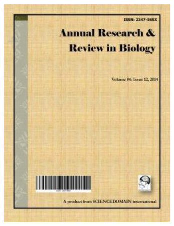

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The Challenges Facing in Commercial Biotechnology: Its Position in Egypt and Some African Countries

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Authors' contributions

This work was carried out in collaboration between the two authors. Author AME designed the study, wrote the protocol and wrote the first draft of the manuscript. Author RM managed the literature searches. Both authors read and approved the final manuscript.

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ABSTRACT

Commercialization of biotechnology can be defined as the conversion of new scientific findings, innovations and discoveries in biotechnology through successful companies and firms or the process by which a product or service in biotechnology is introduced into the general market. Many processes such as sales, production, distribution, marketing, and customer support are required to achieve commercial success. This article deals with factors affecting commercialization of biotechnology in competitive countries and position of biotechnology commercialization in many African countries, including Egypt.

Keywords: Biotechnology commercialization; competitive countries; factors affecting; Africa; Egypt.

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1. INTRODUCTION

There are many important issues to be addressed when commercializing new research in biotechnology. These includes lack of capital and inadequate financial support from governments, lack of commercialization skills and technical personnel, requirement of several specific types of technical personnel such as molecular biologists, immunologist, microbiologists, biochemists, bioprocess engineers, enzymologists and cell culture specialists [1-5]. Most of the commercialized biotechnology depends mainly on biotechnology clusters around universities and institutes dealing with life science research [6,7]. It requires cooperation and actions between government departments, Effective technology transfer, regional economic development agencies, devolved administrations, universities, companies and others [8]. The biggest clusters in the World are San Francisco and Boston areas in USA [9]. In 1973 Stanford's Stanley Cohen and the University of California San Francisco's Herbert Boyer described the practical technique for recombinant DNA production which was the breakthrough that opened up the possibility of using genetic engineering to diagnose and combat disease and other genetic manipulations. In conclusion biotechnology and life sciences are the frontiers of a knowledge-based society. The global biopharmaceutical industries in USA, Europe and Asia Pacific represents an attractive and promising industry of the future [10]. The growth and success of biotechnology sector depends on the ability to take risks, technical, academicians' personals in cooperating with industry and the presence of both good science and good business [11,12]. Chinese are going to be the next generation pioneers providing sustainable support for its Science and Technology (S&T). S&T Development plan in China specifies biotechnology as the first of eight frontier technologies. Gene manipulation and protein engineering are one of the focus areas in biotechnology [13-15].

2. FACTORS AFFECTING THE COMMERCIALIZATION OF BIOTECHNOLOGY

2.1 Governmental Funding of Basic and Applied Research

Basic research is critical to maintain the science base on which a technology rests and to stimulating advances in a technology. Generic applied science can be viewed as bridging a gap between basic science done mostly in Universities & Research Centers and applied proprietary science done in industry for the development of specific products. Generic applied research areas in biotechnology include development of bioreactors, screening of microorganisms for potential products [16]. United States of America has the largest commitment to basic research in biological sciences (95%). Thus have strong basic science base. On the other hand US Government's commitment to generic applied research in biotechnology is relatively small (5%). However the governments of Japan, Germany and UK fund a significant amount of generic applied science in biotechnology. The Japanese Government in contrast is devoting proportionately more public funding to the solution of generic applied science problems than to basic research. For this reason Japan may very well attain a larger market share for biotechnology products than the USA because of its ability to rapidly apply results of basic research available from other countries [17].

2.2 Financing and Tax Incentives for Firms

The availability of venture capital to start new firms and tax incentives provided by Governments to encourage capital formation and stimulate R&D in the private sector are very important to the development of biotechnology [18]. USA has the most favorable tax environment for capital formation and financing small firms. Tax incentives, more than government funding is used to stimulate business and encourage R&D expenditures. The Japanese Government has made the commercialization of biotechnology a national priority and is financing cooperative inter-industry biotechnology projects [19].

