120

Biotechnopreneurship: A Resource for the Developing Countries

Tapaswini Swain
Entrepreneurship Development Institute of India
Ahmedabad

Abstract

Biotechnopreneurship is based upon the integration of two distinctly different disciplines – science and business and all the activities necessary to build an enterprise. Biotechnology enterprise creates, develops and ultimately commercializes a product only through integration of science and business disciplines. Biotechnology enterprises have created some of the most amazing life-saving drugs, medical devices, advanced fuels, and efficient crops. Biotechnopreneurship is a complex phenomenon with several intricacies which needs thorough research to identify conditions which are prevalent and can determine the successful development of enterprises at both national and regional level. A certain part of the research should focus on specific characteristics and profiles of bio-entrepreneurs who are the key players in the process of development. The two major areas capturing the attention of the world for intensive commercialisation are Industrial biotechnology and Medical biotechnology. There is large scope and need for entrepreneurs in this sector who can contribute remarkably to the people and society at large. This paper peaks into the topic to show the need of entrepreneurs in Biotechnology field, challenges faced in the sector and how it has the potential to bring about economic development.

Keywords: biotechnopreneurship, bio-entrepreneurs, prospects, challenges.

Biotechnopreneurship is the sum of all the activities necessary to build an enterprise through the melding *of both scientific and business disciplines.* An enterprise creates, develops, and then commercializes a biotechnology product only through integrated activities. Some of the most amazing lifesaving treatments and medical devices, advanced fuels, and efficient crops, have been created and developed through biotechnology enterprises. The process of entrepreneurship does not rely on one single entrepreneur in biotechnology. It is a distributed process in the sense that it is a mix of competences distributed over a wide range of individuals and organisations. Distributed entrepreneurship is a promising approach where entrepreneurship arises with a collective network of heterogeneous actors, who are inseparable from each other.

The biotechnology industry is characterized as follows

- Long to very long product development lead times
- Highly capital-intensive
- Regulation is high
- Extensive scientific skill sets and thorough technical knowledge is required
- One of the most research-intensive industries in the world

- In several cases, ethical committee approval is required, especially involving animal/human trials;
- One of the most essential component, is Intellectual property rights protection in Biotechnology.
- Collaborations, strong linkages and strategic alliances established with universities, government and private institutions and other biotechnology companies;
- Raising of capital, is crucial and consumes a significant amount of time and resources.

The following essential elements of entrepreneurship apply in the biotechnology industry

- Opportunity recognition
- Product knowledge
- Market knowledge
- Strong desire to innovate
- The ability to effectively employ resources
- Presence of high risk taking propensity, which is the most recognizable of all elements amongst entrepreneurs.

There are similarities between biotechnology entrepreneurship and general entrepreneurship activities.

- Both need a competitive idea,
- Both need an experienced team to lead and manage the functions of the enterprise
- Both require the capital to support the endeavour through innovation to commercialization
- Both require consistent endeavour and perseverance to overcome obstacles, encountered along the way.

However, the differences between these two entrepreneurial paths are way greater than their similarities.

- Biotechnology endeavours come with unique challenges which other entrepreneurial endeavours do not face, this includes the need for exorbitant amounts of money to make incremental product development progress, longer product development lead times, and stiffer regulatory approval formalities in order for products to be commercialized.
- Biotech products also have an inherent scientific uncertainty which often is not fully appreciated.

Role of Biotechnopreneur

Successful development of biotechnology enterprises at the national or regional level needs further systematic research. An important part of this research should mainly focus on the profiles and distinct characteristics of bio-entrepreneurs. Bioentrepreneurs look for commercial value in every aspect of biotechnology that they intend to utilize. Innovativeness is vital for a biotechnology venture creation and credibility serves as the backbone of the bioentrepreneur's character. Several academic and professional papers have thoroughly analysed and discussed the profile of a successful bio-entrepreneur in detail on an intuitive basis without any supporting empirical evidence. Walton (1998) has indicated the following characteristics of an ideal bio-entrepreneur

- Articulating plans with a charismatic personality
- Skilled manager
- Expertise and master of technical knowledge in the specific area
- Super-energetic to the point of being 'driven'

- To be able to lead
- Consistent track record and prior experience.

