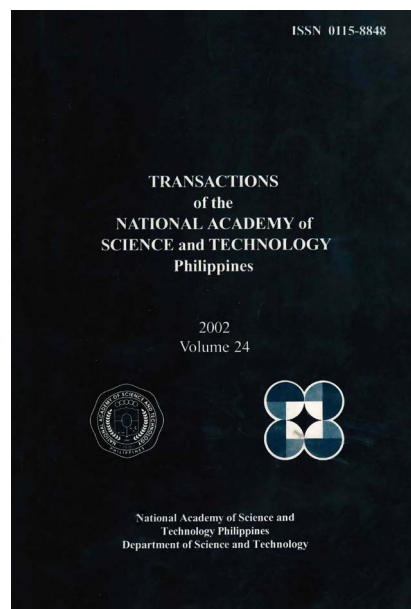


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# Making Philippine Biotechnology Competitive

Acd. Evelyn Mae Tecson-Mendoza<sup>1</sup> and  
Ida F. Dalmacio<sup>2</sup>

<sup>1</sup> Member, National Academy of Science and Technology Philippines and Professor, Institute of Plant Breeding, College of Agriculture, University of the Philippines Los Baños (UPLB) and

<sup>2</sup> Executive Director, PCASTRD, Department of Science and Technology and Professor, Institute of Biological Sciences, College of Arts and Sciences, UPLB

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## **MAKING PHILIPPINE BIOTECHNOLOGY COMPETITIVE**

EVELYN MAE TECSON-MENDOZA<sup>1</sup> AND IDA F. DALMACIO<sup>2</sup>

*<sup>1</sup>Member, National Academy of Science and Technology Philippines and  
Professor, Institute of Plant Breeding, College of Agriculture,  
University of the Philippines Los Baños (UPLB) and*

*<sup>2</sup>Executive Director, PCASTRD, Department of Science and Technology and  
Professor, Institute of Biological Sciences, College of Arts and Sciences, UPLB*

### **ABSTRACT**

Biotechnology-based industries or bioindustries are one of the fastest growing industry sectors worldwide, with annual growth of up to 20% and higher in some areas. Bioindustry includes companies involved in the R & D and manufacture of materials such as cell cultures, catalysts, genetic materials, immune response materials, biochemicals, enzymes, proteins and equipment used in biological and genetic research on humans, plants and animals. It also includes service organizations that perform consulting, testing and processing and storage of such products. This paper aims to analyze the rise of bioindustry in selected European and developing countries, briefly review the status of biotechnology and bioindustry in the Philippines and discuss possible strategies to spur the development of bioindustry in the country.

The United States leads in bioindustries generating US\$20 billion in revenues and 437,000 jobs in 1999. UK and Germany hold the second and third spots. The following have been cited to have contributed significantly to the development of bioindustries in Europe: (a) strong life science research in Universities and strong research partnerships and collaboration between and among universities and industry; (b) enabling policies by national and regional governments such as laws that provide huge financial grants to projects, establishment of bioparks or bioincubators, support start-ups, encourage academics to be entrepreneurs; (c) strategies such as clustering or networking especially at the regional level and (d) strong biotechnology industry organizations. Governments of Asian countries like Japan, China, India, Singapore and Taiwan are cited to have provided enormous financial support to the development of biotechnology R & D and bioindustries.

While biotechnology was institutionalized in the country two decades ago, bioindustry is still largely undeveloped. Among the biotechnologies developed locally, plant tissue culture of orchids and banana can be considered the most widely utilized at the commercial level. Others such as biopesticides, biofertilizers, industrial enzymes, amino acid production, vaccine production have not taken off for several reasons: lack of industry-academe partnerships/interactions; lack of facilities and support capital for piloting technologies; lack of IPR awareness and support.

To help spur the development of biotechnology in the country, the following recommendations are offered: (a) adoption of clustering management for R & D and commercialization at the regional and national levels; (b) establish an enabling environment that will provide financial support to selected projects up to commercialization, provide infrastructure and support facilities such as a biopark, provide incentives for start-up and venture companies, and encourage scientists and business management experts to go into bioindustries and develop intellectual property (IP) culture and innovation among scientists; (c) careful selection of local and foreign mature technologies for commercialization and R & D projects that have potential commercial outputs and (d) creation of a national biotechnology oversight committee to coordinate and orchestrate the implementation of a unified biotechnology agenda.

**Keywords:** biotechnology, bioindustry, cluster management

## I. INTRODUCTION

The biotechnology industry or bioindustry, “includes companies involved in the research, development and manufacture of materials such as cell cultures, catalysts, genetic materials, immune response materials, biochemicals, enzymes, proteins and equipment used in biological and genetic research on humans, plants and animals.” Bioindustry also includes service organizations that perform consulting, testing, processing and storage of such products. Others define bioindustry to be more specific to technologies involving recombinant DNA technology. This paper will adopt the more inclusive definition which we believe is more appropriate for the Philippine situation.

Biotechnology-based industries or bioindustries are one of the fastest growing industry sectors worldwide, with annual growth of up to 20% and in some areas, even more. The United States, United Kingdom and Germany are the world’s top three in bioindustries. Bioindustries comprise of small companies; less than 10% employ more than 250 people. They are into health products (therapeutic pharmaceuticals, vaccines), diagnostics, bioagriculture and industrial enzymes etc.

Many countries have recognized that biotechnology-based industry or bioindustry would be the next big industry, even bigger than ICT. In Asia, the governments of Japan, China, India, Taiwan, Korea and Singapore have poured

huge investments into biotechnology R & D and into the development of bioindustries. Although as early as in the late 70s, biotechnology had been recognized by the Philippine government to potentially contribute to increase its productivity in agriculture and industry, bioindustry still is largely undeveloped.

