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1. Introduction

Biotechnology and life science are considered to be a sun-rise sector that can provide an unprecedented opportunity in accelerating growth in world economy, providing hundreds of thousands of jobs to skilled workers worldwide. India is very well positioned to take advantage of this opportunity because of abundance of young and skillful workforce at reasonable cost on one hand and locally available talent of computational skill on the other. Germany at the same time has its strength of innovation, good investment options and highly developed biotechnology infrastructure. It is therefore very pertinent to consider ways and means through which economies of these two countries could profit through a collaborative approach especially driven by innovations and investment in biotechnology.

Biotechnology is a highly interdisciplinary field that combines biological sciences with computational, chemical as well as engineering technologies to manipulate living organisms or their components to aid simplified and economical processes to produce products that advances healthcare, medicine, agriculture, food, pharmaceuticals and environment control. Biotechnology can be classified into two broad categories: R&D and discovery of new services (includes diagnostic etc.) and new products in Biological Sciences and Industrial Processes. Being multidisciplinary in nature, the category biological sciences encompasses subjects ranging from Computational Biology to Microbiology, Cell biology, Genetics, Molecular Biology, pharmaceuticals etc. for understanding the basic pathology of illness and treatment of diseases including new drug development, development of agriculture, food production, protection of the environment, waste disposal, and many more. The industrial processes aspect deals with the processes of production of drugs, vaccines, biofuels, pharmaceuticals, engineered industrial enzymes, biodegradable polymers, on an industrial scale using biochemical processes and techniques. Thus in summary, Biotechnology applications are meant to:

- Heal the world
- Feed the world
- Fuel the world

Some of the best innovations and developments that have come out of Biotechnology and allied fields are: genomic sequencing technology, better understanding of various pathologies, novel and improved diagnostic systems, production of new bio-pharmaceuticals , procedure to develop vaccine that are more effective, natural alternatives to pesticides, better yielding and resistant crops, production of biofuels, production of industrial enzymes that are engineered for better activity, biodegradable polymers, and developments in stem cells technology. In the subsequent discussions, all such advances will be discussed from the perspective of a potential Indo-German collaboration.

To identify areas of focused cooperation between Indian and German entities, both in academic and industrial spaces, there is need first of an in-depth overview of biotechnology industry in both the countries and then analyze the opportunities available and challenges that may be faced. Therefore, let us have an overview of the progress that India has made in this particular sector.

2. Progress made by India in biotechnology in the last decade

India is ranked 12th in the world in biotech and second in Asia. According to Kiran Mazumdar-Shaw, the Chairman and Managing Director of one of India's foremost biotech company, Biocon in Bangalore, "India's biotech sector is currently valued at over US$10 billion, having grown at a CAGR of ~20% over the last decade. Leveraging the power of biotechnology, India has emerged as the world's largest vaccines producer, a global Insulin manufacturer and the world's largest supplier of Bt Cotton. It is estimated that enabling policies can create a favorable business environment capable of generating biotech revenues of US$100 billion by 2025". This optimism is based on one hand by the fact that the Government spending in biotech sector will see a more than threefold jump during 2012-2017 at $3.7 Billion compared to $1.1 Billion spent during 2007-2012 and the patent expiry driven exponential growth of bio-similars and generics market by 2025.

This phenomenal growth of a CAGR of over 30% that may take a 7-8 Billion Dollar industry in 2015 to the level of 100 billion Dollars in just ten years may sound optimistic but a careful analysis of the underlying factors may provide substance to this claim.

What are the important stimuli available in India that made Kiran Mazumdar-Shaw to make the above forecast?

2.1. Important stimulus promoting biotechnology industry in India.

The robust demand for products required by India's billion-plus population base offers a huge market for biotech products and services (Fig. 1). Also the anticipated higher growth curve of Indian economy that is expected to usher in increasing economic prosperity coupled with health consciousness would continue to fuel demand for innovative products and services not only in healthcare area but also in life style sectors. Improvement of healthcare services and its affordability made possible by rising income alone will generate a huge demand for health related biotech products. Furthermore, innovation in research and increased government support is expected to stimulate research and development at academic institution as well as in industries.

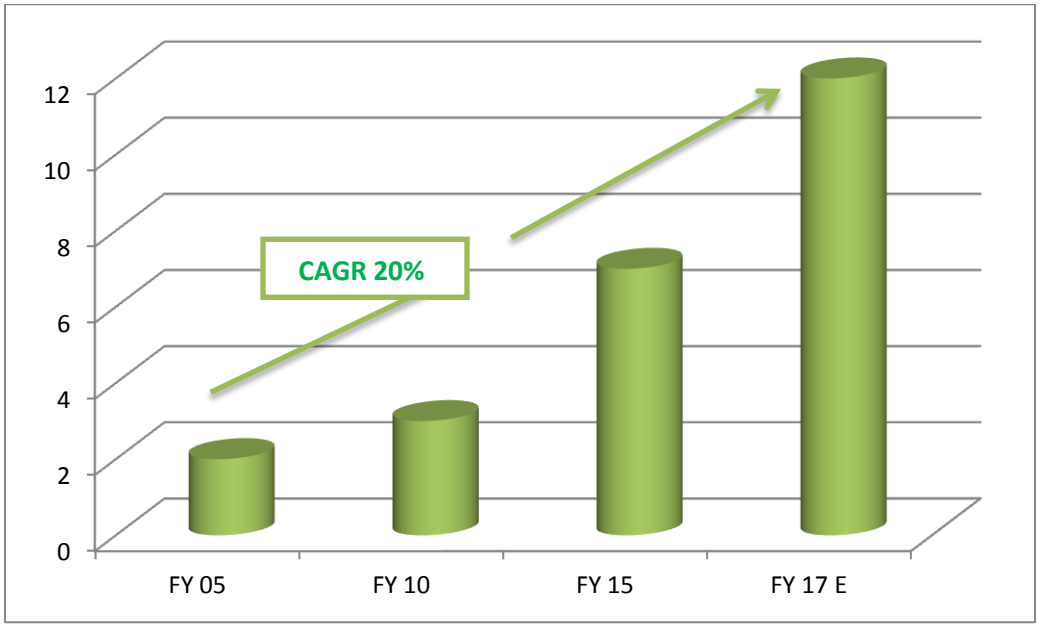


Fig. 1. Growth in market size (in US $ Billions) from Financial Year 2005 (FY05) to Financial Year 2017 estimated (FY17 E).

Also going forward, it is expected that public funding and public-private partnership projects will be important stimuli. This will stimulate the market for research bio-chemicals and services as well. In addition, Government policy support in terms of increasing foreign direct investment (FDI) to 100% via automatic route, launch of

Biotechnology Industry partnership program (BIPP) boosting industry participation, and steps like setting up of biotechnology industry research assistance council and of national rural healthcare mission are expected to boost biotechnology and life science industries in the coming decade. In addition, the incentives and support to be given to startup companies, many of which are in life science space, is expected to further increase the Indian biotech market size.

2.2. Business of Biotechnology in India and its areas of focus

Biotechnology industry in India is composed of several sectors, each contributing to the overall bio-economy (Fig 2).

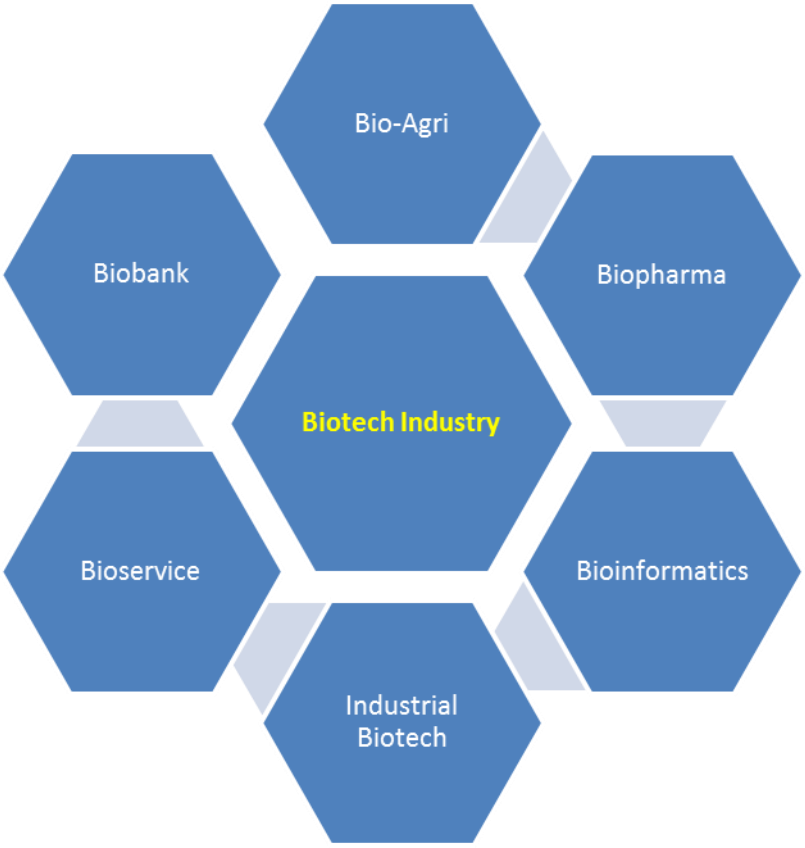


Fig 2. Main branches of biotechnology industry

The important sectors are (a) biopharmaceuticals that includes vaccine development, production of biosimilars and innovative new biological molecules as therapeutics, (b) bioinformatics powered by broad talent locally available in computational sciences, (c)

