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REVIEW PAPER

Excitement of Biotechnology in the New Economy

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ABSTRACT

Today the world economy is no longer driven by material wealth but instead powered by intellectual wealth. Knowledge in the economic context translates to technology, of which information technology and biotechnology are the prime drivers. India has made it in information technology, but not yet in biotechnology. The exciting synergy between information technology and biotechnology in the form of bioinformatics is paving the way for intellectual wealth creation in the areas of health care (including pharmaceuticals), food and agriculture. The race for discovering new lead molecules is frenzied in the pharmaceutical arena, being mined by high throughput screening techniques for new chemical entities. The Himalayan yew tree, for example, has provided a billion dollar cancer drug, taxol. Pharmacogenomics is providing a wealth of information pertaining to defective or missing genes–a new avenue for drug research. A new trend in bioinformatics is *in silico* testing, which involves computational simulation of *in vivo* and *in vitro* tests, providing better predictability of clinical trials. In gene therapy, cloning and expressing healthy genes is simple, but finding a mechanism to deliver these genes into target cells is the difficult part. Promising methods include virus as well as non-virus-based delivery systems. How Indians can take advantage of the exciting opportunities in biotechnology? One can boast of a treasure chest of biodiversities–microbial, plant, animal and human, but it is largely unutilised. A large number of inbred communities in India are offering unique human genome pools for genomic studies. We have the main ingredient for global success in biotechnology–our scientific manpower. We need to harness this talent in an enabling business environment and a pragmatic, entrepreneurial mindset.

Keywords: Human genome, genomics, bioinformatics, biotechnology, pharmacogenomics, high throughput screening, gene therapy, cloning

1. INTRODUCTION

The world economy, up until now, has divided the globe into the haves and the have-nots, based on material wealth where oil has been the key factor. Today, there is an emerging economic phenomenon where the world economy is no longer driven by material wealth but instead powered by intellectual wealth. The haves are those with knowledge and the have-nots are those without! Curiously, many of the rich oil-producing nations like Saudi Arabia and others are today actually have-nots in terms of intellectual wealth whereas poor, third world countries like India are fast emerging as wealthy nations. Knowledge is the new economic divide. Wealth is no longer the preserve of the G7 but perhaps a new K7!!

Knowledge in the economic context translates to technology of which information technology and biotechnology are the prime drivers. Whilst the silicon chip has been the founding innovation platform for information technology, the unravelling of the structure of DNA has been fundamental to the growth of biotechnology. Interestingly, both these great innovations happened almost at the same time in history! India has already demonstrated its ability to generate intellectual

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wealth in information technology, but what we need to see is a similar demonstration of its intellectual talent pool in biotechnology.

2. BIOTECHNOLOGY

The deciphering of DNA in 1953 by Watson and Crick, the decoding of the human genome in 2000 and the exciting synergy between information technology and biotechnology in the form of bioinformatics are paving the way for huge opportunities of intellectual wealth creation in the areas of health care, food and agriculture. Whilst opportunities in biotechnology exist in every sector, the importance of these in the pharmaceutical and health care sectors need to be highlighted.

2.1 Global Trends

There are some emerging global trends, which need to be addressed when evaluating these opportunities. Global outsourcing of cost-competitive intellectual skills is a strategy being pursued by all large pharmaceutical companies. China has been most aggressive in cashing in on this opportunity and it is time for India's English speaking scientific manpower base to steal the march over China. To dimension this opportunity, the cost to the company of hiring a PhD in the US is approximately $250,000 per annum; in Taiwan, it is approximately $100,000 per annum; and in Europe, it is slightly higher. The current value of outsourced research and development is of the order $6 billion and growing at 20 per cent annually. Biodiversity is another sought after resource in the global pharmaceutical context. Whether it be microbial, plant, animal or human, India can boast of a treasure chest of biodiversities. But sadly, this treasure chest seems to be hidden or lost in a huge ocean of inertia and mediocrity.

The most exciting global trend, however, is the emerging domain of bioinformatics. Bioinformatics can be best described as the fusion of statistics, mathematics, computer science and biology, and the opportunities are reckoned to be even greater in magnitude than that of internet-based businesses. The scope of bioinformatics is all pervasive and the skills that exist in India in information technology coupled with our scientific skills in life sciences can prove a formidable global combination. The combination of outsourced research and development, biodiversity and bioinformatics offers a very exciting and formidable niche of global opportunities to Indian scientists and the following are just a few of these to generate a level of interest, excitement and focus.

2.2 High Throughput Screening

The race for discovering new lead molecules is frenzied in the pharmaceutical arena. Plant, microbial and animal biodiversities are all being mined by high throughput screening techniques for new chemical entities (NCEs). It is interesting to note that seven of the top 20 selling therapeutics are fermentation-derived and recent indications are that 70 per cent of the NCEs now under clinical testing are all products of r-DNA or gene-based biotechnology.

A few examples illustrate some interesting findings of this bio-prospecting. A Californian biotech firm, Neurex Corporation, isolated a peptide derived from the squirt gland of a marine Philipino snail which formed the base molecule of a revolutionary new anti-ischaemia drug neutrex. Likewise, the Himalayan yew tree provided another billion dollar cancer drug, taxol. Taxol and its derivatives are now being mined from fungal and bacterial biodiversities in many parts of the world. Many of the large pharma majors have collaborative high throughput screening programmes with universities worldwide. India has not been an option due to our stand on product patenting. Hopefully, 2005 should improve this situation.

Suffice to say that CSIR laboratories and private enterprises need to initiate large-scale work in high throughput screening activities to take advantage of this global pharmaceutical strategy.