This paper aims to (1) analyze the rise of bioindustry in selected European countries and developing countries; (2) review the status of Philippine biotechnology; (3) discuss the possible strategies for the country to jumpstart and create a sustainable bioindustry.

## 2. BIOINDUSTRIES IN VARIOUS PARTS OF THE WORLD

There are 1500 biotech companies in North America and 1200 in Europe. The United States leads the world in biotechnology-based industries which generated a total of 437,000 jobs, \$47 billion in revenues while plowing back \$11 billion in R & D and giving the government \$10 billion in tax revenues (Fig. 1). Of this, agricultural biotechnology generated about \$2.3 billion in revenues while generating 21,900 jobs. There are more than 1500 biotech companies in the US, 350 of which are publicly traded with a total market capitalization of US\$350 B. Of these companies, 15 are profitable and by 2001, more than 30 are expected to have become profitable (Hove, 2001).

Fig.1. Contributions of biotechnology to the US economy in 1999

•	437,000 jobs
○	150,800 jobs in biotech companies
○	286,600 in companies supplying inputs to industry
•	\$47 billion in additional revenues
○	\$20 billion by biotech companies
○	\$27 billion by support companies
•	\$11 billion in R & D
•	\$10 billion in tax revenues

From Ernst and Young, 2000.

The 45 main biotech companies in Europe have a total capitalization of about US\$35 B with four companies which are profitable and which account for more than 70% of the total market capitalization.

Biotechnology is thought to be a maturing sector in the UK (Kirkman, 2000) indicating that many companies are now reaching sustainability. However, for this trend to continue, it is also expected that there will be more mergers and consolidations of companies. UK has also been a trail-blazer in terms of establishing

investment models and markets for biotechnology. The number of publicly listed biotech companies in the UK is now twice as many as the total of those listed companies for the rest of Europe. Major biotechnology activities occur in the so-called "Golden Triangle" which consists of Cambridge, London and Oxford. The universities and a host of interacting companies, organizations and government initiatives have led the growth of biotechnology in this region and in UK. The UK Research Councils, established by a Royal Charter, are independent non-Departmental public bodies that support research and postgraduate training and promote public understanding of science. These councils receive about £2,000 million per year through the Office of Science and Technology. Among the present six grant awarding Councils, two have contributed significantly to the growth of biotechnology: The Biotechnology and Biological Research Council and the Medical Research Council.

Germany holds the second spot in bioindustry in Europe. From 1997, the number of companies involved in bioindustry increased from 173 to 279 in 1999 to 350 in 2000 (Table 1), with 10 being listed as IPOs. These biotech companies in Germany generated DM 1,011 million in sales in 1999 with R & D spending of DM 638 million, almost double the 1997 figure (Stadler, 2001).

Table 1. Bioindustry trend in Germany.

Year	1997	1998	1999
Companies	173	222	279 (350 in 2000)
Listed companies	1	3	10
Employees	4,013	5,050	8,124
Employees in R & D	2,076	2,957	4,346
Sales (DM million)	565	751	1,011
R & D spending (DM million)	276	415	638
Operating losses (DM million)	63	82	104

(From Stadler, 2001)

Several reports have been made on the bioindustries in Europe. An analysis shows that the following have contributed to the development of bioindustries in Europe (Table 2).

### Strengths

Europe boasts of universities, government and industry research institutes which are very strong in the life sciences. Strong research partnerships and collaboration also are common among scientists and institutions. In UK, there are the Cambridge, Oxford and London areas with their respective prestigious universities.

Germany has the prestigious Max Planck research institutes in addition to their centers of excellence in the universities. France has the Centre National de la Recherche Scientifique and the Louis Pasteur University among others while Belgium has the University of Ghent, Catholic University of Louvain, University of Antwerp, Free University of Brussels etc. However, the excellent research results published in journals more often have earlier not resulted in marketable products. Several reasons can account for this: (a) reluctance of academics to commercialize their results; (b) lack of support from institution and/or government; (c) lack of awareness or appreciation for intellectual property rights by researchers; and (d) lack of interaction between industry and the academe.

Table 2. Factors contributing to the development of bioindustries in Europe

1. Strengths	Strong life science research in universities Strong research partnerships and collaboration Strong bioindustry organizations
2. Enabling policies	Strong national and local support Laws/regulations that provide huge financial grants; encourage academics to go into business (France's Innovation Law); encourage regional clustering or networking; establishment of bioparks; encourage capitalists to invest; guarantee to venture capitalist in start up or growth companies; furnishing information on business opportunities
3. Strategies	Government-led/supported clustering Industry-led clustering Industry- and government- support to educate consumers regarding GMOs

### Enabling Policies

Recognizing the potentials of biotechnology to boost their economy and realizing that the United States was already ahead in this field in the late 1980s and in the 1990s, many countries in Europe provided an atmosphere conducive for biotechnology-based industries or bioindustries to develop and flourish by enacting appropriate laws and regulations. Such enabling laws and policies have in general common objectives: to produce high quality research, validate research results and technology, and convert research results to marketable products.

***Huge Financial Support to Projects.*** In the 1980s the Federal Government of Germany provided funds for the establishment of four Gene Centres at the universities of Berlin, Cologne, Heidelberg and Munich. This was followed in the 1990s by the Biotechnology 2000 Programme of the Federal Research Ministry which made available DM 345 million per annum and started the BioRegio Competition

established in 1995 to encourage the formation of regional clusters. During the first round of competition, 17 young clusters submitted proposals; each participating cluster was provided with DM 100,000 for the preparation of detailed proposals. The three winners, Munich, the Rhine/Neckar area and the Rhineland received DM 50 million over the next five years. Notably, the regional government also provided support through establishment of bioparks which provided infrastructure, technical, administrative, marketing and legal support to start up companies.