bio-services ranging from analytical services like molecular diagnostics, supply of vectors, etc. to manufacturing components including cell biological tools to other biotech companies and services provided by Contract Research and Innovation Service Provider (CRISP) companies, (d) bio-agriculture ranging from the production of genetically modified high-yielding or pest-resistant crops, bio-fertilizers, plant extracted library of molecules to bio-pesticides, and (e) industrial biotechnology providing industrial processes to manufacture bio-fuels , engineered enzymes with special characteristics, fermentation products, bio-polymers etc. and (f) Bio-bank which is a branch of biotechnology where highly defined tissues, both normal and pathological collected from patients during the surgical removal of tumors along with samples of patients' blood, plasma etc., to be used mostly as research material for R & D. Even bones removed for example as a part of the hip replacement operation etc. and no longer required by the donor can be banked for use in another patient who may need to replace bones lost during surgery or trauma. Similarly Stem cell banks are in use globally. In India tissue or bone-banking is not so much in vogue, but stem cell banking facilities mostly from cord blood cells, are pretty wide spread. Tissue banking or Bone-banking is still to catch up.

Over the last three decades, India's initial baby steps taken in biotechnology during the period of 1975 to 1990 have matured over the decades to become a reputed player in global biotechnology scenario. An important milestone was set in 1978 with the establishment of the first Biotech Company, Biocon, in Bangalore. Around this time, also another top level biochemistry R & D organization, AstraZeneca India Research Laboratories, under the leadership of Dr. Janakiraman Ramachandran was established in 1979 at Bengaluru, Karnataka with major research efforts focused on seven crucial areas of healthcare – cardiovascular complications, diabetes, oncology, respiratory & inflammation, infection, local anesthesia and maternal healthcare. Both these companies ushered in a research and development agenda in India's biotech scenario and consequently produced much needed skilled workforce. This was followed by setting up of important academic research Institutions like Centre for Cellular and Molecular Biology in Hyderabad, Institute of Microbial Technology in Chandigarh, and the Department of Biotechnology, in the intervening years. In 1994, India benefitted to

a great extent by establishing International Centre for Genetic Engineering and Biotechnology through UNIDO which helped to internationalize the biotech scenario

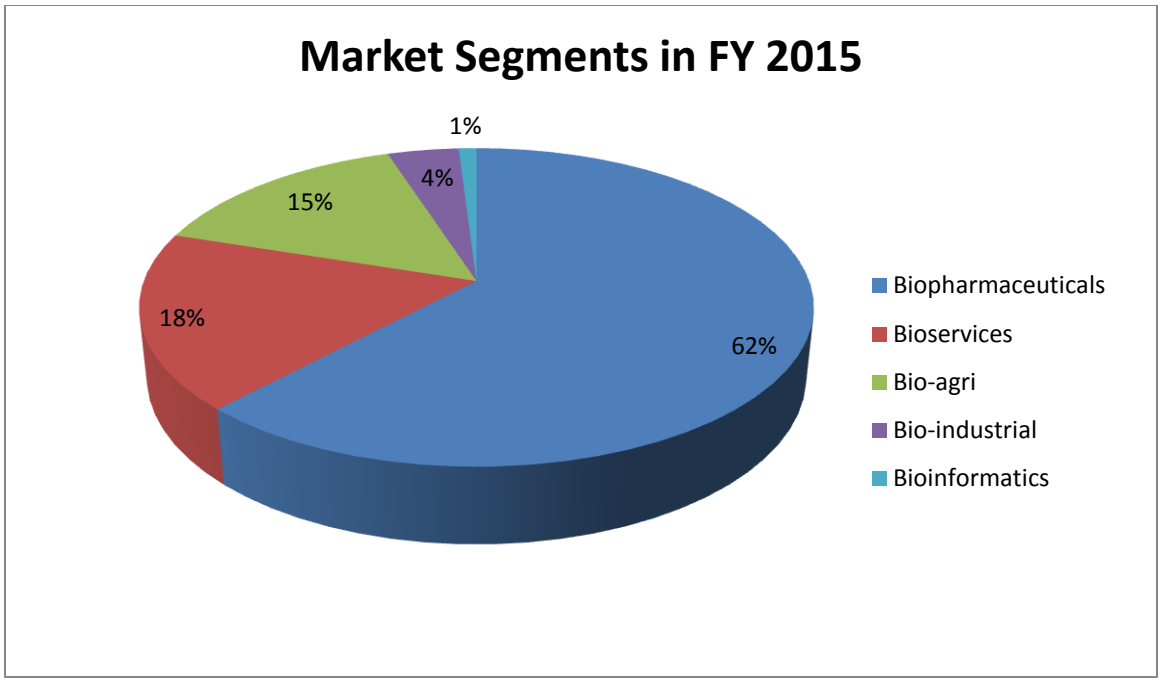


Fig 3. Market segments of various biotechnology sectors in India. *Source:Able-Biospecturm Industry Survey*

in India through promoting international exchange of technologies, on one hand and knowledge and skill development on the other. The period from 1975 to 2000 was thus marked by mushrooming of several Biotech companies as well as many top-ranking biotechnology academic institutions. At the same time, privately run hospitals with high quality facilities appeared in various cities of India which not only helped in ushering in quality medical services for Indians and medical tourists but also helped in the growth of clinical research services. These developments laid a solid foundation for the unprecedented growth of biotechnology market in India in the last decade or so. If one considers total Indian biotechnology market, then almost 62% revenue is contributed by the biopharmaceutical segment, followed by Bioservices (18%) and Bio-agri (15%) sectors (Fig 3). The contribution of Bio-industrials (4%) and Bioinformatics (1%) remains

currently very small. Data on Bio-Banking is not yet available but is expected to be minuscule at the time of this publication going to press.

2.2.1 Biopharmaceutical Segment in India

India's biopharmaceutical sector is growing currently at a double digit growth rate. In 2013, total bio-pharma export contributed to a value of $1.4 Billion showing a growth rate of 25%. India being a world leader in vaccines producing 60 percent of the world's supply, it is obvious that vaccine happens to be the major biotech product being exported from India. As India's biotech companies have the ability to innovate as well as to produce through cost-effective technologies, there is little surprise that the vaccines have become the strongest generators of revenue within India's biopharmaceutical sector. International help organizations, like the World Health Organization and the United Nations International Children's Emergency Fund buy half of their vaccine requirements from Indian biotech companies (Table1). Public health consciousness and economic perspectives have automatically enhanced the importance of vaccines world over. India presently has about 15 vaccine manufacturers who work on over 50 brands for 15 different vaccines. Indian companies that produce vaccines have been able to master the requirements of good manufacturing practices for macromolecules and are continuously earning the goodwill of international companies. Table 1 lists the top vaccine producers of India. Although the revenue generated by vaccines may constitute currently 50% of the total revenue from Biopharma segment, many innovative products especially biosimilars are currently in biopharma pipeline that are poised to take off as large revenue generating products. Financial constraints and regulatory hindrances must be overcome to make this happen.

Recently, Biocon has launched Alzumab also called Itolizumab, a first-in-class monoclonal anti-CD6 antibody effective for the treatment of psoriasis, in India. The global market for psoriasis drugs is expected to reach $8 billion. In addition to Psoriasis, this drug is expected to be useful in treating a range of autoimmune diseases, such as rheumatoid arthritis and multiple sclerosis, and its potential market could significantly increase, if Biocon wins approval for its use in additional indications. The company is in

talks with potential partners to co-develop and market the drug in the United States and Europe. Such innovation will be critical to growing India's bio-economy.