3. GENOMICS

India's vast number of inbred communities, both tribal and others, offer unique human gene

pools as powerful as those of iceland, for exclusive genomic studies. We are losing valuable time in not focussing on this golden opportunity to unravel high value intellectual property rights (IPR) by way of disease-linked genes and the diagnostic and therapeutic products emanating therefrom.

Huntingdon's disease, a fatal hereditary disease that causes neuro-muscular degeneration, is a classic example of how an inbred Venezuelan tribe provided invaluable genetic information to a lone woman crusader, Nancy Wexler. This now makes diagnosis of Huntingdon's syndrome possible. A therapeutic solution is now underway.

If a lone American woman could crack Huntingdon's disease in far-flung Venezuela, just think of what Indian scientists can do with their own inbred communities by way of providing startling, high-value information relating to genetic diseases. Clues already exist to the potential of working on our own population. For instance, Parsi women are known to be prone to certain forms of breast cancer. Thalessemia is another genetic disease prevalent in many inbred Indian societies, and so on and so forth. Given the proper approach, we can convert the disadvantage of these diseases into research and development opportunities which can translate into therapies and cures for thousands in India and others across the globe.

3.1 Pharmacogenomics

Pharmacogenomics is another rapidly growing segment which is providing a wealth of information pertaining to defective or missing genes which call for differentiated medicine–a new avenue for drug research. Given our abundant patient population, Indian scientists can play a significant role in harnessing this very high-value genomic information.

4. BIOINFORMATICS

As stated earlier, this is an emerging discipline that combines both information technology and biotechnology skills in augmenting high speed data mining of both genotypic and phenotypic information with a view to evolving new form of medical diagnostics and therapies. Genomics, and most recently proteomics, are churning out endless reams of data which need to be statistically evaluated and harnessed for commercial end use. Bioinformatics has unlimited scope in doing so. A recent issue of *Nature* magazine highlighted the mind-boggling size of the bioinformatics market and the more serious problems that exist in the form of an acute shortage of skills in this area. Another exciting opportunity in this area is *in silico* testing which involves computational simulation of *in vivo* and *in vitro* tests, a new trend envisaged to ensure greater predictability of clinical trials, thereby, shortening approval times from regulatory authorities.

Indian scientists and Indian business need to make the necessary investments and create the right framework whereby these rare skills can be utilised in the country and not lose them to the enticing opportunities overseas.

5. GENE THERAPY

The method of injecting healthy genes into faulty cells to correct the expression products of defective genes is the essence of gene therapy. Cloning and expressing healthy genes is simple, but finding a mechanism to deliver these genes into target cells is the difficult part. The use of harmless viruses is the best known method to achieve this. But the challenge to scientists is to find a way of injecting healthy genes into the blood stream and getting the delivery virus to find its way to the right spot. The weakness in using such virus-based delivery systems is that the body's own immune system will develop antibodies to fight the virus a second time which makes therapy very difficult. Companies like Gen Vec and Gene Therapy have found ways to this problem by developing stealth delivery systems that change the face of the delivery virus with each treatment. Gene Therapy's products for cystic fibrosis and brain cancer have already cured a number of near-terminal patients. Today, frantic research and development is being pursued to develop non-virus-based delivery systems. Indian scientists have the opportunity to pursue

gene therapy-based research and development over a wide array of platforms, ranging from cloning and expression of disease-specific healthy genes, to designing delivery systems, and the sky is the limit.

These are just few of the exciting opportunities in biotechnology. How do we take advantage, and more important, how do we make things happen?

(a) Focus on generating human resource by revamping curricula in medicine and biotechnology to ensure that genetics, genomics, proteomics and bioinformatics find prominence;

(b) A pragmatic biotechnology policy which alleviates the sensitivities of genomic and recombinant genetics needs to be formulated to encourage (and not discourage) such activity. Karanataka is spearheading this by coming up with an innovative biotechnology policy to address various aspects of this very vital knowledge segment;

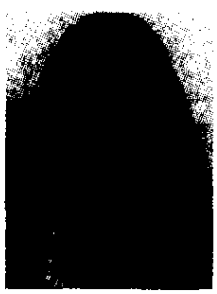
(c) All CSIR laboratories engaging in bioscience-related research need to be encouraged to focus on one or more of these emerging opportunities with a view to providing lead molecules, platform technologies, bio-software, bio-databases, genomic, proteomic and pharmacogenomic information for commercial end use;

(d) Scientist groups at such scientific institutions need to be encouraged and incubated into entrepreneurial projects;

(e) Contract research and development, both at the institutional level and in the private sector needs to be actively solicited. This alone is an opportunity worth several billion dollars.

India has the main ingredient for global success in biotechnology: Its scientific manpower. However, we need to harness this talent in an enabling business environment and a pragmatic, entrepreneurial mindset. If Indian business and Indian scientists fail to take advantage, we may deny ourselves a place in the emerging K7!

Contributor



Dr Kiran Mazumdar-Shaw took her MSc (Malting and Brewing) from Melbourne University, Australia. She has been associated with industrial biotechnology activities for the past 25 years. She is now the Chairman and Managing Director, Biocon India Ltd; Chairman and CEO for both Biochemizyme India Ltd and Biocon-Quest India Ltd; Chairman, Syngene International Pvt Ltd, and Chairman, Helix Biotech Pvt Ltd. She won the *Gold Award for Best Woman Entrepreneur* (1982) awarded by the Institute of Marketing Management, and the *National Award for the Best Small Industry* in 1985. She was honoured with *Padma Shri* in 1989. She was the Convenor of the Industrial Sub-Group of Life Sciences and Biotechnology Panel of TIFAC in 1995, and the Chairperson of the Task Force on Biotechnology constituted by the Institute of Intellectual Property Development, New Delhi. She is also a member of the Confederation of Indian Industry (CII), and the National Committee on Drugs and Pharmaceuticals for 2000-01.