The typical bio-entrepreneur who starts a biotechnology company usually comes from one of the four background types, mentioned below. Each of these backgrounds comes with their own strengths and weaknesses. The four most common backgrounds of bio-entrepreneurs include the following

1. Scientist /Bioengineer who comes from an academic institution (University, Research Foundation, Non-profit Research Institute).
2. Scientist /Bioengineer who comes from another biotechnology company.
3. Businessperson, such as a former executive in biotechnology, pharmaceutical or venture capital industry, who is not a Scientist/Physician/Bioengineer.
4. Core Team of Individuals from a different biotechnology company.

Biotechnopreneur's profile study can be used at three different levels

Using a combination of quantitative and qualitative techniques, several research studies can be conducted to delve deep into the prevalence of different bio-entrepreneurs 'profiles. Such studies are further needed in order to identify the interrelationship between economic, social and cultural environment and the distinct characteristics of a successful bio-entrepreneur.

Bio-entrepreneurs can use such extensive exploratory studies to recognise the areas of expertise which needs to be covered by entrepreneurial team to increase the chances of acceptance and success of the new venture.

Government entities can utilise such research results to offer more effective training courses and consultancy support to budding biotechnology ventures. It is possible to propose a model of bio-entrepreneur competencies which comprise three progressive levels:

- Vision, commitment, proactiveness, Knowledge, leadership, and effective communication are required for biotechnopreneurs.
- Scientific expertise, product and market knowledge, capacity to raise capital, to build the intellectual property portfolio, clinical trials management and regulatory issues are required for biotechnology enterprise.
- The qualities required national biotechnology market in large.

Objectives

- To identity the distinct characteristics and competencies of bio-entrepreneurs requisite for success of Biotechnology enterprises.
- To thoroughly study the biotechnology entrepreneurship ecosystem in developing economies.
- To elucidate the themes identified in Biotechnopreneurship through literature review**.**
- To identify the challenges faced by Biotechnology industry and recommend suitable strategic solutions.

Review of Literature

Mehta (2004), based on empirical evidence describes a more complex model of bio-entrepreneurship. The model involves, the creation of a new biotechnology venture comprising of two main types of bio-entrepreneurs:

- 'Founder-inventor of technology'
- 'Founder-market perceiver'.

In most cases, a successful biotech venture is the result of the collaboration between a scientist and a businessperson. The team of bio-entrepreneurs will then use their complementary competencies to lead the newly created biotechnology firm through the necessary stages of development.

Persidis (1996) has explained bioentrepreneurship as application of the biological sciences in the business context for wealth creation. Proactiveness and innovativeness are vital for the creation of a biotechnology venture while credibility remains the backbone of the bioentrepreneur's character. Bioentrepreneurs seem to occupy the highest end of the educational spectrum. According to Janietz, 2003, the majority of biotechnology ventures are started up by graduates, postgraduates and doctoral students. Bioentrepreneurs are much older at the initiation stage of the biotechnology enterprise as compared to the conventional entrepreneurs. This difference in age is mainly due to the length of time spent in education and acquiring skills at university, as well as the time required to develop a scientific idea into a commercially viable product.as opposed to conventional entrepreneurship, intellectual capital commonly resides with bioentrepreneurs and can be the source of a biotechnology venture's competitive advantage (Schneider 2002). S. Casper (2009) has predicted the future growth and competitiveness of the developing country Argentina's biotechnology sector to be determined by six factors:

- Scientific capital, comprising of scientists with their deeper knowledge and experience
- Scientific and academic institutions
- Human capital mainly comprising of three kinds of personnels: scientific and managerial, entrepreneurial
- Access to appropriate technology and scientific patents
- Financial capital
- Clusters, accelerators, and incubators.