The emerging area of biosimilars promises to increase access and affordability to life-improving and life-saving medicines in India, as well as provide a tremendous global

Table 1. Premier Biotech Companies of India supplying vaccines to the world

Company Name	Revenue (2012-2013) Millions US $	Main Products
Bharat Biotech	45.3	Rotavirus Vaccine "Rotavac" and products such as Chikungunya Vaccine, Typhoid Conjugate Vaccine, Oral Rotavirus Vaccine, Malaria Vaccine, Liquid Rabies Vaccine and Staphylococcus aureus vaccine are in the pipeline.
Bharat Serum and Vaccines Ltd	83.0	Monoclonal Human Anti-rhesus Immunoglobulin (lgG1) containing antibodies to Rho-D, monoclonal tetanus immunoglobulin, mTIG, Equine anti-sera and anti-toxins plus fertility products.
Haffkine Biopharmaceuticals	37.0	Oral Polio Vaccines and other vaccines, antisera, pharmaceuticals
Indian Immunologicals	71.0	Livestock vaccines such as foot-and-mouth disease (FMD) vaccine, vaccine for the blue tongue disease, etc.
Panacea Biotech	78.9	Oral Polio vaccine, Hepatitis B vaccine, Easyfour (Diptheria Tetanus Pertussis +Hib) and Ecovac (DTP+HepB)
Serum Institute of India	521.0	A leading producer of diphtheria, tetanus, pertussis, BCG, r-hepatitis B, measles, mumps and rubella vaccines.

growth opportunity for Indian biopharmaceutical companies. Biosimilars are molecules that are similar and may or may not be identical to innovative biologics that have lost patents protection. Sometimes biosimilars are also referred to as biogenerics but unlike generic versions of small molecule drugs which are chemical synthetic entities, biologics are derived as products of fermentation. Therefore, biosimilars produced by different microorganisms/ animal cells/yeast cells or insect cells can be functionally equivalent to, but may not be identical copies, of the innovator molecule. With the expiry of twelve

biological products with global sales of more than US$67 billion by 2020, the emerging opportunities in biosimilar market will attract several Indian biotech companies. Biosimilar market is certainly not for faint hearted people, as risks are high for failure at the last stages of development and require good amount of investments, yet several leading Indian biopharmaceutical companies have already entered the fray, marketing more than 20 biosimilars currently in India. Biocon, Serum Institute of India, Dr. Reddy's Lab, Intas, Shantha Biotech, Reliance Life Sciences, Wockhardt, and Cipla are among the leading Indian companies active in the area.

2.2.2 Bio services Segment

Apart from bio-therapeutics, the bio services sector that developed from the early days, represents an area of good opportunities. India has skilled workforce at a significantly lower cost although this advantage is gradually disappearing. India's bio services sector provides a range of support to global biotech companies ranging from pre-clinical studies, analytical supports, small molecule and intermediate synthesis, clinical research services to contract research and manufacturing services. Companies from abroad like Quintiles, Covance, Parexel, PPD etc. and Indian companies including GVK Bio, Jubilant Biosys, Jubilant Lifesciences, Cliantha , Siro Clinpharm, Ecron Acunova, CliniRX Tangent Research etc. can be listed as active ones in Indian market.

The Global CRO market in 2014, reached approximately $27 billion and is expected to grow at a CAGR of 6.6 percent to reach $32.7 billion by 2017. However, as the cost of conducting clinical trials in emerging countries is around 40 to 60 percent less than that of developed countries, the CRO market in emerging countries is growing in double digits with growth mainly driven by China and India. The only constraint that India faced was lack of transparency in the regulatory sphere. However recent steps taken by the Regulatory authorities have helped to clarify the situation to a great extent.

Companies like Advinus and Jubilant provide services across the entire drug discovery platform starting from pre-clinical service to synthesis of small molecules, lead discovery to target validation and efficacy evaluation.

Others, such as Syngene on one end, focus just on discovery and lead optimization,

while on the other end some companies, such as Clinigene, focus on clinical development.

"Today most important developments in medical science typically begin in laboratories, such as the discovery of specific new biological molecules, processes, or pathways or innovative applications of existing knowledge. In most cases, these discoveries have limited effect beyond a fairly narrow research goal. Their real impact for public health generally comes after several more significant steps including further R & D, testing, approval by appropriate regulatory bodies (such as FDA), manufacturing and distribution" – National Institute of Health, Office of Technology transfer. Thus, bringing a new molecule from laboratory bench to the bedside of a patient is a time-consuming and costly process that may take 8-10 years and may cost anywhere between 1.5 to 2.0 billion US dollars according to consensus. However, a new study by the Centre for the Study of Drug Development at Tufts University in Massachusetts reckons the average cost for drugs developed between 1995 and 2007 was $2.6 billion. Although the investment in pharma research is rising over the last few years, the success rate of bringing a molecule to market is getting ever smaller. On the top of it, in regulated market there is a pricing pressure from both the Governments and from Health Insurance bodies to keep the product cost as low as possible, thus making it difficult for pharmaceutical industry to recover the escalating R & D costs. Therefore, the pharmaceutical industry is under pressure to speed up the drug discovery program on one hand and to reduce the cost as far as possible on the other. According to several reports published recently, the cost of drug development in India is close to half of what it is in Europe and the United States. Moreover, abundant skilled workers and availability of technology, make it possible to reduce the time taken for the drug discovery significantly which at the end saves costs and increase the productive patent life of a product. Especially a major reduction in costs can be achieved if a part of pre-clinical work, contract manufacturing work and the clinical research part are conducted in India. This is making both pharmaceutical and biopharmaceutical companies to look at India with interest. It is estimated, therefore, that the growth rate of bio-service segment in India is poised for a surge in the coming years. It will be important therefore, for the

Government of India to develop transparent regulatory procedures and clear mandate for intellectual property right protection.

2.2.3 Bio-agri Segment

Bio-Agriculture was the fastest growing biotech segment in 2011-12, registering 20 % growth and a revenue of $621 million as compared to previous year's revenue of $140 million but it is showing currently a declining trend. The animal husbandry segment of Agriculture has seen India make impressive progress especially as many vaccines to protect the health of farm animals have been produced and are marketed by Indian biotech companies like Indian Immunologicals Ltd.

Over the past years genetically modified (GM) crops, bio-fertilizers, bio-fuels and bio-pesticides have contributed to the growth of the Indian agri-biotech market. India has the largest area under cultivation for Bt-Cotton, a genetically modified pest-resistant cotton variety. However resistance from public, erratic monsoon etc. have reduced the farmer's confidence in planting Bt-Cotton and hence biotech companies like Rasi Seeds, Mahyco, Ankur seed and Nuziveedu Seeds are struggling to maintain their market position. At present, 64 companies sell over 780 Bt cotton hybrid seeds in India. It will be important that cotton farmers must adopt the new agronomic innovation to induce a

Table 2. Bio fertilizers commonly used in India

Biotics	Benefits
Azotobacter	Effective for treating soils for non- legume crops including dry land crops
Azospirillum	Nitrogen fixing bacteria effective for non-legume crops like maize, barley, oats, sorghum, millet, Sugarcane, rice etc.
Blue-green algae and Azolla	Lowers the nitrogen containing fertilizer requirement for rice
Microhizae (VAM)	Symbiotic bio-fertilizers for horticulture plants helping to increase fruit yield.
Rhizobium	Nitrogen fixation for legumes like pulses, groundnut, soybean

growth in hybrid cotton seeds market and it is important to make the public aware of the benefits of such genetically modified cotton.

Apart from the genetically modified cotton crops, there are more than 20 biotech crops that are under development by both public and private sectors in the country.

In addition to these, bio-fertilizers, bio-fuels and bio-pesticides are also contributing to the growth of the Indian agri-biotech market.

India is the third largest producer and the second largest consumer of chemical fertilizers. There is a realization that it is time for India to use more bio fertilizers instead of chemical fertilizers for a sustainable development of farm produce. Table 2. lists some of the effective bio-fertilizers produced and used in India.

2.2.3.1 Biofuel

With the spike in the fossil oil prices in 2008, a considerable increase in biofuels (total worldwide production in 2012: 1.9 million barrels) trade was observed and the market now consists of internationally traded products such as bioethanol and biodiesel (83.1 and 22.5 billion liters, respectively, as of 2012). Biofuels are a subset of bioenergy, which is energy derived from biomass (plant and animal matter), and have qualities that are similar to gasoline, diesel or other petroleum-derived fuels. The Biomass can come from any plant or even animal origin ranging from manually gathered fuelwood to animal dung which is then industrially processed to products such as ethanol and biodiesel. Biomass can be used directly for heat, turned into biogas to produce electricity, or processed into liquid forms suitable as alternatives or supplements to fossil fuels for transport.

Currently, around 82 per cent of the global production of liquid bio fuels is in the form of ethanol. USA and Brazil are the two largest ethanol producing countries. In China, wheat, cassava and sweet sorghum are used besides corn for ethanol production. European Union (EU), another major ethanol producer, uses cereals like wheat, corn, barley and sugar beet for production of bio-ethanol.

Currently, India produces conventional bioethanol from sugar molasses; production of advanced bioethanol is in a nascent phase. Presently, only three-fifths of total facilities are actually supplying ethanol.

Improved supplies of molasses and a steady rise in demand from the chemical and potable liquor industries in the face of an expected rise in blending for EBP (Ethanol Blending Program) could raise total ethanol consumption in 2013 to 2.1 billion liters. Exports of ethanol have grown significantly in the last three years.

Blending rates vary from country to country. USA for example mandates 3 per cent blending of ethanol with petrol. Brazil has high ratio of 25 per cent blending. EU, China and Indonesia have opted for a 10 per cent blending.