In Belgium, very strong regional support was provided to the development of bioindustries. The three regions of Brussels, Flanders and Wallonia have provided financial grants to research projects. Wallonia has the BIOVAL or “Valorization of the Cellular Biological Heritage” which provides BEF 250 M (€6.2M) for university projects and BEF 200 M (€12.4 M) for projects submitted by companies. In Flanders, industrial zones and grant programmes were established. Both regional governments favor strong university-industry interactions and collaborations.

France enacted the Innovation Law which allocated FF395 M to life sciences. The Agence Nationale pour la Valorisation de la Recherche (ANVAR) acts as the French national agency for innovation. This led to the establishment of six regional bioincubators or centers designed to help start-up companies in their first stages of development.

In September 1999, FF43 M was given to such incubators, followed by another FF38 M.

***Formation of Regional Clusters; Regional Government Support.*** An interesting characteristic of these bioindustries is the clustering or networking of universities and private companies within a region which has been found to be essential for a successful bioindustry. In Germany, it was noted that although a lot of financial support was given to individual universities and companies in the 1980s to spur the growth of bioindustry, it was only in the 1990s with the BioRegio Competition that the growth of the new industry was triggered. As mentioned above, this regional competition saw the formation of regional clusters in Germany which competed for the huge financial support given by the federal government. This also spurred regional government support to the clusters which included: (a) establishment of bioincubators; (b) assistance to foreign investors by furnishing information on the benefits of locating to their regions, provide fact-finding missions, finding industrial or commercial partners, introducing decision-makers or exploring business opportunities.

***Establishment of Bioparks or Bioincubators.*** To support small and medium enterprises, biotechnology parks have been established in North America and Europe, and in some parts of Asia as well. For example, within the BioRegion of Berlin-Brandenburg in Germany are located seven biotechnology parks. In the Bavarian cluster, there are two major bioparks, the Innovations-Und Grunderzentrum Biotechnologie (IZB) and the BioPark Regensburg GmbH.

In general, bioparks provide: (a) infrastructures for the entrepreneur. Laboratory space can be rented at favorable prices near established research

institutes where expertise and the more sophisticated equipment are available. Bioparks also provide production facilities for bench, pilot and semi-commercial scaling up of technologies.

- (b) a permanent management structure much needed by start-ups which are usually headed by scientists/academics with little business management skills.
- (c) assistance in validating and patenting of research products.
- (d) networks of cooperators and consulting experts
- (e) academic-industry interactions

At Biotech Park Luckenwalde, there is a production facility that meets GMP standards and a Communication Center, which provides advisory service to the companies housed in the park. This may include consultation on setting up a business, developing plans, and help in finding financial support. As of October 2001, there were 40 companies in this 28 ha biopark, about half of which were start-ups.

Bioparks may be owned by the government or by private sector. The BioPark Regensburg in Munich is owned by the city government while the Charlottenburg BioTechPark located in Berlin is owned by an investment group with the international pharmaceutical company Schering which occupies one-half of the 48,000 sq m office, laboratory and production area.

**Support/Encourage Venture Capital.** With France's Innovation Law, up to 50% of the new start-up company's R & D expenses are tax deductible. To make up for lack of investors from private sector, this law also set up a national innovation award scheme to finance the development of individual innovative projects before and after start-up creation. By 2000, 25 to 30% of French venture capital was devoted to biotech.

The Flemish Guarantee Fund provides a guarantee to a venture capitalist that participates in start-up or growth companies with investment between 75,000 and 1 M Euro. The fund covers up to 50% of the losses when the venture fails.

In Germany, Bayern Kapital serves as a partner for private venture capital investors and increases investment through a matching silent share participation. As of 2000, Bayern Kapital had invested DM 165 M, 65% of which was in the field of biotechnology.

**Encouraging Scientists to be Entrepreneurs; Expatriates to Return to Homebase.** France's Innovation Law encourages scientists to venture into entrepreneurship by allowing them up to six years to make their mark as entrepreneurs while retaining their civil servant status. Further, the law provides financial incentives to French scientists who may be awarded up to 15% of capital in the creation of a start-up.

Following the trend in IT, scientists, engineers and highly educated managers flooded out of the universities, pharmaceutical industry and management consultancies and those who were in the United States rushed back to Europe to



take advantage of the new environment. It was also noted that young management experts who would otherwise opt to join bigger companies for stable and high pay, or highly successful individuals would abandon corporate careers, have chosen to join start ups. This is considered as a fundamental change in behaviour and culture, although a great opportunity for investment (Schüsler, 2001).

**Protection of Intellectual Properties.** For high technology sectors like biotechnology, protection of intellectual properties is a key factor for economic growth and advancement. Patents provide incentives to private sector investment in biotechnology development. Patents are therefore the lifeline of biotech companies. "The number of patents issued can assess the success of biotechnology companies." The rise of Germany in bioindustry is characterized by a dramatic increase in the number of patents issued in the fields of biotechnology and genetic engineering from 1995 to 1999. In 1995, 142 of the 1613 patents in said fields filed with the European Patent Office, were from Germany. This increased to 251 in 1997. Patents filed with the German Patent Office showed a more dramatic increase of 61% with 618 patents issued in 1995 and 994 in 1997. The increase has continued. As of 2001, 1433 patents had been issued in the fields of biotechnology and genetic engineering in Germany compared with 3569 issued in the United States.