Biotechnology Ecosystem

Role of Government

Government's involvement as a policymaker and as a funding partner leads to success in developing economies. For more than 30 years, the governments of most developing nations have carried out research and entrepreneurship in Biotechnology, when the biotechnology industry was in its infancy in developed economies. For example, India focused on the developing its pharmaceutical and biotechnology sectors as early as 1980 (Thorsteinsdottir 2004). India has created a devoted Department of Biotechnology and has invited several international and regional experts as a part of its committee to maximize the usage of government funds (Verma, 2005). Similarly, Egypt has adopted a comprehensive to secure the health sector of its citizens and to plan a thorough systematic course of action for the nation's expanding biotechnology industry which will ensure that its resources will be used effectively whenever crises arise in the future (Thorsteinsdottir 2004). In South Africa, government resources devoted for the R&D of biotechnology are meagre, still the nation's leaders are committed to innovation and have made scientific research a national priority. This approach has resulted in strong emphasis on top national and social concerns like HIV/ AIDS research and fatal infectious disease treatment (Burton 2002). In Argentina, the government accounts for 65 percent of the total funding's, with 43 percent fixed for public entities and 22 percent for public universities.

Niches Defined by Rich Resources

Developing nations have successfully utilized their natural resources and traditional competencies to create a well-established biotechnology industry. For example, India has capitalized on its highly educated youth population and its large pool of well-trained science and technical experts to bring in foreign investment (Jayaraman 2004). Brazil has used its abundant natural resources from the Amazon rainforest to create a $3 billion industry linking private companies, foreign investment entities, and university research entities. Brazil's animal biotechnology industry is one of the largest in entire Latin America and the fifth largest in entire world, producing vaccines for farm and domestic animals (Resende 2003). Cuban scientists

have created pharmaceutical medicines, derived from the sugarcane plant – mainly PPG, a cholesterol-lowering agent which is exported to several developing nations (Carr 1999). In Egypt, there has been a breakthrough in the area of plant biotechnology which witnessed the initial development of a plant-based hepatitis B vaccine that is way cheaper and allows widespread immunization (WHO, 2001, Ciccio 2004, Thorsteinsdottir 2004). South Korea is mainly based on its traditional low-cost technological innovation and an educated, skilled workforce to gain a competitive advantage over others. Its biotechnology companies have expertise in the production of next generation biotechnological products like microarrays, biochips, and bioinformatics where skilled, experienced workers are able to leverage limited resources to obtain dramatic profits exponentially (Wong 2004).

Health and Education Sector

Healthcare and educational system are the backbones for the development and sustained growth of any economy. For example: Cuba's health and its research system are inseparable; each and every health center is part of a national clinical trial program. Its citizens enjoy a relatively high standard of health compared to other developing nations, with an average life expectancy of 76.7 years even though the research centers suffer from a lack of funds. (UNDP 2004b). The decentralization of China's educational system along with the traditional emphasis on merit-based promotion has fuelled its tremendous growth with a vast educated man force that has the skills needed for a demanding industry like biotechnology (Mok 1999). India similarly benefits from a cultural emphasis on education and the willingness of its youth to learn and develop new scientific and technical skills.(Verma 2005).

Private-Sector Support

There is significant contribution of the private sector in the biotechnology industry in developing economies. Government funding has been viewed as the primary source of capital for biotechnology research, but now in many countries this pattern is changing. For example: South Korea is the pioneer among prosperous developing countries in terms of private-sector involvement. They have successfully created a model that in many ways mimics the business model of the United States of America (Wong 2004). China has recently adopted a business model that promotes free-enterprise creation. Several public research institutions are converted to private companies, with both scientists and academicians working together in collaboration (Thorsteinsdottir2004a.India's reputation as an outsourcing destination and generic drug powerhouse is being leveraged to create a biotechnology sector that specializes in modifying existing chemical entities to create new improved genomic products (WHO2004). These outstanding efforts highlight the important role that the private sector plays in promoting sustainable development and growth in research.