In India, biodiesel production is only at the nascent stage, with about 95 million liters being produced from jatropha and pongamia oil. Biodiesel in India is mostly produced from the oils extracted from the seeds of Jatropha, mainly because of the fact that edible oil is scarce and the country already depends on huge quantity of imported oils for edible purposes. Jatropha plantation is a subject for state governments.

Public-sector petroleum companies and private sector firms have entered into memoranda of understanding with state governments to establish and promote Jatropha plantation on government wastelands or to contract with small and medium farmers. However, only a few states have been able to promote Jatropha plantation actively despite the government's initiatives.

2.2.3.2 Other Products in Bio-Agri segment

There are several other economic opportunities in the Bio-Agri segment which remain to be properly exploited yet. Animal biotechnology, with development of various animal vaccines has made so far a good progress. However, other products helping in the healthcare of animals or cloning technology to select better yielding varieties are yet to be taken up. Aquaculture, marine biotechnology, medicinal and aromatic plants, silk production, plant-based natural food-colors may offer potentially interesting opportunities.

2.2.4 Bioinformatics

The global bioinformatics market has reached the level of $4 to 5 billion in 2014, depending upon which report is read, and is poised to reach $13 to15 billion by 2020 at a CAGR close to 20% from 2015 to 2020.

The bioinformatics technology and services market is segmented into knowledge management tools, bioinformatics platforms and bioinformatics services. The bioinformatics platform market was the highest revenue generating market in 2013. This was due to the increased application usage of the platforms in various genomic applications. However, the Knowledge Management Tools is expected to emerge as the highest revenue generating segment by 2020 due to the increasing number of data generated due to the increasing clinical trials. These tools provide both cost and time efficiency for the pharmaceutical companies. The Chemoinformatics and Drug Design is expected to be the highest revenue generating segment by 2020 due to its ability to use information in the selection and designing of the drug cycle.

Some of the major drivers which help in increasing demand for bioinformatics are growing applications of bioinformatics in drug discovery, as mentioned above and accompanying diagnostic/prognostic tools based on genomics, and development and increasing bioinformatics support in development of personalized medicines and clinical diagnostics. Rising need for integrated bioinformatics systems in proteomics and genomics also supports the growth of bioinformatics market. However, lack of skilled and trained professional and high cost is restraining the growth of the bioinformatics market. In addition, lack of interoperability among data formats is also restraining the growth of the bioinformatics market.

Factors such as increasing government initiatives and funding, and growing use of bioinformatics in drug discovery and biomarkers development processes, especially through the use of in Silico solutions, are leading to the growth of the market. However, factors such as dearth of skilled personnel to ensure proper use of bioinformatics tools, and lack of integration of a wide variety of data generated through various bioinformatics platforms are hindering the growth of the market. India can boast of some of the world's top ranking bioinformatics companies (Table 3).

Table 3. Bioinformatics Companies operating in India

Companies	Revenue Million $ in 2013	Areas of business
Strand Life Sciences	10	Solutions for clinical genomics, pharmaceutical R&D, and basic genomics research by integrating in vivo, in vitro and in silico biology.
Ocimum Biosolutions	10	Started as a pure bioinformatics company but has added wet lab facilities, have created large gene expression databases – BioExpress and ToxExpress.
NovoInformatics	0.1	R&D Company with a mission to develop Biological Software for drug development.
Polyclone Bioservices	0.1	In-silico Biology, Bioservices
BrainWave Biotechnology Private Limited	N.A.	BrainWave's Life Science Informatics expertise covers Healthcare KPO process, Healthcare BPO process, Medical Writing, and Healthcare services
Biobase International		A Quigen company specialising in various database cre ation and providing worldwide bioinformatics solutions.

2.2.5 Major academic institutions involved in innovative biotech research and teaching in India

The subject of Biotechnology as any other branch of science is knowledge-driven, the growth of which is driven by a flowing development of new ideas and concepts generating new tools for research, new processes for manufacturing and innovative business models. Therefore, it was recognized very early that there is a requirement for specialized personnel and centers of excellence for R&D. In 1986, the Department of Biotechnology was set up exactly with a view to promote this.

This was followed by setting of National Institute of Immunology in Delhi and the Centre of Cell Biology and Molecular Biology in Hyderabad. Of course, the centers of biochemistry research and education at the Universities in Kolkata, Varanasi, Delhi,

Mumbai, Hyderabad and in Indian Institute of Science, Bangalore already had internationally reputed scientists in their faculties in early 70s (Table 4).

Table 4. A list of some of the reputed biotechnology research institutes in India

Institutes	Location	Website
Centre for DNA Fingerprinting & Diagnostics,	**Hyderabad, Andhra Pradesh**	www.cdfd.org.in/
National Institute of Biomedical Genomics	**Kalyani, West Bengal**	http://www.nibmg.ac.in/
National Centre for Cell Science	Pune, Maharashtra	http://www.nccs.res.in/
National Brain Research Centre	**Gurgaon, Haryana**	http://www.nbrc.ac.in/
National Institute of Immunology	**New Delhi**	http://www.nii.res.in/
Regional Centre for Biotechnology	**Faridabad, Haryana**	http://www.rcb.res.in/
International Centre for Genetic Engineering and Biotechnology	**New Delhi**	http://www.icgeb.org/home.html
Centre for Cellular and Molecular Biology,	**Hyderabad, Andhra Pradesh**	www.ccmb.res.in/
Institute of Genomics & Integrative Biology	**New Delhi**	www.igib.res.in/
National Institute of Plant Genome Research,	New Delhi	www.nipgr.res.in/

The policy goal for the Government has been to facilitate the availability of scientific and technical human resource in all disciplines relevant to the life science and biotechnology

sector. For a successful and vibrant biotechnology sector, large talent pools are required in multiple scientific disciplines such as molecular and cell biology, chemistry, physics, engineering, bioinformatics, medicine, agriculture, microbiology, technology transfer & commercialization, bio-enterprise & bio-financing and intellectual property rights management. Product and process development are inter-disciplinary in nature and deficiencies in specific areas may weaken the whole sector. Together with Council of Scientific Research, Indian Council of Medical Research and Indian Council of Agricultural Research, Department of Biotechnology has drawn up a road to develop an integrated biotech policy with concurrent attention to education, social mobilization and regulation to promote a synergy between technology and public policy.

2.2.6 Biotechnology Parks in India

Silicon Valley is the best example of how clustering of high-tech firms in a particular geographical location can be beneficial for the rapid and sustainable growth of the firms in the cluster. The clustering of firms, very often a group of start-ups, mostly the high technology firms in a particularly location, is known as 'Technology' or 'Knowledge" or 'Science" Parks. In the developed world, such parks have proven beneficial not only for the firms included in such clusters but also for the local economy. For the success of such clusters, it is imperative that the management of the clusters is in the hands of professionals, who can help the companies in the cluster navigate through the maze of regulatory authorities, intellectual property management issues, applying for grants and financial support often in group applications, getting access to international markets and fostering intra or inter-cluster cooperation. Thus the management board of such parks are not just renting agencies who lease out the space to a particular company or start up but they have an important role to play to foster not only the health of the cluster as a whole but that of individual companies in the cluster as well.

To establish a successful cluster of biotech companies, it is essential that world class universities, research institutions – either Government funded or autonomous or even privately run and perhaps funded by Companies, and hospitals, where research is carried out, are in the proximity. Ideas coming out of such clusters with supports by private investors, Venture Capital funds etc. can crystallize into startup companies,

which then form a cluster (Fig 4). To and fro flow of talents is an essential part of this concept.