The world leaders in the field of genetic engineering and pharmaceuticals-related biotechnology have their portfolios of technologies which are protected by patents. Table 3 shows the number of patents granted to the companies which top the list of patent holders in said fields.

Table 3a. Top international/European companies/institutes in number of patents granted in the field of genetic engineering.

<b>Top international companies/organizations</b>	<b>Number of patent</b>	<b>Top European companies/organizations</b>	<b>Number of patent</b>
Genentech Inc	108	Pasteur Institut	74
Pasteur Institut	74	Hoescht AG	70
Hoescht AG	70	BoehringerMannheim GmbH	53
Kyowa Hakko Kogyo KK	60	Ciba Geigy AG	51
Lilly Co Eli	54	Bchtingwerke AG	46
BoehringerMannheim GmbH	53	Hoffman La Roche	42
Chiron Corp	51		

(From Biotech International, 2000)

Table 3b. Top international/European companies/institutes in number of patents granted in the field of pharmaceuticals-related biotechnology

Top international companies/organizations	Number of patent	Top European companies/organizations	Number of patent
SmithKline Beecham plc	123	SmithKline Beecham plc	123
Incyte Genomics Inc	89	Aventis SA	61
Isis Pharmaceutical Inc	65	Ludwig Institute for Cancer	17
Aventis SA	61	Deutsches Krebsforschungszentrum	
		Srftung des Oeffentlichen Rechts	15
Human Genome Sciences Inc	52	Boehringer Ingelheim Crop.	14
Millenium Pharmaceuticals Inc	46	Merck & Co. Corp	13

(From Biotech International, 2000)

**Role of Biotechnology Associations.** Biotechnology associations have, in general, contributed to the establishment and success of bioindustries in various countries worldwide. Such associations bring together companies, experts, public organizations with the primary aim of promoting biotechnology development. Their specific objectives and missions vary from organization and country.

For example, the Biotechnology Association Berlin-Brandenburg (BBB) has for its main aim to provide a broad platform for common activities for the development of biotechnology within the region since Berlin and Brandenburg have different biotech potentials that have to be integrated into a larger structure. Thus, the Biotechnology Association works to address the problems in integration and to promote regional strengths. BBB resulted from the merger of the Association of Biotechnology e.V. and the Biotechnology Berlin-Brandenburg e.V. in 1997 and has more than 60 members from industry, science and industry.

The Belgian Biotechnology Association (BBA) comprises of 38 firms, 20 university laboratories, and 10 public organizations in Belgium. BBA helps its members "to reinforce their competitiveness and succeed in their development" by assisting them in obtaining up-to-date information and in lobbying for measures that favor research and investment in Belgium.

Perhaps the largest biotech association is the Biotechnology Industry Organization (BIO) in the US which merged the Industrial Biotechnology Association representing larger established companies and the Association of Biotechnology Companies representing the smaller emerging companies and universities in 1993. The missions of BIO are:

- Advocate the industry's positions to elected officials and regulators.
- Inform national and international media about the industry's progress, contributions to quality of life, goals and positions.
- Provide business development services to member companies, such as investor and partnering meetings.

Membership in BIO has doubled since the organization's founding, to more than 1,000 companies, academic institutions and biotechnology centers.

The All India Biotech Association (AIBA) was established in 1993 and has 44 industry members and 10 institute members plus individual members. This association has sponsored several national and international conferences held in India. Interestingly, AIBA has identified and published listing of biotechnology products India has locally developed and produced and more so, her needs or requirements in the areas of human and animal health, agriculture, and industrial and others, citing market and investment figures. For example, for vaccines, AIBA, with the help of industry members, determined the need to increase production of more effective vaccines, and cited the immediate demand for cocktail vaccines of DPT and hepatitis B, Hepatitis A with B, injectable polio vaccine, influenza, varicella and meningitis vaccines. It also cited the unmet demand for several animal and poultry vaccines. AIBA estimated that Rs 300 to 400 million are expected to be invested in vaccine production in the next five years.

Biotechnology industry associations have also been very much involved in explaining to the public issues on biosafety and food safety for better understanding and appreciation of GM products. The Biotechnology Coalition of the Philippines (BCP) has led and supported activities in this regard for the past years. BCP has also initiated efforts to develop bioindustries in the country.

## Strategies

A major strategy that has been adopted in probably all of the countries that have successful bioindustries is that of **clustering or networking**. Clustering or networking provides a pool of expertise and infrastructure and "creates and exploits synergies." Further, it could inspire healthy competition among the different regions of a country as well as their regional governments. In clustering, all possible aspects of industry needs are looked into and supported by either the industry or government or both.

As already mentioned above, bioindustry in Germany took off in the 1990s with BioRegio competition in which the different regions competed for grants. Aside from federal support, the regional governments also contributed significantly to the efforts by building bioparks or bioincubators, assisting investors, and promoting public understanding of biotechnology. The German or French networking can be classified as government-led networking. On the other hand, The Cambridge-East of England cluster is considered industry-led without government financial support but is nonetheless expected to grow and further strengthen by merger and acquisition. However, the opinion of several company officials in this cluster was divided on whether the unavailability of public money or government support in UK for the biotech companies is not affecting their competitiveness compared with other countries in Europe like Germany. For example, Mark Bodmer, CEO of Lorantis believes that the role of government is "to create permissive environment for doing

things,” and the UK government has addressed this in terms of science and financial policies, but not in some areas like rewarding employees with share options. Unfortunately, some restrictions seem to restrain companies from giving such incentives to employees.

