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Keynote Speech

India's Bioeconomy: A Brief Overview of the Status, Challenges and Opportunities

Jeena T Srinivasan
Associate Professor, Centre for Economic and Social Studies, Nizamiah Observatory Campus, Begumpet, Hyderabad, India

Abstract
The Bioeconomy sector of India of which biotechnology is a major driver of growth has set a major goal of growing from its' current $4.3 billion to about $100 billion by 2025. The bio-pharmaceutical sectors followed by agricultural biotechnology are industry's biggest sources of revenue. However, these sectors which have tremendous potential to contribute to the economic growth of the country and to contribute towards addressing some of the major problems that the country faces, such as, food security and health of the population is also facing several challenges. Against this background, this paper presents an overview of the status of the Bioeconomy sector, the opportunities and challenges faced by the sector in India with specific reference to health and agricultural sectors. The paper also briefly touches upon the way forward for India to utilize the full potential of this sector to address food security, and health concerns of its population and also to contribute to the country's economic growth.

Keywords: Bioeconomy, biopharmaceuticals, biotechnology, India
****Corresponding author:*** Jeena@cess.ac.in

Introduction

The Indian economy which saw initiation of major economic reforms in the early 1990s has grown to become one of the fastest growing economies in the world along with China and even surpassing it in growth despite the global recession and melt down in the recent years. Despite the impressive growth rates recorded for over a decade or more, India is the home not only to large number of world's poor but also to it's under nourished people. The pressure on land and other natural resources are very high, and the benefits that have been brought out by Green Revolution since the early 1960s have largely faded away due to excessive use of chemical fertilizers and pesticides as a result of which most of the land resources are in a degraded condition. Not only that, India also faces huge challenges in terms of population growth and related health and malnutrition concerns. Solution to these challenges lies in increasing agricultural productivity and improved health care through technology. Several studies have argued that biotechnology can improve agricultural production by promoting the use of disease resistant crops, enhance the flavor and nutritional value of food products and subsequently impact global health and economies, especially and among developing nations and thus biotechnology can have a lasting impact on global agriculture sector and can play a significant role in improving economies across the globe. It is in this context that biotechnology has emerged as one of the major engines of growth not only to address growth of India but also to build upon it current strength as a global destination for innovations in biotechnology. The Biotechnology Industry Organization and the Association of Biotechnology Led Enterprises provide a white paper titled 'Accelerating Growth: Forging India's Bioeconomy' and observes that the Indian Bioeconomy grew to $ 4.3 billion at the end of fiscal 2013, from $530 million in fiscal 2003. India's biotechnology industry started in 1978 with the founding of Biocon and the industry today has over 350 companies working in the areas of vaccines and biopharmaceuticals, agricultural biotechnology, industrial biotechnology, bioservices and bioinformatics and is mostly concentrated in Bangalore and Hyderabad though it also spreads to other parts of the country.

But this important sector currently faces several challenges which are both related to policy as well as regulatory environment. In such a situation, an obvious question which arises is whether India can really sustain and accelerate its growth in its Bioeconomy and become a global destination for innovations in biotechnology? Where does India stand in terms of its strategies on Bioeconomy and what are it the opportunities and challenges that India faces. The modest objective of the paper is to throw some light on the above issues, with specific reference to health and agriculture sectors in India.

The rest of the paper is divided into the following sections. Section 2 briefly reviews the concept of Bioeconomy and then specifically

focus on how it is understood and defined in the Indian context. Section 3, discusses, health sector followed by a discussion on agricultural sector. In section 5, some of the major hurdles or constrains that India faces in promoting Bioeconomy discusses the way forward are discussed.

The Bioeconomy in India

The use of the term Bioeconomy is only a few decades old and was probably first defined by Juan Enriquez-Cabot and Rodrigo Martinez in 1997 (Enriquez 1998) though better accepted definitions evolved slowly. According to the Bioeconomy Council of the German Government "Bioeconomy is the knowledge-based production and use of biological resources to provide products, processes and services in all economic sectors within the frame of a sustainable economic system." (Bioeconomy Council 2013). The European Commission (2012) defined it as, 'the Bioeconomy encompasses the production of renewable biological resources and their conversion into food, feed, bio-based products and bioenergy. It includes agriculture, forestry, fisheries, food and pulp and paper production, as well as parts of chemical, biotechnological and energy industries. Its sectors have a strong innovation potential due to their use of a wide range of sciences (life sciences, agronomy, ecology, food science and social sciences), enabling and industrial technologies (biotechnology, nanotechnology, information and communication technologies (ICT), and engineering), and local and tacit knowledge.'