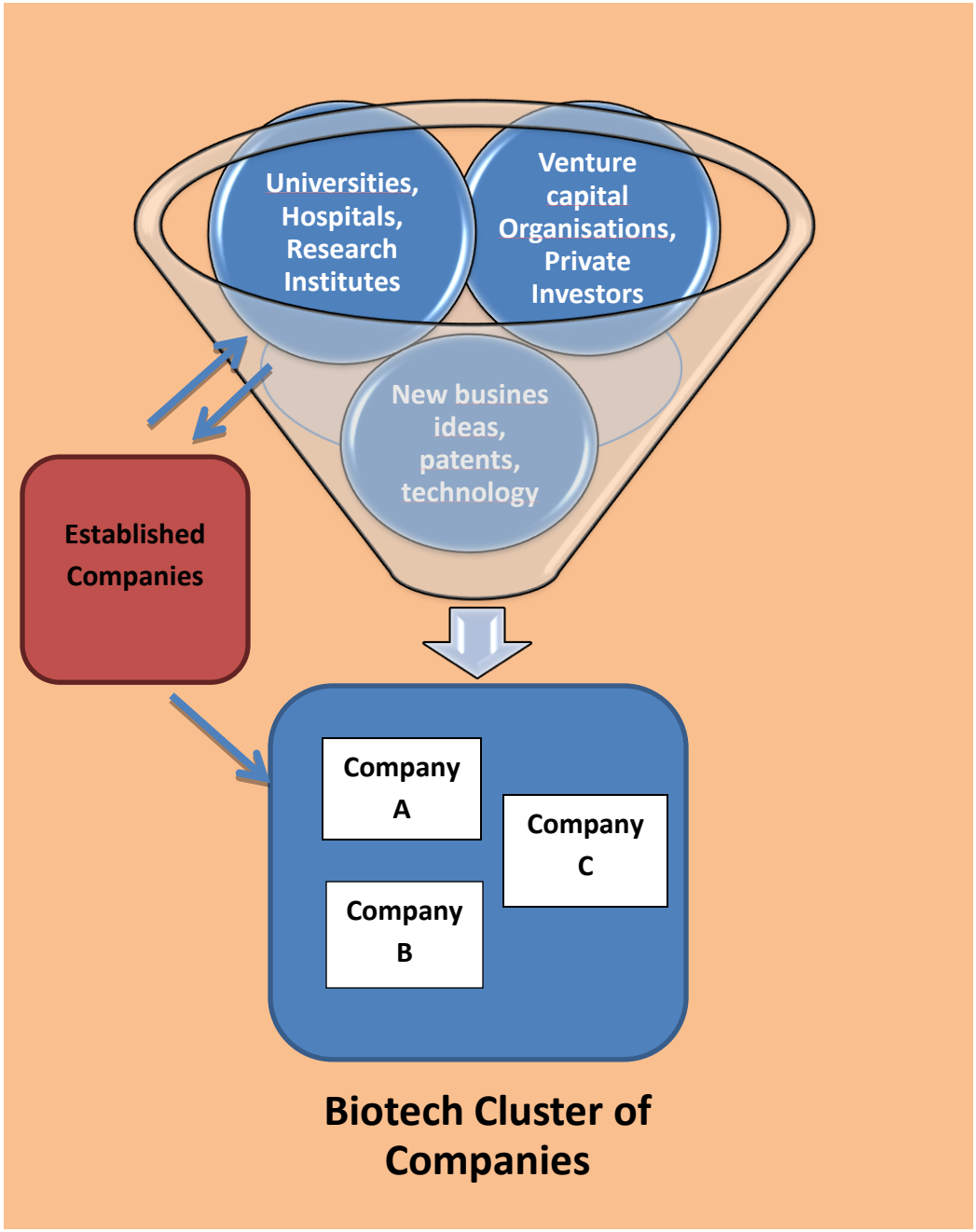


Fig 4. Formation of Biotech Cluster

Established companies play a major role in collaborating with the academic and research establishments as well as with the Biotech Cluster for innovative ideas, flow of innovation and bringing a product to market. Bringing product to market is a highly

expensive and time consuming process, especially in biotech business, for which collaboration with big companies is essential. Such collaboration need not be within the national limits. In fact, internationalization with the support of transparent policies should be encouraged and welcome.

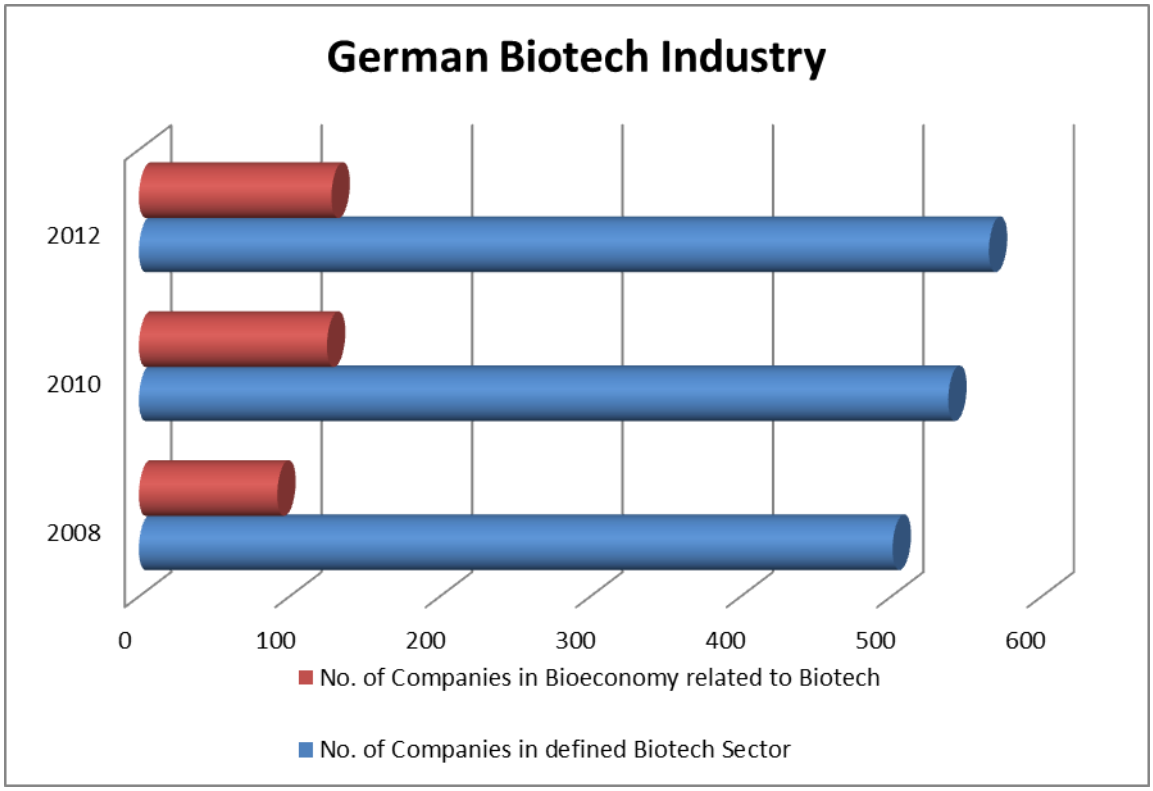
One of the most successful Indian biotech parks is Genome Valley in Andhra Pradesh. Among various factors, proximity to reputed educational cum research institutions like the Indian Institute of Chemical Technology, National Institute for Nutrition, Center for DNA Fingerprinting and Diagnostics, Center for Cellular and Molecular Biology, L. V. Prasad Eye Institute, University of Hyderabad on one hand and to established pharma companies like Dr. Reddy's Laboratories Ltd. on the other, has contributed to its success. In addition Hyderabad can boast of another park named as Alexandria Knowledge Park (previously known as Shapoorji Pallonji Biotech Park). IKP Knowledge Park in Hyderabad is another very well managed and successful park. Although it is not a dedicated biotech park, it does have some life science companies located in the cluster. Biotech clusters such as Bangalore Helix, Biotech Park in Kharagpur, West Bengal or Inspira Infrastructure Biotech Park in Aurangabad can be considered as well functioning clusters. However, there is a need to develop many more efficiently managed Biotech clusters, especially in the context of newly launched startup initiative by the current Government of Prime Minister Modi. According to Mr. Utkarsh Palnitkar, Partner, Head of Advisory and Head - Life Sciences, KPMG in India, "a constraint is the low availability of specialized infrastructure. Today, there are very few operational biotech parks in India which support industry with ready-to-use lab facilities for R&D, incubation support for startups, dedicated land for scaling up activities". He has very clearly underscored the important role of regional clustering as a means of securing innovativeness and competitiveness, especially for young and small firms in knowledge intensive industries such as biotech. Being in a cluster, such small firms can generate new business ideas, concepts of technology, patents etc. by close interaction with other members of the cluster. For eventual success, it is important that such clusters must be led by highly experienced and entrepreneurial-minded leaders, to make the clusters one-stop support system designed to foster entrepreneurial business environment for both academia and industry.

3. Biotechnology in Germany

Having discussed in detail about the progress that India is making in biotechnology sector, let us now turn to examine the Biotech Scenario in Germany.

German Biotech industry has been divided into two categories: (A) companies defined as biotechnology and (B) companies in bio economy but only distantly related to biotechnology (Fig 5). In 2012, about 15 thousand people were employed by 565 category A companies. A similar number of employment was registered for Category B companies.

Fig. 5. Growing number of Companies in German Biotech and allied Industry



Last year, 2015, was a year of cheer for German biotechnology scene, as the combined revenue of German biotech industry reached Euro 3.00 Billion with an increase of 5.8% over the last year (Fig 6). Out of the total German Biotech companies, approximately

48% (273) belong to the field of biopharma segment looking for new drugs, vaccines or biomarkers. German biopharmaceutical companies have a robust pipeline of drugs in the market (Table 5). Several new products are getting ready for launch. A big number of companies (73) are working in the field of developing new diagnostics and another 55 companies are focused on the development of therapeutics which already have one or more products from phase I clinical trials in the pipeline. The rest of the companies (145) are service providers in the preclinical field of therapeutics research or offer technology platforms as a service in the health area.