2.3 Personnel Availability and Training

Adequately trained scientific and technical personnel are vital to any country's industrial competitiveness in biotechnology. The commercial development of biotechnology will require several specific types of technical personnel such as molecular biologists, immunologist, microbiologists, biochemists, bioprocess engineers, enzymologists and cell culture specialists [20]. USA has a competitive edge in the supply of molecular biologists and immunologists able to meet corporate needs. Like USA, the United Kingdom and Switzerland have funded life sciences well and have a sufficient supply of basic biological scientists. Unlike the USA, Japan, UK, and Germany maintained a steady supply of both industrial and government funding for generic applied microbiology and bioprocess engineering in the past few decades and have adequate personnel in these fields. In Japan and Germany, slight shortages of molecular biologists and immunologists exist. The training of personnel is important to the continuing commercialization of biotechnology. The training of bioprocess engineers and industrial microbiologists will require greater interdisciplinary cooperation between engineering and biology departments within universities. USA has good training programs for basic scientists and does not have more than a handful of training programs for personnel in the more applied aspects of biotechnology. The USA promotes and funds the training of foreign nationals in laboratories in the United States, yet funds very little training of Americans abroad [21,22].

2.4 Health Safety and Environmental Regulation

The analysis of this factor focused mainly on the drug laws for humans and animals, and to a lesser extent, on laws governing the production of chemicals and the deliberate release of novel organisms into the environment [23]. In all competitor countries, there is some uncertainty as to the environmental regulation governing the deliberate release into the environment of genetically manipulated organisms. The United States has the most liberal guidelines, whereas Japan has the most stringent in this respect. Since companies generally approach domestic markets first, the countries with the least stringent regulation may have products on the market earlier. Japan has the most stringent health and safety regulation for pharmaceuticals and animal drugs, followed by USA. Switzerland appears to be the most liberal. The regulatory environment favors the European companies over those of Japan and USA reaching their own domestic markets sooner for pharmaceuticals and animal drugs. A country with liberal regulation may attract production facilities and, as a consequence, gain access to technology. Countries wishing to market their products abroad will have to abide by the regulations of the countries to which they are exporting [24].

2.5 Intellectual Property Law

The ability to secure property interests in or otherwise protect processes, products, and know how will encourage development of biotechnology, because it provides incentives for a private company to invest the time and money for R&D. Without the ability to prevent competitors from taking the results of this effort, many new and risky R&D projects would not be undertaken. A strong intellectual law system will enhance a country's competitiveness in biotechnology. The areas of intellectual property law most relevant to biotechnology are those dealing with Patents, Trade secrets, and plant breeders' rights [25]. The patent laws of the competitor countries provide fairly broad protection for biotechnological inventions, but the laws differ to some degree in the types of inventions that are protected. In this connection, USA provides the widest coverage as patents are available for living organisms (including plants and possibly animals, their products, their components, and methods for making or using all of these. In UK, Germany, France, Switzerland, and Japan, patent coverage is almost as broad, but patents are not permitted on plants and animals or on therapeutic and diagnostic methods. In addition, Switzerland does not permit patents on microorganisms. In Japan, the relatively strict guidelines governing rDNA research also may bar patents on those genetically manipulated organisms viewed as hazardous. USA provides the greatest degree of protection of new varieties of plants, because the plant breeder has the greatest number of options among which to choose in securing property rights for a new variety of plant. US intellectual property system appears to offer the best protection for biotechnology of any system in the world [26].

2.6 University/Industry Relationships

University/industry interactions are very effective way transferring technology from research laboratory to industry. Such interactions promote communication between industrialists and academicians, a two-way interaction that benefits both sides. Industrial scientists learn the latest techniques and research results, while academicians gain increased familiarity with challenges of industrial R&D [27]. Neither Japan nor the European countries have as many or as well-funded university/ industry relationships as the United States does. In Japan, the ties between university applied research departments and industry have always been close. Japanese Government is implementing new policies to encourage closer ties between basic research scientists and industry. The Ministry of Science and Technology in Germany has a history of promoting close contact between academia and industry. Switzerland encourages communication between individuals in academia and industry and relationships are easy to maintain. The Universities in both the UK and France have had few ties with industry in biotechnology, but the governments of both countries have recently set up programs designed to encourage university/industry relationships International Technology Transfer, Investment and Trade.

