

LEGAL ANALYSIS OF ROLE OF BIOTECHNOLOGY IN HEALTH SECTOR IN INDIA: BOON OR BANE**Dr.P.R.L.Rajavenkatesan****Assistant Professor(Sr),VIT School of Law,
VIT University, Chennai Campus,Chennai-600 127.****Abstract**

Biotechnology involves the modification of the basic genetic material in living things namely DNA, which imparts new properties and capabilities in organisms including plants, animals and microorganisms which can be harnessed for a number of useful applications. There is a developing trend as per as the biotechnological area is concerned that approximately 60 % of the industry is contributed to human health related matters and rest of it for other areas. Further, The Recombinant DNA (rDNA) technology is being successfully used in health care. Nowadays, foreign companies are showing interest to have partner with India at the drug discovery stage of research and use the Indian companies for contract research and manufacturing as there is a lack of research that too in drug discovery process-in-house. This paper is focus on value of biotechnology sector and legal regulation of the same in health sector in India.

Keywords: Biotechnology, Biological Resources, Health, Technology.

Introduction

Biotechnology has emerged globally as a high growth sector with tremendous potential for applications in areas of human and animal health, agriculture, environment and processing industry. In the pharmaceutical sector, advances in the modern biotechnology have initiated a radical change in the production of new or rare molecules and drugs with lower costs, novel means for quicker and more accurate diagnostic tests, and new and safer vaccines. Globally, the health sciences convergence between biotechnology and pharmaceutical companies is most advanced. Biotechnology is leading the new health economy with around 30 of the 200 top selling medicines worldwide being developed by either biotechnology companies alone or in partnership with the pharmaceutical companies. The importance of the health biotechnology is further derived from the fact that 70% of the firms in the list of Top 20 biotechnology firms in India are in the health biotechnology business segment. Prominent among India's notable achievements in modern health biotechnology in the recent years include: the development of a recombinant Hepatitis-B Vaccine, Human Insulin, Erythropoietin, Granulocyte Colony-Stimulating Factor, Interferon, Streptokinase, an international patent for solid state fermentation called 'Pia Factor', bioinformatics software's like 'A vadis' and 'Biosuite'. The first indigenously developed recombinant Hepatitis-B Vaccine by the company Shantha Biotechnics, Hyderabad drastically brought down the cost from \$16 (imported price) per dose to around 50 cents in India (BCIL 2003, Kumar et al 2004). The Indian health biotechnology firms have developed niche in the vaccines segment. These firms operate on low cost- high volume strategy primarily influenced by the demand from the public agencies and international health organisations such as WHO for the poor/ developing countries which makes the entry of global pharma players commercially unviable.

Role of Biotech Companies in Health Care

The leading vaccine firms in India such as Shantha, Bharat Biotech, Indian Immunologicals etc are associated with the development and manufacturing of vaccines through national initiatives

involving the Public-Private Partnership (PPP) and also through the global initiatives with the agencies such as International AIDS Vaccine Initiative (IA VI), Bill Melinda Gates foundation etc. for developing vaccines in the area of AIDS, Cancer etc. Key firms established prior to 1980s like Wockhardt Ltd., Hindustan Antibiotics Ltd., Lupin Ltd., Gland Phanna, Venkatesawara Hacheries etc., were primarily active in pharmaceutical business and later got diversified into healthcare biotechnology. The last decade (beyond 1991) has seen the emergence of Dedicated Biotechnology Finns (DBFs) like Shantha Biotech, Bharat Biotech, Xycton Diagnostics, Strand Genomics (now Stand Life Sciences), Syngene International etc., and the active participation by phanna majors like Ranbaxy, Cadila, Reddy Research Foundation, Daburetc in the health biotechnology. The first successfully established Spin-off Company from the Indian Institute of Science (IISc), Strand Genomics (now Strand Life sciences) also emerged in this period. Interestingly, subsidiaries of MNCs like GlaxoSmithKline and EillyLilly also emerged on the scene during this period (beyond 1991). The reasons for the active participation by the MNCs during this period could possibly be the signing of WTO treaty by India coupled with the comparative advantages the country offers like cost competitiveness, skilled manpower etc in the health domain.