Thematic Identification

The patterns which served a function in the other patterns were only considered for inclusion as themes.

Theme 1

"The practice of biotechnopreneurship involves interplay of a dual approach, which can be seen as a "system" or as an "individual".

There is interplay of dual approaches to the process of biotechnopreneurship in developing economies. For instance, due to availability of infrastructure and support structures, in Brazil, the "system" approach to biotechnology entrepreneurship was adopted. On the other hand, the lack of infrastructure and support structures in South Africa, led to adoption of the "individual" approach to biotechnology entrepreneurship.

Theme 2

"Opportunities in Biotechnology can be found in the form of issue, efficiency, and innovation scopes".

Most of the entrepreneurial opportunities in Biotechnology are present in the areas of biodiversity and problems pertaining to diseases and food security. Such opportunities, linked to the problems of diseases, food security, environment and energy are referred to as "Problem opportunities." The second form of

entrepreneurial opportunities in Biotechnology identified by the respondents is designated as "Efficiency opportunities", which occurs in the areas of bioprocessing, biomanufacturing, biodiversity, bioenergy, genomics and pharmaceuticals.

Theme 3

"An overall conducive business and regulatory environment is vital for the effective development of Biotechnopreneurship."

The issues prevalent in developing countries include a policy and regulatory environment which is not conducive to biotechnopreneurship; lack of appropriate and sufficient funding; the habit adopted by universities to prioritise publications over commercialisation of research; lack of government's proactiveness, leadership skills and management; lack of clear vision and commercialisation skills; and lack of a well-developed market for biotechnology products.

Theme 4

"Research and development is the most crucial and defining step in Biotechnopreneurship".

For research and development to be effective in any country, there are certain primary requirements which need to be fulfilled. These include well equipped universities and research institutions, a well-developed scientific research curriculum at par with developed nations, a national culture supporting scientific investment and rigor, a favourable regulatory environment supporting research and talented diligent and self-motivated individuals. The funding reserved for R & D is perceived to be inadequate and seen as a major gap towards the development of the biotechnology industry.

Theme 5

"There are mainly four kinds of skills required in biotechnopreneurship: research, scientific, entrepreneurial, and commercialisation skills".

Al four kinds of skills may not be present in the context of a developing country. For example, scientific and research skills are available in abundance in South Africa, whereas the entrepreneurial and commercialisation skills are lacking there but present in other developing countries.

Theme 6

"Strategic collaboration among key stakeholders is crucial for the development of biotechnopreneurship in developing economies".

The importance of effective collaboration is manifested among the stakeholders in biotechnology entrepreneurship in developing economies when there are collaborative assignments, leading to positive outcomes and not so effective collaboration when there are more numbers of negative outcomes.

Theme 7

"The government plays a vital role in biotechnopreneurship in developing economies".

The challenges to biotechnopreneurship identified are mostly in areas of government responsibility such as the policy and regulatory environment; bureaucracy politics; corruption, inefficiencies of the government agencies; high cost of funding; lack of government leadership. The role of the government in biotechnology entrepreneurship is not only to provide a conducive regulatory environment but also to act as a facilitator (Fontes, 2001; Muller, 2004; Ahn and Meeks, 2007; Nilsson, 2010). The regulatory environment comprises of the policies and laws that have tremendous impact on biotechnopreneurship.

Theme 8

"Funding is a critical factor in biotechnopreneurship in developing economies".

The government is considered to be the only sole source of funding for biotechnopreneurship in most of the developing economies. In terms of risk profile and timeframe constraints, government funding is mostly

not appropriate for the type of the biotechnology industry. Developing economies mainly depend upon government funds owing to the lack of a developed venture capital industry for biotechnology industry (Audretsch, 2008) unlike in developed economies where venture capital funding is a core component of biotechnopreneurship.