In India, the Ministry of Science and Technology drafted a National Biotechnology Development Strategy in 2007 which was updated in 2014. It uses the term' bio-economy' which it understands as 'translating life sciences knowledge into socially relevant ecofriendly and competitive products'. In India, biotechnology is the important driver for Bioeconomy and therefore, growth of biotechnology sector is important in country's assessment in the area of Bioeconomy. Biotechnology is applied in the field of agriculture health, energy, environment and manufacturing. These include the red biotechnology sector (pharmaceuticals and personalized medicine), the green biotechnology sector (transgenic plants and cloned animals) and the white or industrial biotechnology sector, which makes use of renewable primary materials to make bioplastics and biofuels, among other products. The red biotechnology sector dominates the Indian biotechnology market and specializes in the production of various vaccines and diagnostics. The same is also applied in the field of Food and Nutrition, viz bio fortification of food crops to address micro nutrient deficiencies. India is also widely cultivating genetically modified cotton varieties and has been testing several other crops.

Health sector

India maintains a strong grip in the pharmaceutical market potential due to its large and rapidly expanding population supported by research and development, sales, commercialization and alliance of biopharmaceutical firms (Sandhya and Visalakshi, 2000; Ghosh, 2004). India has set a goal of reaching $100 billion biotechnology industry by 2025 by increasing industry's growth rate to around 30 per cent. Though it has grown at a compound growth rate of about 20 per cent over the past decade ending 2013, the growth rate has slowed down (BioSpectrum). It is the biopharmaceutical sector which contributes to more than 63 percent of the total revenue from this sector. India's biopharmaceutical sector is a world leader in vaccines producing 60 per cent of the world's supply (Burrril Media, 2014). Such is the contribution of this sector that today India supplies more than half of all the vaccines to international organizations, such as the World Health Organization and the United Nations International Children's Emergency Fund. India, which has long standing strengths in generic drug and active pharmaceutical ingredient manufacturing, is also demonstrating its capability in creating innovative biologics. Biologics typically address diseases conventional drugs cannot treat very effectively -such as cancer and genetic disorders and command premium prices in most markets when they are first launched, because there are no effective therapeutic alternatives. While conventional drugs are derived from chemicals biologics are very complex products derived from genetically modified microorganisms or animal cell lines.

India has relative strength in biosimilars which promises to increase access and affordability to life-improving and life saving medicines. Biosimilars, as compared to traditional generics are more difficult to develop and manufacture as it is almost impossible to produce an exact replica of a biologic because changes to the structure of the molecule can take place during the production process and also must be subjected to additional clinical testing to ensure that they do not cause adverse response or immune reactions. The emerging market for biosimilars is attracting not only leading Indian biopharmaceutical companies, but generic drug makers as well. Biocon, Serum Institute of India,

Dr. Reddy's Lab, Intas, Shantha Biotech, Reliance Life Sciences, Wockhardt, and Cipla are among the Indian companies active in the area. Already Indian bio-pharmaceutical companies market more than 20 biosimilars in India. However, it has been pointed out that biosimilars may face hurdles in emerging markets as it will be a competitive market and likely to contribute to less than 5 per cent of the $100 billion goal by 2025. Therefore, innovation will be critical to drive growth.

Another emerging area is that of cell therapies and India had been ranked third in the word primarily because both the government and private industries have invested heavily in R & D (Acharya *et al.*, 2004). Some of the leading institutions in the area of stem cell research include the All India Institute of Medical Sciences, Centre for Cellular and Molecular Biology, Reliance Life Science, Indian Institute of Science, L V Prasad Institute, etc. India has also established stem cell banks, and the success with stem cell transplantation provides an example for other developing countries in health care (Chakraborty *et al.*, 2009). However, some of the major hurdles have been lack of proper regulatory framework, which includes licensing, for stem cell banks, institutions for running clinical trials of stem cell therapies etc.