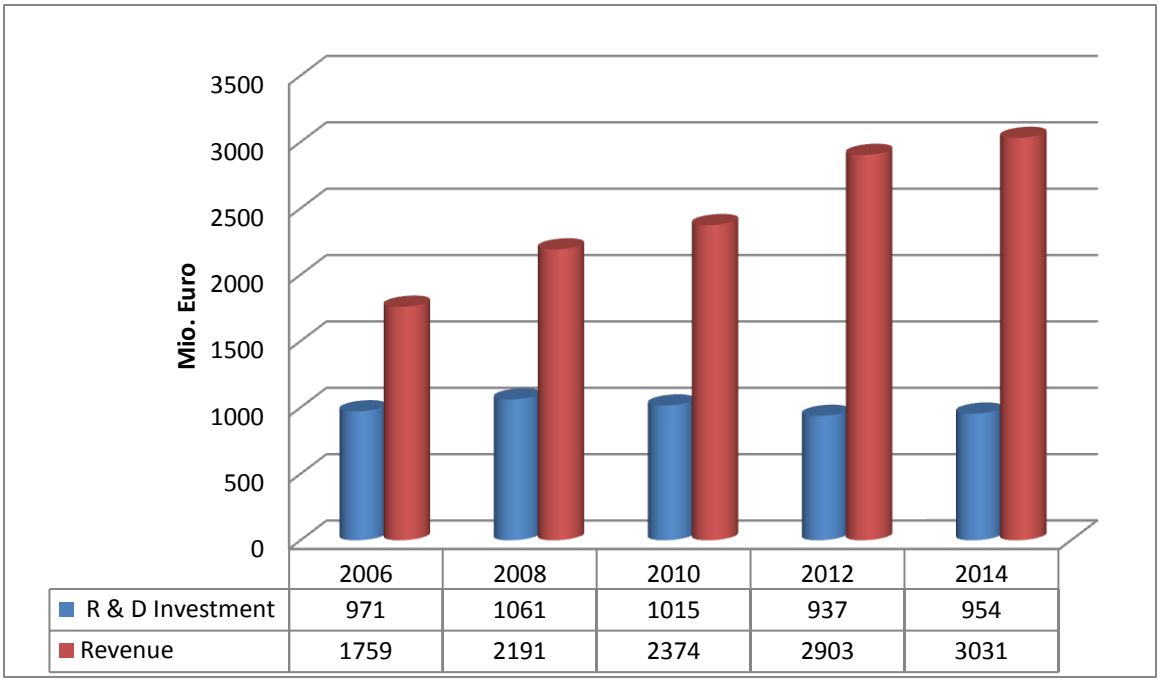


Fig. 6. German Biotech Industry Revenue and Investment in R & D from 2006-2014.

Apart from the Biopharmaceuticals, Germany has made astounding progress in developing technology platforms, e.g. high throughput screening platform (Evotec AG, European Screening Port,), engineered antibody generation platform (MorphoSys AG), platform for generation of genetically engineered cells for expressing recombinant proteins (ProBioGen, Artes, PlasmidFactory GmbH & Co KG, Rentschler Biotechnologie GmbH , Trenzyme GmbH), contract manufacturing processes especially for biopharmaceuticals (Rentschler , Boehringer Ingolheim, Richter Helm) .

A very interesting concept is to set up technology platforms not just focused on a single

Table 5. Pipelines of drugs developed by German Companies

Company	Product	Indication
Bavarian Nordic GmbH	PROSTVAC®PIII, immunostimulant	Prostate cancer
BioGenerix AG	2 candidates	Unspecified
DermaTools Biotech GmbH	DermaPro®	Wound healing, especially for Diabetic Foot
Euroderm GmbH	Epidex,	Wound care
immatics biotechnologies GmbH	IMA901, multiple tumor-associated peptides	Renal cell carcinoma
Medigene	Eligard, polypeptide	Prostate Cancer
Merckle Biotec GmbH/Teva	Ratiograstim	Neutropenia
Merckle Biotec GmbH/Teva	Epoetin theta, rec. erythropietin	Anaemia
Oncoscience AG	Theraloc, Nimotuzumab, EGF receptor antibody	Pontine glioma
PAION AG	M6G, Morphine-6-glucuronide	Post-surgery pain
PAION AG	Remimazolam, a benzodiazepine derivative	Anaesthesia

type of product but a continuous process to keep churning out various leads at regular intervals. For example, the antibody-based platforms (Morphosys) remain undoubtedly dominating but other platforms that may provide leads based on RNAi, genome, proteome, system biology, cell therapy etc. may become even more lucrative, as such platforms not only provides leads new drug development but also companion diagnostics. Examples of such companies can be Indivumed, CureVac, Noxxon etc.

Bio-agriculture segment remains rather subdued in Germany, as the public opinion is very much against the genetically modified organisms. Therefore field trials of genetically modified plants/crops have seen drastic reduction from the heights of 2007, when more than 60 field trials were performed, to 2012 when almost none were run. Despite the constraints , Germany has world-class developers of GE crops, such as Bayer CropScience, BASF, and KWS. These companies are major suppliers of GE seeds and technologies to markets outside of Europe. Some other companies have worked on the production of innovative bio-based pesticides (Euroferm). Otherwise use of crops and biological waste products for production of fuel, especially bio-diesel and ethanol is quite widespread and top technology is a great strength here.

In Bio-industrial field German companies have assumed global leadership position. It is now being discussed as industrialization of biotechnology. Bio-catalysis platforms based on engineered enzymes (EVOcatal, c-lecta, , Enzymical , etc) have established a solid foundation for green chemistry. Research in production of Biopolymers that are both environment friendly and bio-degradable by companies like Evonic AG, Brain AG, BASF have already resulted in several products in the pipeline.

In summary, Germany has already made a strong impact in various segments of Biotechnology and life sciences. One of the major factors that contributed to this success is large number of biotech clusters spread across the country. Three of the four largest are in Munich, Rhine-Neckar and Rhineland. A further biotechnological network does research and development in the Berlin - Brandenburg area. Under successful clusters one can count BioM AG and BioM Biotech Cluster Development GmbH, Life Science Nord, BioCon Valley, BioTop etc. The Biopolymers/ Biomaterials cluster brings together around 150 companies and 40 research institutions from all over Germany with the aim of developing plastics based on renewable raw materials. Similarly BioCat Cluster brings together 15 large and 19 small and medium sized companies as well as 27 research institutes. These clusters not only help to pool available technology, knowledge and resources together helping to achieve synergy. Individually many of these small companies will not be able to sustain themselves over a longer period as R & D in biotechnology is an expensive proposition but coming together in a cluster they have the highest degree of survival potential. Contests for funding support in regional

clusters like Bio Regio have provided tremendous competiveness and innovative edge for the members of such clusters.

4. Comparison of Biotech developments in India and Germany

Indian biotech market at about 6-7 Billion Euros in 2015 can be considered to be bigger than the German market, which is valued at 3 Billion Euros. However, German bio-pharmaceutical segment is qualitatively far ahead of India having several innovative bio-pharmaceutical candidates in the pipeline, many of which are in the advanced stages of development. Also in terms molecular diagnostics, some of the German companies have several innovative products that have already reached market. Even in the sectors such as bio-industrials, especially in bio-catalysis, Germany has made tremendous progress from which India could benefit.

Indian bio-pharmaceuticals are getting stronger in bio-similars and vaccine production. This particular segment of biotechnology is going to be an important driver of growth both in India and Germany in the near and mid-term. If one counts the top twenty innovative drugs, each with revenue of several billion Euros, one will find at least half of them as biomolecules. The top selling ten bio-pharmaceuticals have been listed in Table 6. On top of it, several top selling products will see patent expiry in the coming five years. Products like Lantu, Abilify, Copaxone, Neulasta, Tracleer, Namenda, Avodart/Jalyn, Zyvox, AndroGel and Synagis can be listed as those losing the intellectual property protection with a global sales of about 32 billion US$ in 2015. A loss of exclusivity for its top-selling drug, Lantus (Insulin glargine) next year is imminent for Sanofi. FDA has already approved a biosimilar from Elli Lilly, Basalgar, developed in partnership with Boehringer Ingelheim. But Merck working together with Samsung Bioepsis is also readying a biosimilar to reach the market in 2016-2017. However, all the drugs listed will not immediately face the competition from the copy-cat versions. For example, Synagis (Astra Zeneca) will go out of patent next year but a bio-similar is still not ready. Therefore, some of the bio therapeutics, for which patents may expire, will not immediately face any threat from the competitors. Thus Biosimilars may have a great potential but these are not easy to produce unlike the small molecules.

Table 6. Top selling biopharmaceuticals in global market.