Challenges Faced by Biotechnology Industry

- There is a need to increase research on Biotechnology entrepreneurship education at all levels. There is a need for both the entrepreneurial biotechnology theoretical learning and practical training courses in the universities, including subjects from business management. There should be a perfect amalgamation of biotechnology courses and business management for boosting entrepreneurial spirit among students at a very early age. The graduates after passing out would be in position to set-up their own biotechnology enterprises instead of seeking for government or private jobs.
- Bio-networking is recognized as an effective tool for interaction, which include formulation of policies and plans to integrate related biotechnology enterprises. It would also encompass issues related to biosafety and bioethics, intellectual property rights and regulations,
- There is a need for development of more specialized human resource capital which could be achieved by setting-up of educational programs in biotechnology which should be accessible to the far flung areas too.
- There is an acute shortage of expertise in India particularly in taxonomy (the science of the classification of the living and extinct organisms) and microbial ecology. We need to take urgent steps to rectify this.
- Formulation of a policy to regulate the procurement and sale of medicinal plants in India.
- There is only one international depository authority (IDA) in the country at the Microbial Type Culture Collection at IMTECH, Chandigarh; but for securing IPR interests, few more centres as IDAs should be established.
- End products from bioprospecting need to be tested for a variety of parameters before commercial production can begin. There is a need to set up appropriate facilities and norms for such late stage testing of products.

Recommendations

- Government should develop a definite policy and a systematic roadmap for implementation of new biotechnopreneurship curriculum that may be developed in due course. Project work in collaboration with biotechnology companies or premier research institutes like CSIR and DBT would be the best way to allow students to have industry experience and develop appropriate knowledge and skills.
- Training of University lecturers should be done in regular intervals, this could be an effective way of evaluating and assessing progress of the trainer and lecturers.
- Further research can be done to study the variability of bio-entrepreneurs profiles in depth by using a mixed method which is a combination of quantitative and qualitative techniques. Such studies are needed to identify the causal connections and the interrelationship among the economic, social and cultural environment and the specific characteristics of a successful bio-entrepreneur.
- Government organisations can utilize research outcomes to offer more targeted and effective training courses and consultancy support to the new biotechnology enterprises.

- Support to capacity building in microbial taxonomy through intensive training programmes at graduate and post-graduate levels can be given.
- Promotion of horizontal networking between remote sensing experts, field biologists and computer specialists for inventorisation of bioresources based both on primary and secondary sources of information.
- Promotion of closer and effective interaction between biotechnologists, foresters, oceanographers and field biologists.
- Close working relationship should be established between field scientists, pharmacologists and clinicians so that an all-round integration is achieved.
- Public-private partnerships need be promoted for product innovation and drug commercialization.
- A gene bank should be created for maintaining 'mined' genes.

Conclusion

Biotechnopreneurship is now one of the key areas driving the frontier of knowledge and job creation leading to economy development of the nations. The provision of research grants is meagre for research and development, which is a major issue of sustenance of biotechnology enterprises in developing nations. Financial budget allocation for biotechnology companies should be high on government policy and educational agenda. Biotechnopreneurship can only be entrenched in developing countries with the establishment of a strong research base and business culture. Finally, any country that can assist its scientists and entrepreneurs in successful biotechnology start-ups will enjoy economic growth.

References

Ahn MJ, Meeks M (2007). Building a conducive environment for life science-based entrepreneurship and industry clusters. J. Comm. Biotechnol. 14(1): 20-30.

Alper, J. (2002) _The rise of the European bioentrepreneur', *Nature Biotechnology*, Bioentrepreneurship Supplement, Vol. 20, pp.3–5.

Audretsch DB, Stephan PE (1998). How and why does knowledge spill over? The case of biotechnology. CEPR Discussion Papers.

Audretsch DB, Taylor Aldridge T, Perry M (2008). A survey review of university biotechnology and entrepreneurship commercialization. Handbook, Bioentrepreneurship. pp.175-187

Burton SG, Cowan DA. Development of biotechnology in South Africa. *Electronic J Biotechnology*. 2002;5(1). Available at: «http://www.ejbiotechnology. info/content/vol5/issue1/issues/03/index.html». Accessed Dec. 7, 2005.