Technology transfer across national boundaries can be promoted or inhibited by export control laws and by laws governing international joint ventures and technology licensing [28]. The export controls of the United States are the most restrictive one, which include the control of pharmaceuticals and many microorganisms that potentially could be used in biotechnology product production. These controls may have a slightly adverse affect on the competitiveness of US companies commercializing biotechnology because they could cause delays that result in sales being lost to foreign competitors. The US Government has no laws governing international joint ventures and technology licensing among US and foreign companies. As a consequence, technology can be transferred readily to other countries [29]. In contrast, France and Japan have Government programs for the review of potential transnational agreements, but it is uncertain whether such programs help or hinder the transfer of technology into those countries. Foreign exchange and investment, control laws, help prevent, access to domestic markets and technology by foreign firms. The United States has the fewest controls, whereas Japan and France have the most control mechanisms. US markets are the most accessible to foreign firms and therefore the most vulnerable to foreign competition. Trade policy was accessed by examining the competitor countries' abilities to protect domestic industries from imports and to control foreign investment in domestic industries. Trade policy is not important for the commercialization of biotechnology today because of the small number of products that have reached the market and because trade in biotechnologically produced products is not likely to raise any unique trade issues [30].

2.7 Antitrust Law

Antitrust laws are based on the general economic assumption that competition among a country's industries will result in greater productivity, innovation, and general consumer benefits than will cooperation [31]. The antitrust laws of the United States and the other major competitors in biotechnology are generally similar in that they prohibit restraint of trade and monopolization. The other countries are often less restrictive than in the USA. Countries differ in the consequences to firms for failure to comply with antitrust laws. In USA, the consequences of noncompliance can be more severe than in the competitive countries because private, in addition to Government, suits can be brought against alleged antitrust violators, and treble damages are assessed if a violation is found [32,33].

2.8 Government Targeting Policies in Biotechnology

The Governments of Japan, Germany, UK, and France have instituted comprehensive programs to help domestic companies develop certain areas of biotechnology [34,35]. The targeting policies are intended to reduce economic risk and lessen corporate duplication in biotechnology R&D. In Japan and Germany, the Governments carry out their policies mostly through projects that combine the resources of the Government and private companies to meet specific objectives set by the Government. UK and France have adopted a different approach; they support startup of small firms, which are expected to commercialize the results of Government-funded basic and applied research [36-38].

2.9 Public Perception

Public perception of the risks and benefits of biotechnology is of greater importance in countries with representative, democratic forms of government [39]. Because of the greater attention paid to public opinions in democracies and the independence of the media. Public perception could influence commercialization of biotechnology in all the competitive countries in this field. Public perception is probably of greater importance in the United States than other competitor countries. Given the lack of public knowledge in the United States, it is particularly important that the media play a responsible role with respect to biotechnology [40].

2.10 Cultural Attitudes toward Risk-taking

Since investment in biotechnology is considered risky, countries that are more risk averse are less likely to move rapidly to commercialize biotechnology [41]. The United States is not averse to risk-taking in business because risk-taking is a part of the American lifestyle. European countries are more risk adverse [42].

2.11 The Availability of Natural Resources

The absence or presence of certain natural resources may also determine how quickly a country moves into the commercialization of biotechnology. Example: Japan does not have domestic petroleum resources, so it may be more interested in applying biotechnology in the chemical industry because biomass can potentially replace petroleum as a feedstock in the chemical industry [43,44].

2.12 Historical Patterns of Industrial Commercialization

Historically, industries in some countries have moved research results into commercialization rapidly, while industries in other countries have moved more slowly [45,46]. Example: UK has a good science base, trained personnel and industries that could be using these new technologies; however, the UK may not be a major contender in the commercialization of biotechnology mainly because it does not have a history of rapid commercialization. On the other hand USA and Japan historically commercialize scientific advances rapidly.