India's skilled labor force in this sector, attractive cost advantages and information technology provide major opportunities for India to develop further in the biopharmaceutical sector. However, improving efficiency is a major concern. Success rate of drug development have not been all that impressive despite research and development, though it still has cost advantage as compared to the US and Europe as compared to drug development. For example, a study conducted by the Boston Consulting Group in 2011 points out that the cost of drug development in India is almost less than half of what it is in Europe and in the United States. India's large population is also an advantage when it comes to clinical trials and have less stringent norm for clinical trials as compared to developed countries. However, this has given rise to several controversies in the recent period that patients have been recruited for clinical trials without sufficient safeguards and consent and compensation and has been blocking several clinical trial attempts. Therefore, there is a need to have proper mechanisms to safeguard patient's health and interest while consenting for clinical trials and at the same time promoting research and development of new drugs. All biotech products are obligated for a thorough review by central and state monitoring committees in India involving the Departments and Ministries of the government. All the biopharmaceutical products have to get the approval from the Drug Controller General of India prior to sale in India and the National Pharmaceutical Pricing Authority is responsible for setting prices on all new drugs in the market in India.

The proportion of GDP spent on health care in India is very meagre when compared to its population and its requirement. While most of the OECD countries major share of the health care spending is by government sector, it around 30 per cent in India, thus leaving individuals to shoulder the cost of their health care. Even though India has made remarkable progress in indicators of health as compared to what existed at the time of independence, the existing inequalities within the country mean that health care is not accessible to large section of the population even today. Therefore, provision of affordable health care is one of the major priorities of the government. Biotechnology seems to provide some great opportunities in this direction. However, the entry of multinational corporations and clinical trials on poor patients without sufficient regulatory and compensatory measures creates suspicion and leads to legal and policy issues and battles, thus stalling the growth of biopharmaceuticals. Issues related to intellectual property rights, drug pricing, licensing etc. are areas of concerns which needs to be addressed for attracting R & D investment in this sector.

Agricultural sector

With increasing pressure on land and water resources, climate change, etc., Indian agriculture is facing fresh challenges during the recent years. Even though the contribution of agriculture to the nation's GDP had declined, it still employs more than half of its population. Despite the impressive economic growth of 7 to 9 per cent registered during the last decade growth in agriculture sector has been around 3 per cent. Poverty and hunger persists while the land available for cultivation has remained almost unchanged for the last several decades and the productivity levels are insufficient to feed the growing population. Moreover, rising incomes and changing lifestyles has created changes in consumption habits with increasing demand created for fruits, vegetables and meat. In such a situation, agricultural biotechnology offers new opportunities for addressing the problems associated with declining resources as well as addressing poverty in the country.

The agricultural biotechnology sector in India includes both domestic and multinational

technology development companies and seed companies. Agricultural biotechnology includes not only genetic modification of crops but also marker assisted selection to accelerate the breeding of desirable traits without the controversies surrounding genetically modified crops.

The first major experiment in India with agricultural biotechnology has been in the case of Bt.cotton, a genetically modified seed that produces a protein to kill bollworm, a pest that attacks cotton crops. It contains an implanted gene for the production *Bacillus thuringiensis*, a bacterium in the soil that produces a protein that acts as a pesticide. In India, bio-agri sector has a mix of both multinationals such as Monsanto as well as Indian players. The leading players in this sector are Nuziveedu seeds, Rasi seeds, Mahyco, Ankur seeds, etc and Bt. Cotton has been a success story in India since the time it was introduced in 2002. A large number of studies have in fact shown the productivity gains from bt cotton in India (for details refer Rao and Dev, 2010). Now nearly 11 million ha are under Bt cotton in India and more than 90 per cent of all cotton produced in India is Bt cotton. According to recent estimates, riding on the success of Bt cotton, agricultural biotechnology has emerged as the third largest component in India's domestic biotech industry with $734 million during 2012/13 fiscal year thus accounting for more than 18 per cent of the total revenue from this sector. However, since Bt cotton is the only genetically modified product approved and the area under its is almost at its maximum, growth of biotechnology has slowed to five per cent as compared to 15 per cent in 2011/12 and is likely to slow further in the coming years.