Carr K. Cuban biotechnology treads a lonely path. *Nature*. 1999; 398 (suppl):A22–A23.

Ernst and Young (2000) _Evolution', *Seventh Annual European Life Sciences Report 2000*, London: Ernst and Young International.

Fontes M (2001). Biotechnology entrepreneurs and technology transfer in an intermediate economy. Technological forecasting and social change. 66: 59-74.

Gillis, S. (1998) _Factors for success in biotechnology: then and now', *Nature Biotechnology*, Bioentrepreneurship Supplement, Vol. 16, pp.9–10.

Hodgson, J. and Ward, M. (2003), _The habits of successful bioentrepreneurs, *Bioentrepreneur*, 23 June, http://www. nature.com/cgitaf/gateway.taf?g=6& file=/bioent/building/entre/ 062003/full/ bioen t740.html (accessedDecember 2004).

Janeitz, E. (2003), _Biotech _ medicine', *Technology Review*, **106** (8), 72–9.

Lähteenmäki, R., Plant, D. and Michael, A. (1997) _Europe's enthusiasm for entrepreneurism',Nature *Biotechnology*, Vol. 15, No. 9, pp.852–853.

Marcel, T. (1999) ‗An emerging European model for bioentrepreneurship', *Nature Biotechnology*, Bioentrepreneurship Supplement, Vol. 17, pp.9–10.

Mehta, S. (2004) ‗Paths to entrepreneurship in the life sciences', *Bioentrepreneur*, October, Vol. 26, http://www.nature.com/cgi-taf/gateway.taf?g=6&file=/bioent/building/entre/102004/full/bioent831.html (accessed December 2004).

Müller C, Fujiwara T, Herstatt C (2004). Sources of bioentrepreneurship: the cases of Germany and Japan. J. Small. Bus. Mngmt. 42(1): 93-101.

Nilsson A (2001). Biotechnology firms in Sweden. Small Busin. Econ.. 17(1): 93-103.

Persidis, A. (1998) ‗Bioentrepreneurship around the world', *Nature Biotechnology*, Bioentrepreneurship Supplement, Vol. 16, pp.3–4.

Rienhoff, Jr., H.J. (1998) ‗Becoming a bioentrepreneur', *Nature Biotechnology*, Bioentrepreneurship Supplement, Vol. 16, pp.37–38.

Saxenian AL. The Silicon Valley-Hsinchu connection: technical communities and industrial upgrading. *Berkeley Planning Journal*. 2001;15:3–31.

Schneider, J. (2002), ‗Intellectual property: the driving force for growth and funding', *Journal of Commercial Biotechnology*, **8** (4), 320–24.

S. Casper, *The Marketplace for Ideas: Can Los Angeles Build a Successful Biotechnology Cluster?* Report to the John Randolph Haynes Foundation, Keck Graduate Institute of Applied Life Sciences, 2009;

Shane SA (2003). A general theory of entrepreneurship: the individual-opportunity nexus. Edward Elgar Publishers, UK.

Thorsteinsdóttir H, Quach U, Daar AS, et al. Conclusions:promoting biotechnology innovation in developing countries. *Nature Biotechnology*.2004a;22: DC48–DC52.

Thorsteinsdóttir H, Sáenz TW, Quach U.Cuba – innovation through synergy. *Nature Biotechnology*. 2004b;22:DC19–DC24.

Verma I. Then and now. *Nature*.2005;436:478–479. Available at: «http://www.nature.com/nature/journal/ v436/ n7050/full/436478a. html». Accessed Dec. 7, 2005.

Wong J, Quach U, Thorsteinsdóttir H, etal. South Korean biotechnology – a rising industrial and scientific powerhouse. *Nature Biotechnol.* 2004;22:DC42–DC47.