In this connection, Chinese are going to be the next generation pioneers providing sustainable support for its S&T. As the Chinese economy develops the governmental decision has shifted the national objectives from agriculture to medicine, in addition to other important biotechnology fields, such as environmental protection and alternative energy. The “Medium- and Long-term S&T Development plan in China specifies biotechnology as the first of eight frontier technologies. Focus areas of biotechnology include gene manipulation and protein engineering, stem cell-based human tissue engineering, drug target discovery, animal and plant models and drug design and new generational industrial biotechnology [13-15].

3. POSITION OF BIOTECHNOLOGY IN EGYPT

In a report introduced in 2009 (GAIN Report Number: EG9012- USDA Foreign Agricultural Service) indicated that although Egypt has planted GM corn and cotton in several regions throughout the country to conduct field trails, the situation of biotechnology in Egypt is rather complex. The situation of biotechnology in Egypt is rather complex due to bureaucratic system, lack of institutional development, mistakes on the commercial side and finally the Parliament’s involvement. Egypt consumes large quantities of biotech products such as corn and soybeans, although it has not produced any commercial biotechnology crops. Egypt leads the Middle East and North Africa region in the development and acceptance of agricultural biotechnology. The Agricultural Genetic Engineering Research Institute (AGERI) has developed a number of GM products for commercialization by working with leading biotechnology companies and universities in the United States [47, 48]. Genetically modified organisms (GMO) products that AGERI has considered in research are: tuber moth and fungal-resistant potatoes, virus -resistant squash, sugar cane, figs, and tomatoes, corn borer-resistant, drought resistant, fungal resistant maize, and drought-tolerant rice and wheat (Table 1). Collaboration of AGERI with Monsanto, Cotton Research Institute (CRI) has developed an insect-resistant long-staple GM cotton strain, which is considered the crop No1 for commercialization. AGERI is the main research body of agricultural biotechnology in Egypt. It is a part of the Agricultural Research Center (ARC), which is directed by the Ministry of Agriculture. Although Egypt has ratified the Cartagena Protocol, it does not have national legislation on biotech. It has a general government policy regarding the importation of genetically modified crops into Egypt based on law #53 for 1966. Egyptian government leaders recognize the importance of biotechnology as a tool for national and global development and have set excellence in biotechnology and genetic engineering as a national goal. Egyptian government leaders recognize the importance of biotechnology as a tool for national and global development and have set excellence in biotechnology and genetic engineering as a national goal. The Egyptian government made a strategic decision that the first commercialized GMOs would be products of Egypt’s AGERI/NRC, rather than imported products grown commercially in their country of origin [49].

Table 1. Biotech products approaching commercialization in Egypt

Crop	Trait category
Cotton	Resistance to certain insects such as leaf worm and boll worm
Wheat	Drought tolerance
Maize (already approved)	Resistance to stem borers, and resistant to drought and fungal strains.
Rice	Drought resistance
Potato	Resistance to infestation by potato tuber moth and fungal resistance varieties
Squash	Resistance to a major viral pathogen (ZYMV)
Sugarcane	Virus resistance
Figs	Virus resistance

The following are some examples of application of biotechnology in Egypt :- Genetically Modified Organisms (GMO), Transgenic crops, Recombinant DNA Technology, Transgenic animals, Restriction Enzymes, PCR and the use of Reverse Transcriptase to clone expressed genes. The success of Egypt's public health system has been traditionally measured by its ability to satisfy local demands and to respond rapidly and effectively in times of crisis. For example, the Egyptian authorities were able to respond to a shortage of insulin, through the rapid local development of recombinant human insulin.

Egypt has had similar success in producing diagnostics and treatments for hepatitis B and C. There is a large discrepancy in available estimates of the incidence of the hepatitis C virus (HCV) in Egypt: the government estimates 7–8% of the population are infected, whereas the World Health Organization (WHO, Geneva, Switzerland) puts the figure at 15–20%. Researchers at the National Cancer Research Centre (Cairo) have also developed a new synthetic peptide of the core protein, which demonstrated 99%sensitivity and 100% specificity for HCV antibody in serum that could be used in large-scale population screening of HCV infection. The Schistosomiasis Research Vaccine Development Project has been initiated in cooperation with US partners to help combat the disease in Egypt. The project's aim is to develop the two vaccine candidates, paramyosin and the synthetic peptide called MAP4, identified by the WHO. On the other hand the success of Egypt's Agricultural biotechnology sector can be measured by its capability to produce some transgenic plants resistant to indigenous biotic and abiotic stress, to reduce the use of agrochemicals and pesticides and their environmental risks, to improve the nutritional quality of food crops and to reduce the dependency on imported agricultural seeds and crops-products.

