufacturer for monoclonal antibodies and therapeutic proteins with state-of-the-art cGMP manufacturing facility in Putra Nilai, Malaysia. Its multi-product mammalian cell culture facility has been designed in compliance with both EMEA and US FDA guidelines. It also specializes in CHO Cell Expression System and provides molecular biological, clonal selection and medium services associated with the cell expression system.

Pharmaniaga Bhd is yet another example of a local company which has entered into the biotechnology arena. It is the largest integrated local healthcare company in Malaysia with core businesses in generic pharmaceuticals manufacturing and R&D, warehousing and distribution of pharmaceutical and medical products, sales and marketing as well as hospital equipping. In its latest annual report, Pharmaniaga announced that it not only has the capability of developing biogenerics but also has the potential to develop drugs from local herbal remedies.

Another company known as Malaysian Bio-Diagnostics Research Sdn Bhd (MBDr) is into medical diagnostic kits for use in pregnancy, drugs of abuse and Brugian filariasis. It was initially incorporated to commercialize research based on the diagnosis of typhoid fever. Through its strategic alliance with universities and research Institutes, MBDr is now in an even stronger position to develop more specific and sensitive diagnostic kits for the detection of tuberculosis, malaria, HIV, paratyphoid, Nipah virus and dengue. MBDr has the vision to be a global leader in the development and marketing of diagnostic kits for use in healthcare industries.

Malaysian biotechnology-related companies have also ventured overseas. An example of this is the setting up of Hovid Bhd's first overseas manufacturing plant in India to produce generic drugs by the end of 2007. Generics is a rapidly growing area, with several blockbuster drugs scheduling to go off patent soon. The pharmaceutical giant,

Pharma, is expected to lose almost US\$23 billion worth of patents for these lucrative drugs in 2005. India, with its thriving generics industry, is certainly the destination for the company to be in. The lessons learned from overseas joint ventures will certainly help Malaysian companies adapt to the demands and practices of cGMP as well as varying management styles and practices in foreign countries.

Conclusion

Two years have elapsed since the National Biotechnology Policy was announced. During that time, there has been progress in biotechnology activities within the country. The beginnings may be slow but the results are apparent in the increasing number of Malaysian companies venturing into biotechnology. Constraints such as intellectual property rights and legal issues, the long gestation periods and the long term financial investments as well as the promotion of opportunities in Malaysia are being addressed by the Malaysian Biotechnology Corporation using the guidelines enunciated by the National Biotechnology Policy and the Ninth Malaysia Plan. Like any other industry, biotechnology in Malaysia will initially face a lag phase before the quantum leap begins.

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