During the recent times, there have been a lot of apprehensions about the environmental and health impacts of introduction of genetically modified crops in India. The environmental, health and food safety concerns on both humans and animals have led to strong campaigning of activist groups against introduction of more such crops thus fueling fears about biotech crops among the general public which has finally led to stalling of trials on new crops by the government. On the whole, it can be said that in the case of food crops where agricultural biotechnology issues transcend beyond industry growth and includes issues of food security and food safety as well. In India, the debate is certainly polarized on the food safety issue with a large number of civil society organizations protesting against the field trials on genetically modified crops which has finally resulted moratorium on testing of genetically modified crops in India. Research and development have been stalled by imposing moratorium by the governments.

For example, in 2009 Regulators approved genetically modified eggplant but the Ministry of Environment and Forests instituted an indefinite moratorium on its cultivation on the question whether it violates India's Biodiversity Act which seeks to maintain the diversity of its complex of organisms within India's ecosystem. Because of major gaps in the regulatory system, an expert panel of scientist convened by the Supreme Court in 2013 recommended an indefinite moratorium on field trials of Bt crops of which the court was critical. Although Bt cotton has become a major crop in India, the moratorium also prevents seed producers from entering the market thus inhibiting price competition. Moreover, the moratorium also limits India's potential role in innovation and growth in the biotech sector as compared to other countries.

The Way Forward

There is clearly a policy logjam with regard to biotechnology and specifically with respect to genetically modified crops stalling research and development in this field (Chaturvedi and Srinivas, 2013). If India delays clearing of this policy logjam, it stands to lose the advantages that it already had in the field of biotechnology as several other countries have heavily invested in research and development in the field of biotechnology and related fields to develop their bioeconomies by 2030. This is very important as India will have to face more challenges due to climate change in dealing with health issues and in food and nutrition security as well. Every if India adopts precautionary principle in clearing genetically modified food crops, it should clear the logjam for field testing so that there will be a resurgence of interest in R&R and spending by agriculture biotechnology companies in India. India will eventually have to move to other areas where application of biotechnology is more beneficial in solving some of the major problems of India like energy problem, and reduce dependence on coal and other fossil fuels and move towards cleaner energy.

In other words, while the industry expected that the government might build measures based on the success of of *Bt* cotton and reproducing it with other crops, India's agricultural biotechnology industry has been crippled by protracted legal battles, public campaigns from activists' groups fueling fear of biotech crops, and this according to the industry has been a

major impediment for promoting growth in the sector. While a detailed account of this is beyond the scope of the present paper, it suffices to say that some of the common concerns of the industries in the sector need to be addressed if technological advancement in this field is to be utilized for economic growth and development of the country.

One of the major concerns is lack of clarity on the regulatory framework in the country and its predictability. In the absence of predictability of the regulatory framework, investments are hard to come to this important sector which has a huge potential. While the government has early on recognized the importance of biotechnology as a future driver of growth and taken steps to promote it starting by the setting up of the National Biotechnology Board in 1982, later on regulatory regimes become more complex with many agency having overlapping authorities and functions. India has also to compete with the global economy and its lower labor cost and information technology are favorable factors if India wants to take advantage of the opportunities offered by the technology. It is also important to attract more private funding to this sector for which more clarity on the regulatory framework is essential.

Biopharmaceutical sector is also suffering from inefficiency and issues related to multiple agencies involved in review and approval of new products. All these seem to discourage innovation and product development that particularly meet the needs of Indian population. Therefore, there is a demand for consolidation and reorganization of regulatory agencies which follow similar functions and structures at state and central levels. India should also have its own quality control of drugs suitable for Indian market. Government inaction on advancing legislation, which has been viewed as important by the industry, such as, the Biotechnology Regulatory Authority of India Bill which would establish a new regulatory body responsible for overseeing biotechnology products and research outside of therapeutic recombinant proteins is still not implemented. As a result, according to the industry, this sector has been muted, advances languished, investment stalled and opportunities have been lost (White paper, 2014).

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