The aim of a research conference held at the AUC new campus in Cairo, Egypt (April 5, 2009) was to present examples of ongoing biotechnology research activities in Egypt with focus on agricultural and biomedical biotechnology and to highlight the expansion of academic biotechnology research to industry. Participants gave a general overview of ongoing research activities that would contribute extensively to the biotechnology industry. Egypt has dealt with biotechnological needs in several sectors including the biomedical sector by local synthesis of needed biotechnology products. (e.g, Recombinant human insulin). Local Egyptian companies have successfully produced other biological products including recombinant human interferon α-1b, erythropoietin α and streptokinase. Hamza El-Dorry from the American University In Cairo, discussed a project entitled "Genomic approach for ethanol fuel production from cellulose from *Trichoderma ressei*. Mahmoud Sakr at the CEAS and GEBD, NRC, in Cairo, Egypt discussed ongoing research and development in Egypt that allowed the launching of new local biotechnology products. One of these activities is the establishment of a pilot unit for the application of genetic engineering and biotechnology. Examples of their biotechnology diagnostic and research kits products include: QTEST™ Brand Name diagnostic Test Kits for the treatment of congenital haemophilia, Peroxidase and urease diagnostic kits, Triplet PCR for HCV detection kit, Plasmid DNA isolation kit. Dr. Mohei ElDin Soliman, at the vaccine development unit, NRC also discussed efforts in designing and engineering hepatic C virus vaccines. From the agricultural biotechnology aspect they also discussed genotyping Egyptian barley resistant to net blotch disease, biopesticides and biofertilizers, Virus-free potato seeds, tissue culture plants and transgenic plants [50,51,52]. Many problems faced the development of biotechnology in Africa such as poor funding of research, shortage of skilled manpower and lack of appropriate policies and civil strife. Nevertheless, countries like Egypt, South Africa, Zimbabwe and Kenya are taking practical steps to ensure that they can use biotechnology for sustainable development [53]. Egypt was one of African countries to realize the importance of genetically modified (GM) crops in achieving sustainable agriculture. Technology transfer and building capacities for the development of agricultural crops through biotechnology started in 1990. GM technology has been developed to solve the problems of hunger and poverty, and also to create job opportunities and improve the quality of life in developing countries. In 2008, Egypt approved the cultivation and commercialization of a Bt maize variety, marking the first legal introduction of GM crop into the country. In South Africa GM crops have been in commercial production since 1997, when Bt cotton and maize were approved by an advisory committee acting under interim legislation [54]. In general, biotechnology will suffice as a revolution in every discipline of life sciences including veterinary medicine and advanced bio-molecular engineering and biotechnology in many parts of Africa. Egypt has demonstrated the precedence in the African continent in the application of Biotechnology in the diagnosis in veterinary medicine [55]. The agricultural sector in Egypt contributes to the overall food needs of the country, and provides the domestic industry with agricultural raw materials. The next steps that has been taken from the agriculture sector in EGYPT include Removing governmental constraints on the private sector in importing and exporting agricultural crops, Imposing limitations on state ownership of land and sale of new land to the private sector, gradual removal of governmental controls on farm output prices and Increasing farm-gate prices to cope with international prices. Egyptian Government reported that commercializing biotechnology products for the first time in Egypt is a big challenge and some issues related to transparency and clearness should be considered and all information related to the process of production and commercialization should be available for all partners at the same level. Future Egyptian Government goals in agriculture biotechnology are to develop drought and salt tolerant crops as well as pest and disease resistance traits through highly qualified professionals in biotechnology in Agricultural Research Centre (ARC) and Agricultural Genetic Engineering Research Institute (AGERI). In Egypt construction has already started public-private project to develop an internationally ranked graduate school that would build the region's next generation of scientists, entrepreneurs and technologists.