The Vienna BioCenter, the biotech cluster in Vienna, is a case example of successful interaction between corporate and academic institutions. The cluster management plans and coordinates all future developments in the Vienna area to establish biotechnology clusters; although its major aim is to develop one cluster first and make it work before starting another. It however also recognizes that a similar cluster formation can be carried out in other outstanding research institutions in the area.

In addition to the development of biotech companies in the clusters, many supporting businesses (for equipment, facilities, communication, travel etc) and legal and patent offices abound.

### **Biotechnology In Asia**

Many countries in Asia have recognized the potential of biotechnology and have adopted the use of biotechnology as a state policy to increase productivity in health, agriculture and industry.

While Japan has several biocompanies which have multimillion to multibillion dollar turnover (Takeda Chemical Industries, Takara and Kyowa Hakko Kogyo), it considers itself to be behind bioindustries. In 1999, the Japanese government allocated US\$18 for biotechnology R & D for five years in addition to the \$4.6 billion annual budget to spur the further development of bioindustry (Asiaweek, 2000). The Japanese government has approved the use of about 20 GM crops for food and/or feed.

China leads all Asian countries in the adoption of GM crops. In 2001, 1.5 million ha of Bt cotton were planted in China. Other GM crops are in various stages of field testing such as transgenic rice resistant to three major rice pests (stem borer using *Bt* and *CpTI* genes, planthopper and bacterial leaf blight using the *XA-21* gene), wheat, maize and many others. It was estimated that China spent \$112 M in 1999 on plant biotechnology research (Huang et al, 2002). In the mid 1980s, China's biotech industry started to combine R & D and manufacturing and marketing. By early 1990s, the first recombinant health product— Sinogen (human interferon alpha 1b) was released by Shenzhen Kexing. By the end of 1998, 15 types of genetically engineered pharmaceuticals and vaccines had been launched with estimated sales of US\$265 M. Now, recombinant insulin, interferon, growth hormone and erythropoietin, are being produced in China not only for the local market but also for export, considering that the patents of these products have expired or about to expire. At the turn of the new century, the Chinese government invested US\$ 9 M in biochips R & D and commercialization. In 2001, there were 200 biotech companies and 30 biotech production plants in China.

The Indian government recently approved the planting of Bt cotton in commercial scale following several years of limited and multilocational field testings. Private and government laboratories are developing and testing other GM crops with various desirable traits such as rice with pest resistance. India has also advanced in other fields of biotechnology. It has developed its pharmaceutical industry into one that produces medicines for local and export markets including first world countries. Almost all conventional vaccines for human and animal health are produced locally. Bharat Biotech (Hyderabad) produces recombinant hepatitis B vaccine and is developing streptokinase and VEGF. Shantha (Hyderabad) also produces recombinant hepatitis B vaccine and has several products in development: insulin, IFN-alpha; GM-CSF; streptokinase, EPO, hGH; tPA. Dr. Reddy's Labs has marketed G-CSF. Its dual-acting insulin sensitizer drug DRF 2725 has been licensed to Novo Nordisk in 1998 and is now in phase three clinical trials. This product has brought in about US\$8-9 M in upfront and milestone payments from Novo Nordisk (Biotech News Asia Pacific, 2001).

Singapore aims to be home to world class bioscience companies in the year 2010. In June 2000, Singapore launched its US\$34 M Genomics Program to study the diverse genetic make-up of the Asian peoples. Moreover, Singapore is into developing novel drugs by high throughput screening and genomics.

Table 4 shows biocompanies in Asia and their products and income.

### 3. Biotechnology and Bioindustry in the Philippines

Agricultural biotechnology in the Philippines traces its roots to the College of Agriculture of the University of the Philippines Los Baños. Table 5 summarizes the milestones in R & D and policies in the country from the 1960s to date.

After two decades of biotechnology R & D in different institutions in the country, products in various stages of post R & D into commercialization can be summarized in Table 6. Among locally developed biotechnologies, tissue culture of orchids and banana is the most widely utilized at the commercial level by both small and big companies.

Notably, the major tissue culture companies are based in Mindanao and include: Davao Musatech Corporation, an affiliate of Stanfilco (which is a division of Dole Philippines, Inc), based in Davao, Dolefil Tissue Culture Laboratory also of Dole Philippines based in South Cotabato, Lapanday BioTrends in Davao City, and Marsman Drysdale Biotech Research Corp. in Davao del Norte. Other companies that provide tissue cultured seedlings are Intelligent Agro-technical Resources Inc., Tropical Research and Technology Center, Inc and Secura Plant Genetics Inc. in Davao. Musatech has an annual capacity of 23 million seedlings. Dolefil serves the different subsidiaries of Dole; this includes Dolefil for pineapple, Stanfilco for banana and Tropifresh for asparagus. It has produced 2.5 million pineapple meristems per year since 1999 for commercial planting. The full annual capacity of Dolefil is 3

Table 4. Biocompanies in Asia, their products and annual turnovers.