In recent years, the Indian biotech industry has attained a critical mass in manufacturing and research services and has doubled in size within last two years. The growth of health biotechnology companies gained momentum in post 1990s, with a phenomenal growth being observed in the post WTO period i.e. 1995 onwards. This period has seen the emergence of dedicated biotechnology firms (DBF) or start-ups, large pharmaceutical firms adopting biotechnology, spin-offs from the established pharma majors like Dabur, Ranbaxy, Reddy, Cadilaetc as well as the biotechnology majors like Biocon and ShanthaBiotechnics. Interestingly MNCs subsidiary like Eli Lilly, GlaxoSmithK.lineetc also gained entry during this period. The R&D efforts of Indian biotechnology firms are substantially lower than that of the global counterparts and one of the prime reasons for this is lack of research infrastructure as compared to that of other developing countries like Brazil, Taiwan, China and Israel. Vaccines and recombinant therapeutics are the leading sectors driving the growth of the biotechnology industry in India. The production and commercialization of the first therapeutic recombinant human protein humulin (human insulin) in 1982 by Eli Lilly marked the dawn of a new era of unprecedented economic opportunities - the era of biotechnology hitherto unrecognized. The impact of biotechnology revolution was so strong in the U.S. that by late eighties all the 15 to 20 top multibillion pharmaceutical companies were into it and several entrepreneurial new biotechnology firms were established (Gibbons, 1984). For the most part they have been founded since 1976 - the same year the U.S. firm Genentech was founded. The peak year for the formation of biotechnology start-ups in the U.S. was 1982; in the UK. It was 1987. Start-ups in Japan were only few probably that the Japanese environment is more suited to the commercialization of bio products licensed from elsewhere. Biotechnology has provided many investigational tools- autoradiography and tracer techniques, X-ray crystallography, HPLC GC-MS and NMR Spectroscopy, Monoclonal antibodies, peptides, anti-sense oligonucleotides and aptamers to probe molecular events in the living human body including brain. Knock-out, diabetes, Atherosclerosis, neuro-degenerative disorders and cancer.

Legal Regulation of Biotechnology In Health Sector

Biotechnology have touched every corner of the world laying major stress on applications to the environment, drugs, vaccines including a range of biopharmaceuticals, diagnostics, transgenic crops, improved tools for upgrading animal reproduction and quality, useful microbes and food ingredients. The importance of ensuring healthcare access cannot be overstated for a developing country like India. This is because apart from the straightforward thesis that links health care to the well-being of citizens, it also enhances the productive capacity of its population thereby enhancing economic growth of the country. Part IV of the Constitution of India talks about the Directive Principles of State Policy. Article 47 under Part IV lists the "Duty of the State to raise the level of nutrition and the standard of living and to

improve public health". Despite the consensus among political and academic circles of living up to the principle, successive governments have failed to address India's health care needs for a vast majority of its population. According to the latest KPMG report, around 80 per cent of all doctors and 75 per cent of dispensaries serve 28 per cent of the country population.

Second, dismal health-care expenditure has aggravated the inadequacy of our health-care infrastructure. India accounts for over 17 per cent of the world's population while spending less than 1 per cent of the world's total health expenditure. Our total health care expenditure stand 4.1. per cent GDP which is among the lowest in the world. India requires an urgently integrated action on health care to make it universally accessible and affordable at the same time. Japan and China are investing more on the health care sector. India needs to follow a similar strategy to make its citizens more competitive and act as an asset to the country's growth. Biological diversity also plays a vital role regarding biotechnology. Biological diversity is fundamental to agriculture and food production. From the millions of genes that serve as building blocks to the thousands of plants and animals that inhabit the earth, almost limitless combinations of organisms that make up natural ecosystems. The biotechnology industry in India is the third biggest industry of its kind in the Asia-Pacific region, and is posed to grow more than 20 fold by 2025 to become a USD 100 billion industry, a staggering 30% growth for the next decade. Biotechnology exploits biological materials, living or non-living, and is broadly classified as classical and modern biotechnology. The age-old fermentation process for producing alcohol, isolation of antibiotics from moulds or other micro-organisms are only a few examples of classical biotechnology. Modern biotechnology started with the gene splicing technology or genetic engineering which developed in the late seventies of the last century. By using genetic engineering, many useful things like human insulin, human growth factors, monoclonal antibodies, etc. have been developed.