Trade Name	*Active principle*	**Biochemical property**	**Global Revenue Billion Euros**
Humira®	Adalimumab	Monoclonal antibody against Tumor necrosis factor (TNF) α	10
Enbrel®	Etanercept	Recombinant protein, a TNF inhibitor	8
Lantus®	Insulin glargine	Recombinant protein, long-acting basal insulin analogue	7
Rituxan®	Rituximab	Monoclonal antibody against CD20	7
Remicade®	Infliximab	Monoclonal antibody against TNF-α	6.2
Avastin®	Bevacizumab	Monoclonal antibodyn an angiogeneis inhibitor, anti VEGF A	6
Herceptin®	Trastuzumab	Monoclonal antibody that interferes with the HER2/neu receptor	
Neulasta®	Pegfilgrastim	Recombinant protein, PEGylated form of the recombinant human granulocyte colony-stimulating factor (GCSF)	4
Copaxone®	Glatirameracetat	Mixed peptides, immunmodulator for treatment of multiple sclerosis (MS)	4
Lucentis®	Ranibizumab	Monoclonal antibody fragment used as antiangiogenic factor for age related macular degeration (AMD)	4

Moreover, legally biosimilars must be named differently than the original innovator molecule. Thus the branded molecule may still carry its marketing advantage. In this complex scenario, it may be argued that Indo-German cooperation at multiple levels of drug development may be beneficial for companies of both countries to take advantage of multibillion dollar opportunity arising out of patent expiry of innovators drugs.

German biotech industry is characterized by the following strengths and weakness:

Strengths

- Highly developed culture of innovations.
- Availability of latest technologies
- Highly developed manufacturing capabilities
- Excellent link between academia and industry
- Very efficient cluster formation and management.

Weakness

- Lack of adequate funding especially in comparison to USA
- High cost of innovations
- Lack of adequate managerial competence, in certain specific sectors

<u>The strength of Indian biotech industry can be summarized as:</u>

- Abundant skilled manpower available at a relatively lower cost
- Top Quality research projects being run at a number of academic institutions and at research labs of companies
- The cost of innovation, manufacturing and clinical trial is a fraction of that required in the developed world.
- Sophisticated skills in computational biology and data analysis are available.
- Knowledge of chemistry, especially in synthesis of molecules is abundant.
- Expertise in plant extract/natural product database is available.
- Clinical research capability is comparable to developed countries.

The weakness of Indian biotechnology industry can be listed as:

- Funding crunch especially in R & D
- Poor link between academic research and biotech industry
- Research ambience in general is not upto the level of developed countries.
- Securing intellectual property right of innovations in university labs is not widespread resulting in failure of product development.

- Intellectual property related issues causing uncertainties in the mind of international innovators, although signing of TRIPs agreement by India has been an encouraging development.
- Regulatory issues remain somewhat unclear.
- Cluster development lacks the required quality and strength

5. Areas of potential collaboration, challenges and opportunities.

Having discussed above the progress that India and Germany have made in this sun-rise sector, an attempt will be made now to delineate the areas of potential collaboration with respects to opportunities available and challenges that may have to be faced. It becomes obvious from the discussions above that certain specific sectors of biotechnology can turn out to be profitable focal points of cooperation between Indian and German entities.

The foremost is the production of bio-pharmaceuticals including bio-similars and vaccines as well. Skills in running various technologies and in synthetic chemistry as well as in clinical research are available adequately in India. If German companies can make the technology platform and funding available to selected Indian Companies, then it is possible to speed up the lab to market strategy with a considerable saving both in terms of time and money.

Genomics skills are well established in India and German companies especially those active in molecular diagnostic area could profit by cross-border cooperation with India.

Biotechnological services ranging from pre-clinical research to contract manufacturing, including computational Biology backed by cloud computing could be another area of profitable Indo-German cooperation.

In bio-informatics and in Silico Biology sector there are several success stories of Indo-German Collaboration. India based Polyclone, a biotech company with expertise in molecular, cell and computational biology has collaborated with the Dept. of Biotechnology & Enzyme Catalysis of the Institute of Biochemistry at Ernst-Moritz-Arndt University Greifswald for a joint research project to engineer transaminase enzymes to broaden substrate scope as these biocatalysts are useful to make chiral compounds for

the chemical and pharmaceutical industry. “This collaboration will strengthen our research on engineering transaminases as Polyclone’s advanced computational tools will substantially help us in understanding different transition states of the enzyme to guide improvement of these very important biocatalysts” said Prof. Uwe Bornscheuer. “This collaboration creates a fruitful feedback loop: Polyclone will predict how we can improve our enzymes, and we will check this experimentally. The results will help us in deepening our understanding of the transaminases, and Polyclone to validate and further strengthen their computer modeling algorithms” said Jun.-Prof. Matthias Höhne. “The advances in molecular modeling and molecular dynamics techniques have been underutilized so far when it comes to understanding the behavior of biocatalysts. Many conformational and quantum mechanics attributes like reaction coordinates of the transition states, electrostatic potential, pi-pi interactions and many more such descriptors provide an insight into the enzyme mechanism like never before. We hope this collaboration will address many such challenges in the future and help pave the way for better productivity of critical enzymes” added Mr. Naveen Kulkarni, CEO of Polyclone Bioservices, Bangalore.

The market for high-end diagnostics in India is expanding at very high rate and most of the products are being imported. Contribution from Germany is quite significant. However production of such items locally in India may bring down the prices giving access to a bigger market.

Another area of cooperation would be bio-banking. This is an area where Germany is advanced. Indian companies, when supported and guided, can acquire the required skill set fast. Maintenance of such tissue/ cells/bone banks can be a costly proposition in developed countries. The cost can be minimized if such banks are set up in India. Moreover with the availability of a large patient pool in India, such banks could be filled up quickly with tissues/cells/bone sample obtained during surgery in Indian hospitals.

Agricultural biotech opportunities including genetically modified resistant crops, production of bio-pesticides and biofuels are an attractive area of Indo-German cooperation.

When Kiran Mazumdar-Shaw was asked to give her comments on her wish-list about segments of Indo-German cooperation in biotechnology apart from bio-pharmaceuticals, she said spontaneously, “Germany has a long history of public and private sector activity in biological technologies, especially in the areas of water and soil bioremediation. With studies indicating that 75% of India’s surface water is contaminated by human and agricultural waste as well as industrial effluents, Indo-German collaboration on bioremediation can help de-pollute Indian rivers”. Indeed this is an important area that will improve the quality of life of Indians in general.

Opinion leaders both in India and Germany agree that the collaboration between India and Germany in areas listed above may yield rich dividend for both German and India entities. At the same time, there are words of caution as well. Utkarsh Palnitkar, Partner, Head of Advisory and Head - Life Sciences, KPMG in India listed three major constraints as he said “One of the constraints is in terms of regulatory approvals. There are multiple ministries and departments are involved in regulating biotechnology industry, be it for product approvals, clinical trials approval, manufacturing approval. Another constraint is lack of specialized infrastructure. Today, there are very few operational biotech parks in India which support industry with ready-to-use lab facilities for R&D, incubation support for startups, dedicated land for scaling up activities. Third key constraint is availability of funds.

Biotechnology sector is known for its complexity which is highly knowledge driven, has long gestation period and has very high risks, number of PE/VCs focusing on this sector are far and few”. To help to sort out the regulatory hurdles, the Government of India has taken various steps to address this challenge by proposing Biotechnology Regulatory Authority of India (BRAI), releasing guidelines for marketing authorization of biosimilars. At the same time, Biotechnology Industry Research Assistance Council (BIRAC) is instrumental in funding many startups and innovative companies but still a lack of growth capital will again have an impact on overall growth. Here perhaps the German investors including VC and PE capital may step in and give a helping hand. Lack of properly functioning clusters/incubators managed by professional leaders need to be addressed by the policy makers as an urgent necessity.

6. The joint path to progress

The potential of benefit of working together has been fully understood by both Indian and German decision makers in politics, academia and in business. Hence India and Germany have taken during the last decade a number of steps to promote and to strengthen this relationship. As a result Institutions like Indo-German Science and Technology Centre (IGSTC) in Gurgaon, has come up in India. IGSTC has been established by the Department of Science and Technology (DST), Government of India and the Federal Ministry of Education and Research (BMBF), Germany to foster innovation through Indo-German R&D networking including industrial research partnership in PPP mode. Similarly there are offices of German Research Council (Deutsche Forschungsgemeinschaft, DFG), Frauenhofer Society and Max Planck Society linking the German institutions to Department of Biotechnology, Department of Science and technology, Indian Council of Medica research etc. Apart from this, European Union research funds have been made available to promote scientific cooperation between India and Europe, including of course Germany.

6.1 Promotion of Academia-Industry link

Kiran Mazumdar Shaw, Chairperson and Managing Director of Biocon, Bangalore, who received a prestigious award, ‘2014 Global Economy Prize' for Business, from the Kiel Institute for the World Economy at the Institute's 100th anniversary celebrations at Kiel in Germany, has this to say, “Germany and India can do great work together in the field of biotechnology. Already, several joint projects in areas such as agri-biotech and nanotechnology are ongoing at the Indo-German Science & Technology Centre in New Delhi. Moreover, Germany and India already have more than 150 joint Science & Technology research projects and 70 direct partnerships between universities of both countries. India’s scientific establishments have close partnerships with premier German R&D institutions, including the Max Planck Society, Fraunhofer Laboratories and Alexander von Humboldt Foundation.”