Company	Products	Turnover (US \$)
Takeda Chemical Industries (Japan)	For prostate cancer Biochemicals	8.6 B
Takara (Japan)	(Taq polymerase), biochips	1.8 B
Kyowa Hakko Kogyo (Japan)	Cancer, allergy, hypertension drugs	3.6 B
Schenzhen Kexing Bioproducts (China)	Alpha 1b interferon for hepatitis and viral infections; alpha 1a interferon; human interleukin; human growth hormone; human EPO; human G-CSF; hepatitis A vaccine oral cholera vaccine	30 M (for alpha 1 b interferon); 265 M for all.
Shenyang Sunshine Pharmaceuticals (China)	Erythropoietin (EPO) for anemia and cancer;	9.7 M
Shantha Biotechnics (Hyderabad, India)	Hepatitis B vaccine, interferon alpha	10 M
Bharat Biotech (Hyderabad, India)	Epidermal clot dissolver	6 M
Dr. Reddy's Labs (Hyderabad, India)	G-CSF	
General Biologics	Test kits for hepatitis, AIDS, cancer	6 M
LG Chem (Seoul)	EPO; hGH; IFN-alpha-2a; IFN-gamma; GM-CSF; hepatitis B vaccine	

million pineapple seedlings and up to 6 million banana materials. Secura Plant Genetics produces 80,000 banana meristems per month and caters to small banana planters (Mendoza, 2002).

Table 5. Timeline of Biotechnology Research and Policy Initiatives in the Philippines

1960s-70s	Propagation technique using embryo rescue for mutant makapuno coconut developed at UP College of Agriculture CA)
1970s	Micropropagation and embryo rescue techniques for orchids, including indigenous orchids developed (UPCA)  Micropropagation techniques for banana varieties developed (UPLB IPB)
1979	National Institutes of Biotechnology and Applied Microbiology (BIOTECH) established at UPLB [Presidential Decree (PD)] under President Ferdinand E. Marcos
1986-1992	Department of Science and Technology identified biotechnology as a flagship of leading edge technologies “as a strategic tool for achieving sustained economic development” during the term of Pres. Corazon C. Aquino
1990	National Committee on Biosafety of the Philippines created by Executive Order to review and monitor R & D involving GMOs
1990s	Marker technologies for use in crop improvement developed at IPB and PHILRICE
1992-1998	Under President Fidel V. Ramos, biotechnology remained as a major program of DOST’s S & T program
1992	The Institute of Plant Breeding, of the College of Agriculture at UPLB mandated by the Seed Industry Development Act of 1992 to lead in plant biotechnology activities
1995	National Biotechnology Network under the University of the Philippines System created by Pres. Ramos
1997-1998	Facilities and manpower for cloning plant genes and transformation developed at IPB
1997	Pres. Ramos approved 5-year Crop Biotechnology Program with the budget of PhP 65 million for year 1
1997	Agriculture and Fishery Modernization Act of 1997 included a provision for biotechnology in its budget for R & D
2000	Institutionalization of biotechnology in government programs approved by former President Joseph E. Estrada

Table 5 (continued)

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Dec 1999- March 2000	First field testing of Bt corn in South Cotabato by Monsanto Philippines
2000	Papaya transgenic plantlets at IPB; screenhouse testing of XA-21 rice at PHILRICE
2001	Policy Statement on Modern Biotechnology approved by President Gloria Macapagal Arroyo
2001	Multilocational field trial of Bt corn by Monsanto Philippines and Pioneer-HiBred

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From: Mendoza, 2002

Unfortunately, there are no statistical data on the number of biocompanies in the Philippines, their products and revenues.

While there are a number of locally developed biotechnologies, the development of bioindustries in the country has been slow. Several factors have been cited to account for this: lack of R & D funds; lack of industry-academe partnerships/interactions; lack of facilities and support capital for piloting technologies; lack of IPR awareness and support.

#### **4. Making Biotechnology Work for the Philippine Economy**

Based on the above discussion of the experiences of other countries in developing their bioindustry and considering conditions of our economy and S & T and the culture of our people, we hereby propose strategies to help stimulate the development of a sustainable biotechnology in our country and be able to utilize such technologies to the advantage of our country and people. These include: (a) adoption of clustering management; (b) selection and prioritization of appropriate technologies for commercialization; (c) enactment and/or implementation of enabling policies and laws and (d) coordination and orchestration of a unified biotechnology agenda.

##### **Clustering Management**

The clustering concept as a collaborative model of governance has been strongly advocated (Follosco, 2001) in the country. It was approved in the 1994 Export Summit, 1999 Philippine Export Development Plan (PEDP) and the MNAAP 2000 as a collaborative model for productivity. Industry clustering, as defined by the PEDP, is "grouping of firms in an industry through the provision of goods, services, machinery and specialized inputs (e.g. knowledge) and the buyers, all operating under



Table 6. Biotechnologies in the Philippines

<b>Human and animal health</b>	<b>Existing products</b>
1. Vaccines	only a few animal vaccines are locally manufactured by conventional methods; the rest of animal and human health vaccines are imported; Riverdale Biological Laboratories has commercialized several animal vaccines including Hemo-Bac against septicemia. BIOTECH has developed vaccines against pasteurales, hemorrhagic septicemia
2. Diagnostics	Mostly imported; locally developed diagnostics for mycotoxins and red tide toxins await commercialization
3. Bioactive therapeutic proteins	Insulin, alpha interferon, hepatitis B surface antigen based vaccine, erythropoietin, filgrastim are all imported
4. Other products	Blood and blood products, monoclonals, bioactive peptides, effective biotech drug delivery systems are all imported
<b>Agriculture</b>	
1. Improved crop varieties	Have been developed by various govt research institutions and private companies; GM crops for selected traits are emerging technologies.
2. Tissue culture raised planting materials and cut flowers	Tissue cultured orchids, banana and pineapple; makapuno coconut; sugarcane
3. Biopesticides	BIOCON for control of nematode pests; preparations of Bt
4. Biofertilizers	Rhizobium, etcMycorrhiza, Azospirillum, Bio-N, Nitroplus, Cocogroe, Cocorich
5. Diagnostics for plant diseases	Immuno-based and DNA/PCR based diagnostics for various diseases
6. Animal improvement	Embryo transfer