The growth of technology is revolutionizing the way we conduct our lives and is challenging established legal principles, which are struggling to adapt to rapid technological advances. Biotechnology is not a new science. It has existed in some form or the other for centuries. However, the advent of genetics has opened exciting opportunities in this sector, because of its numerous applications, which range from improvement of human health and food production to reduction of environmental damage. It is also true that clinical research and trials are expected to grow exponentially over the couple of years. The Biotechnology industry in India is governed by the following enactments depending upon their relevance/applicability on case to case basis: Environment Protection Act, 1986; Laws pertaining to Intellectual Property Rights; Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells, 1989 notified by Ministry of Environment & Forests on December 5, 1989 under Environment and Protection Act, 1986; Revised Recombinant DNA Safety Guidelines; Guidelines for Research in Transgenic Plants & Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, 1998; National Seed Policy, 2002; Seeds Act, 1966; The Plants, Fruits and Seeds [Regulation of import in India] Order 1989 issued under the Destructive Insects and Pests Act, 1914. Guidelines for Generating Preclinical and Clinical Data for rDNA Therapeutics, 1999; Drugs & Cosmetic Act 1940 along with Drugs and Cosmetic Rules Drug Policy, 2002 and Biological Diversity Act, 2002.

Conclusion and Suggestions

The biotechnology revolution is gaining momentum all over the world and India is no exception. India has been a forerunner among the developing countries in promoting multi-disciplinary activities in this area, recognizing the practically unlimited possibilities of their applications in increasing agricultural and industrial production and in improving human and animal life. Given Indian strengths in producing generic medications, companies are looking to increase their capabilities in biotechnology processing and manufacturing in anticipation of a new series of biotechnology-based generic drugs. As drug patents

on some of the earliest biotechnology drugs expire in the coming years, there will be a new market for biotechnology-based generics. The Indian biotechnology industry is ranked third in the world in terms of stem cell research, primarily because both the government and private industry have invested heavily in research institutes studying human disease and searching for treatments. As well, the issues of embryonic stem cell research have not generated the same moral debate in India as they have in Canada, the United States, Britain and other countries. In fact, a bioethics committee has determined that human embryonic stem cells may be harvested, with full and informed consent from the donor, up to the 14th day of gestation. The biotechnology sector of India is highly innovative and is on a strong growth trajectory. The sector, with its immense growth potential, will continue to play a significant role as an innovative manufacturing hub. The sector is one of the most significant sectors in enhancing India's global profile as well as contributing to the growth of the economy. The Indian biotech industry holds about 2 per cent share of the global biotech industry. The biotechnology industry in India, comprising about 800 companies, is valued at US\$ 11 billion and is growing at a Compound Annual Growth Rate (CAGR) of 20 per cent. Health and health care need to be distinguished from each other for no better reason than that the former is often incorrectly seen as a direct function of the latter. Health is clearly not the mere absence of disease. Good Health confers on a person or groups freedom from illness - and the ability to realize one's potential. What we need is vision, imaginative thinking and sustained and determined efforts in a fast track mode to survive in a highly competitive environment. In addition to this, Biotechnology Regulatory Authority of India Bill and Regional Centre for Biotechnology Act, 2016 have carefully protecting the interest of the right holder on the one hand and innocent public on the other hand. The time has come to look into the wider use of biotechnology in health sector and efforts to be taken for the larger interest of society.

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