4. POSITION OF BIOTECHNOLOGY IN SOME AFRICAN COUNTRIES

African countries investment in biotechnology and R&D depends mainly in partnership with private and sector institutions of the North indicating that they believe in the promise of biotechnology in impacting agricultural growth and development [56,57]. The status of African countries involved in biotechnology R&D indicates that nine African countries are engaged with biotech crop-improvement at various stages of laboratory, green-house, and CTFs (Table 2). Four of these countries South Africa, Sudan, Burkina Faso, and Egypt have commercialized some biotechnological crops, and have others in the R&D [58,59].

Table 2. Status of some African countries investment in biotechnology

Country	Type of investment
Uganda	Biotech crop R&D improvements on maize, banana, cassava, cotton, sweet potato, and rice.
Burkina Faso, Malawi, Sudan, Cameroon	Focusing on cotton improvement.
Nigeria	Working on biotech crop R&D for improvement of cassava, cowpea, and sorghum.
Kenya	Conducting biotech R&D for improvements of maize, cotton, cassava.
Egypt	Has biotechnology R&D for improvement of maize, cotton, wheat, potato, tomato, sugarcane, rice, and strawberry.
South Africa	Has biotech R&D for improvement of maize, cotton, cassava, potato, flower bulbs, and sorghum.

In conclusion, in the past two decades increased investment in biotechnology research and development R&D by many African countries were reported. The levels of investment and the nature of activities in biotechnology vary from one country to another and from one sector to another. The entry of African countries into biotechnology has been stimulated by the cumulative nature of the technological change in biotechnology. Egypt, South Africa, Kenya, Zimbabwe and Nigeria have a long tradition of scientific research conducted in reputable institutions. Their accumulated experiences have made it possible to jump into the second generation of biotechnology. Scientists classified three categories of African countries in biotechnology. The first category includes those countries that are generating and commercializing biotechnology products and services using third generation techniques, such as Egypt, South Africa and Zimbabwe. The second category includes those countries that are engaged in third generation biotechnology R&D but not developed products and processes yet, such as Ghana, Ughanda and Kenya. The third category includes those African countries whose their biotechnology activities have focused on enhancing agricultural productivity such as Zambia and Tanzania [60]. Egypt and South Africa are biotechnology leaders in Africa. They have considerable scientific infrastructure and clear programs. They have focused on cutting-edge biotechnology areas and they have commercialized some of their products. Egypt has mainly invested in genetic engineering of tomatoes, potatoes and maize, while South Africa has focused on genetic engineering of cereals such as wheat, maize, barley, sorghum, millet, soybean as well as lupins, sunflowers, sugarcane, vegetables and ornamentals [61-64] .

5. CONCLUSION

In order to maintain competitive advantage in the commercialization of biotechnology increased funding of research and training personnel in basic and generic applied science may be necessary. Japan is the most serious competitor of USA in the commercialization of biotechnology. Japan has a very strong bioprocess technology base. Government has specified biotechnology as a national priority. Germany, UK, Switzerland, and France lag behind the United States and Japan in the commercialization of biotechnology. The European countries generally do not promote risk-taking; either collaboration of AGERI with Monsanto. Cotton Research Institute (CRI) has developed an insect-resistant long-staple GM cotton strain, which is considered the crop No1 for commercialization. European countries are not expected to be as strong competitors in biotechnology as the United States and Japan. The Agricultural Genetic Engineering Research Institute (AGERI) in Egypt has developed a number of GM products for commercialization by working with leading biotechnology companies and universities in the United States. Concerning the position of biotechnology in Africa South Africa, Sudan, Burkina Faso, and Egypt have commercialized some biotechnological crops, and have others in the R&D. Egypt and South Africa are biotechnology leaders in Africa. They have considerable scientific infrastructure and clear programs and they have focused on cutting-edge biotechnology areas.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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