Table 6 (continued)

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**Industrial and Other  
Biotech Products**


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1. Industrial enzymes	Technologies developed for production of $\pm$ amylases, proteases, cellulases, glucoamylase, lipase, pectinase, xylanase, ligninase
2. Amino acid production	Amino acids mostly imported
3. Specialty bio-molecular chemicals	$\beta$ -monoglycerides biopolymers such as Nata de coco, applications of high strength, biodegradable membrane;
4. recovery of value-added products from wastes	Chemical fertilizer substitutes, composts, organic fertilizer formulations; Soil amendments or supplements
5. Bioremediation	Microbial inoculum formulation; commercially available imports; microorganisms for degradation or degradation of recalcitrant organics (pesticides, PH Bs, etc)

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an environment shaped by government, the physical and cultural heritage, and available infrastructure.” The clustering concept used in the Philippine programs is strongly based on the studies made by Prof. Michael E. Porter and adapted to suit the country, its different regions and provinces, stages of development and socio-cultural differences. As shown earlier, clustering has been important in the development of bioindustry in Europe and in North America.

The following need to be considered in clustering industries (Follosco, 2001):

- human resources (skills)
- technology or knowledge
  - education
  - research and development
  - intellectual property rights (IPR)\*
  - commercialization/extension
  - manufacturing
- networking infrastructure
  - physical
  - social
  - marketing and distribution

- capital
  - o equity
  - o venture
  - o credit
- transportation
- tax and regulatory structure
- quality of life

\*The authors believe that it is important to add IPR (intellectual property rights) as part of the above considerations. Follosco (2001) further illustrated industry clustering as shown in Figure 1.

There are several models of clustering which can be considered for adoption in Philippine biotechnology.

1. National clusters for
  - a. Biomedicine—human and animal health
  - b. agri-food and forest products
  - c. environmental improvement
  - d. biotech products for industrial use (industrial enzymes etc.)
2. Regional clusters, each region having one or several of the sub-clusters
3. A coordinated national-regional clustering program

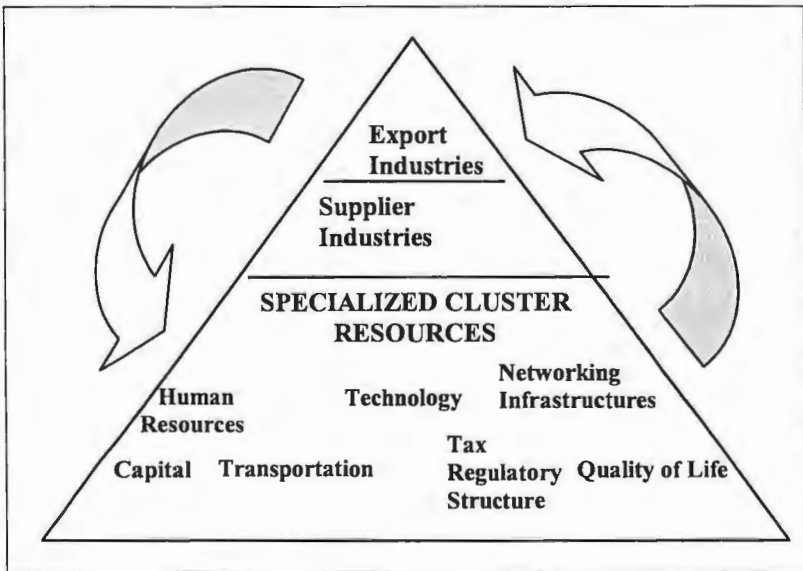


Fig. 1. The clustering concept in industry.  
(From Follosco, 2001)

Clustering can be industry-led or government-led; either way, there should be close cooperation between the two and among all stakeholders.

As seen from the European experience, clustering done at the regional level was an essential strategy for the successful take off and development of bioindustry. At the national scene, the technology sources in the region (universities, research institutes in government and private industry) are sufficiently rich. Perhaps, we can start with national clustering for each of the areas and see how regions can participate. We can foresee that clusters can be formed around quality research institutes with substantial research funding sources. Challenges for these clusters include active participation of industry, building up the manpower skills and infrastructure for validation and upscaling. Manpower herein includes not only high level expertise but more so, the support staff for the biotechnological processes.

### **Selection and Prioritization of Appropriate Technologies for Commercialization**

Considering the state of the economy and our human and technology resources, it is imperative that technologies that will be supported for commercialization under clustering management have to be selected and prioritized with utmost care. In this section, we present a few examples of biotechnologies which are candidates for commercialization. In choosing and prioritizing technologies, economic feasibility studies must be undertaken to ensure market value and acceptance of product. As seen below, this will be undertaken in close collaboration among industry, government and research institutes.

#### **1. Mature Technologies**

##### **(a) Local technology**

- (i) Multiplication of makapuno seedlings by embryo culture
  - Demand for makapuno nuts: 4.0 M tons bottled in 1999, expected to be 7.0 M tons in 2002
  - Demand for processed makapuno by secondary processors: 312,000 kg by ice cream manufacturers for local consumption
  - Other untapped markets: high quality galactomannan for food, pharmaceutical and microchips industry
  - Situation: 20,000 makapuno coconut trees in the Philippines with 2-20% yield of makapuno
  - Embryo-cultured makapuno trees yield 75-100% makapuno nuts
  - PCA-ARC has 40 ha of makapuno trees with potential of 20,000 seedlings (quarantined)
  - Total of 9.5 ha of makapuno trees in satellite labs with combined capacity of 10,000 seedlings per year
  - Target: 1000 ha

Lead Institution – PCA-Albay Research Center (ARC)

Partner Institutions

Region 1	Private laboratory (Pangasinan)	
Region 4	UPLB-FI	(UPLB)
	PCRDF Lab	(Sto Tomas, Batangas)
Region 5	PCA-ARC	(Guinobatan, Albay)
Region 7	ViSCA	Leyte
Region 11	PCA	Davao
Food Processors	Makapuno coconut growers	

Suppliers of biochemicals, glasswares, flow hoods, etc  
Exporting firms

Support Agencies

DA  
DOST  
DTI  
Regional/provincial governments

Laboratories can later be diversified to work on ornamentals, bananas etc depending on location and needs (Rillo, 2002).

(b) Adoption of mature tested foreign technology

(i) Production of rabies vaccines

Lead institution: Research Institute for Tropical Medicine (RITM)

Partner Institutions

UPLBCVM  
BAI  
Private companies

Specific problems: Manufacturing  
Testing and quality assurance

(ii) Production of recombinant hepatitis B vaccine or erythropoietin

Technology can be accessed in India, China or Korea.

Lead institution: Private sector

**Partner Institutions**

UP Manila Biotech  
St. Luke's Hospital Biotech Group  
UST College of Medicine  
Private companies

**Support Agencies/units:**

DOH  
DOST  
DTI  
Professional organizations

Specific problems: Manufacturing  
Testing and quality assurance  
Manpower development for manufacturing

**2. Development of new technologies**

It is also important to choose new projects that can generate novel products. The rich genetic resources of the country can be a source of drugs for various diseases and disorders. However, since development of drugs costs about US\$600 million per drug, the Philippines can get into this area by being involved in the areas of screening for specific biological activities, isolation, identification and characterization of active principles, and isolation and cloning of gene of active principle. For these activities, we need to further develop capabilities and strengths in high throughput screening, proteomics, genomics and bioinformatics. Interesting active principles can be licensed to interested parties for further development and testing. This is an area where biocompanies thrive and several have made their mark. Millennium Pharmaceuticals Inc. of Cambridge, Massachusetts is a leading edge drug-discovery and development company which started with thirty researchers in 1993 and has grown to more than 700 scientists, managers and technicians. Millennium has made partnerships with big companies such as Monsanto, Eli Lilly, Hoffman-La Roche and Bayer AG. In almost all these partnerships, Millennium has been paid millions of dollars by its collaborators in return for drug discovery, targets and leads, and technology transfer services. The value of a company such as Millennium has been recognized by Wall Street to be based on the "innovative interplay of partners and platforms, processes and technologies" (Jonash and Sommerlatte, 1999).

## Drugs discovery in Philippine bioresources

### Participating institutions:

UP Diliman	MSI, Biotech Inst., IC
UP Los Baños	IPB, Biotech, IB, IC
UST	NPRI
UP Visayas	Biotech Inst.
Private sector	

### Support Agencies:

DOST PCASTRD, PCHRD, PCAMRD, PCARRD  
Regional/provincial govts  
DOH  
DTI

Specific Needs: Upgrading of manpower and facilities for high throughput screening, microarray, proteomics, genomics  
Bioincubator for purification, testing/bioassay, validation  
IPR

## Enactment and/or Implementation of Enabling Policies and Laws

Regulation of R & D involving genetically modified organisms is covered by an Executive Order which created the National Committee on Biosafety of the Philippines (NCBP). More recently, the Department of Agriculture Secretary Leonardo Q. Montemayor issued DA Administrative Order 8 in May 2002 "Rules and Regulations for the Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology." On June 8, 2002, President GM Arroyo signed the Plant Variety Protection Act of 2002 (RA No. 9168). The Intellectual Property Code of the Philippines (RA No. 8293) was passed into law in 1996. There is also Senate Bill No. 953 introduced by Sen. Manuel B. Villar Jr entitled "An Act Declaring a National Framework for the Protection of Biodiversity in Terrestrial, Aquatic and Agricultural Resources and Creating the Institutional Mechanism for its Implementation." While the bill aims to increase the coverage of protected areas in the country, this bill also provides the conduct of biotechnology activities on the rich flora and fauna genetic resources for drug discovery, mass utilization and eventual commercialization. The bill further proposes the creation of a National Commission on Biodiversity and Biotechnology under the Department of Science and Technology to implement the provisions of the act. These existing and proposed laws and department regulations probably cover all aspects needed to develop bioindustry in the country.

In general, there is a need to assure the support by government in terms of the following:

- a. Sustained national and regional financial support for R & D grants and establishment and running of biopark(s)
- b. Incentives and support to start-ups and private sector, in general
- c. Protection of intellectual properties, support to researchers/institutes in patent preparation and application
- d. Incentives to researchers and their institutes to push the commercialization of their research results

Many countries in Europe and Asia enacted laws to provide funds to support biotechnology R & D and commercialization. The government should find the means to fund such undertakings. Innovative ways to obtain sustainable funds for these should be looked into.

### **Coordination and Orchestration of a Unified Biotechnology Agenda**

To be able to more efficiently and effectively utilize the resources we have, we propose the creation of a national biotechnology oversight committee which can coordinate and orchestrate a unified biotechnology agenda for the country. This recommendation has been presented before at different for a (Mendoza, 2001; Peczon, 2002). Presently, there are at least two biotechnology programs in two Departments, and even in the same department, there is more than one program! The projects will stay in their respective departments, but complementation rather than duplication and cooperation rather than competition will be the rule. Such Committee should also be concerned with commercialization and thus promotion of IP awareness and protection of intellectual properties.

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