It has become clear that the progress that Germany has made in biotechnology is underpinned by the close link between its industry and academia. This was unfortunately lacking in India in the past years. Prof. Anjali Karande, Professor, Department of

Biochemistry, Indian Institute of Science, and Bangalore says optimistically, “Academic research is the basis of application-oriented research. Therefore, academic research will have to go on. In India, academia-industry interaction in the Biotechnology area has been initiated in the last two decades and is increasing slowly but steadily”.

With its world class institutions like Max Planck Society, with more fundamental focus in research, and Frauenhofer Society, with more application oriented bias in its research, apart from the countless Universities dotted all over the country, German biotech industry has been served well. Many top biotech companies with innovative products in the pipeline today have originated as spin-offs from afore-mentioned institutions. This is one area where India and Germany should strengthen its link and IGSTC has already initiated several projects with both academia and industry in so called 2 plus 2 projects. This means projects funded by IGSTC will have one academic and one industry partner each from Germany and India. Examples of such projects are:

- “Developing sustainable transgenic crop plants tolerant for drought or a combination of drought and heat stress by manipulating ABA signaling and Ascorbate-Glutathione pathways”, jointly operated by International Centre for Genetic Engineering and Biotechnology, New Delhi, and NSL Group Companies, Nuziveedu, Hyderabad from India and the Leibniz Institute of Plant Genetics and Crop Plant Research (IPK), Gatersleben and Saaten Union Biotec GmBH, Leopoldshohe from Germany.
- “Biotechnological approaches to improve chickpea crop productivity for farming community and industry”, operated jointly by the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) , Hyderabad and Bench Bio Private Limited, Valsad from India, and Goethe University , Frankfurt/M and GenXPro GmBH, Frankfurt/M from Germany.

This is a very pertinent model system to bring academia and industry somewhat closer, a fact that is vital for progress and new developments in biotechnology.

However among many success stories there are some problem cases as well, which can give us an insight on how to make the system work better. It is the 2+2 Indo German project entitled, “Nanochitosan in plant protection”.

The initiator of this project, Prof. Bruno Moerschbacher said, “This has been possibly the most successful and most rewarding project of my scientific career, with a clear and satisfying result “. In this project (financially supported by the German Federal Ministry of Education and Research BMBF and its Indian counterpart, the Department of Biotechnology DBT), four research teams from Indian and German Universities and Industries have collaborated to explore the potential of copper-loaded chitosan nano- and microparticles in combination with microbial bio-control agents to protect crop plants from disease. We have in particular targeted diseases caused by oomycetes such as Phytophthora and Peronospora, e.g. on grapes or potato, and on Trichoderma BCA strains selected by the two Indian partners, the teams of Prof. Jatinder Kumar from G.B. Pant University of Agriculture and Technology and that of SriBiotech company in Hyderabad. The team of Prof. Bruno Moerschbacher at Münster University produced and characterized a broad range of chitosan polymers which were used for the production of nano- and microparticles which in turn were loaded with various advanced copper compounds provided by the team of the German agro-company Spiess-Urania. Chemical and enzymological techniques were used and further optimized for the generation and characterization of the chitosans and their oligomeric degradation products when treated with chitosan hydrolyzing enzymes of Trichoderma. The chitosan polymers, particles, and oligomers were analyzed for their biological activities towards oomycete pathogens and their host plants. The results of the project were stunning. The scientists were able to develop stable and viable formulations of dual and triple combinations of the three active ingredients, namely copper, chitosan, and Trichoderma. The synergistic combinations allowed a reduction of copper to about half the current dosage which translates into a very significant protection of the environment. Importantly, this reduction was achieved while maintaining the plant disease protecting activities of the product and at the same time adding a plant growth promoting effect. Thus, yield and quality of the harvested grapes and potatoes were at least equal to and sometimes even exceeded the levels reached with conventional chemical plant protection.

The collaboration between the German and Indian partners has been smooth and constructive from the very beginning, the expertise and infrastructure of the partners

have been perfectly matching, exchange of information and materials has been open and easy because of a trusting atmosphere between the partners, the two financial agencies have been supportive and flexible, and the results are highly satisfying as they have the potential to contribute making agriculture more sustainable, protecting the environment and providing safe crop harvests for both farmers and consumers. The only bitter pill to swallow was the fact that even though the Indian side had already extended the project into "phase 2", the German side did not grant the matching funds required to convert the amazing results into marketable products. It is unfortunate in this case that the project had to be stopped before a logical conclusion of the project could be made. Still there are many positives to be taken from the experience of Prof. Moersbacher.

In addition to such laudable efforts, one may hope in future, such 2 plus 2 projects will involve at least one start-up company in biotech areas. The new initiative promoted by the Prime Minister Modi, to support a start-up culture in India is expected to benefit biotech business as well. Such startup biotech companies will undoubtedly benefit a great deal by getting exposed to international research ambience. Therefore, it will be helpful if DBT and BMBF jointly make proposal for a special support fund, especially dedicated to biotech 2+2 projects where the Indian Company must exclusively be a startup.

6.2 Bilateral Conferences on focused themes:

Since biotechnology is a knowledge driven business dependent on collaboration and cooperation, there should be ample opportunity for meeting and discussing the specific areas of business. A big conference on generalized theme like “International Biotechnology Conference” does not help much. Rather, conferences like the 7th “Hanseatic India Colloquium on “ Drug Development & Research: Opportunities for Indo-German collaborations” or the 8th Hanseatic India colloquium on "Transnational Cooperation in Drug Development and Clinical Research" are more valuable. This colloquium is being held in Hamburg since 2006 and in 2017 its 10th version is being planned. A personal experience narrated by Prof. Anjali Karande of Indian Insitute of Science exemplifies how such focused theme conference can bring interested people together which almost automatically generate a fruitful collaboration. In her words, “my

personal experience of collaboration was rather informal. I met Prof Arne Skerra (Technical University of Munich, Germany), in Copenhagen in August 2003, at a much focused meeting, 'The Benzon Symposium on Lipocalin Protein Superfamily'. We were able to express a protein in our lab through recombinant expression technology. Prof Skerra also was interested in this protein. Our interest was to study the biological property of the molecule and Prof. Skerra was interested to study its structural aspect. The protein that we had expressed was unfortunately devoid of biological activity and was not of much use to us but for Prof. Skerra it was never the less of interest and we provided him with the plasmid so that he could express the protein in his lab and study its structural properties. I was glad to share the reagent. His group published a paper in 2004, using the construct. In 2014, based on another publication from his group, I requested for the reagent generated in his laboratory, to which he responded and sent it immediately. While his group focused on the elucidation of structural aspect of the protein and eventually solved the much eluded structure of the protein glycodelin. At the same time by modifying the original construct provided by us, he was able to generate a protein that was now biologically active. He was kind to provide us this new construct which then helped our lab to demonstrate that the recombinant glycodelin corresponding to the modified gene construct obtained from the Skerra group harbors immuno-modulatory activity. We are putting together our findings to submit a paper for publication". It can be said that this type of unforced cooperation develop spontaneously when like-minded people meet. To promote such cooperation, funds must become available to support such international/bilateral meetings between India and Germany organized with a focus on a specific theme.

For such Conferences, special funds should be made available enabling startups from India to participate.

6.3 Mentoring of Indian Startups

To help the smaller and start up biotech companies in India, it may be a good idea to set up a "Mentoring Service" utilizing the knowledge and expertise of retired senior executive officers of German biotech companies. This can be built up in the same line as the non-profit organization SES (Senioren Experten Service is the Foundation of

German Industry for International Cooperation, Stiftung der deutschen Wirtschaft für internationale Zusammenarbeit). SES offers interested retirees the opportunity to pass on their skills and knowledge to others, both within Germany and abroad. For smaller companies and startups with limited managerial and financial competence, such "Mentoring" by SES can be extremely valuable to run the companies and to generate funds and products.

Also for startups and smaller biotech companies, funding crunch is a major problem. There is a need of overhaul in the policy regarding Angel investments. Tax break offered for startups is a right step in this direction. Perhaps waiving of capital gains tax could be another good option to encourage private investment. In recent years some investments from private sources have flown in the life sciences companies. Tata Sons' chairman emeritus Ratan Tata, for example, has invested in a cancer therapeutic startup Invictus Oncology, the New Delhi. One of the Indian startups in oncology area received a major funding boost from Roche with a deal worth up to $555 million on immunotherapy to combat cancer. US-based Hysun Biomedical Inc has recently formed a joint venture with an investment of $15 million with Phyto Biotech in Bangalore. Deals and funding are coming through, but a revamp of policy is needed to energize the biotech potential that India has.

6.4 Promoting and Strengthening of Clusters/incubators

While discussing various constraints faced by Indian biotech industry, Utkarsh Palnitkar mentioned about the lack of enough clusters/ incubators being a major constraint. In India there are some clusters in and around Hyderabad, Bangalore etc. but these must be more professionally managed. The cluster managers are not running just realty services to house the biotech businesses or rent out their premises to companies. According to Steven Casper, Associate Professor, Keck Graduate Institute, Claremont, CA, "Successful clusters develop social networks linking managers, scientists, and financiers They are populated by individuals and organization with a diverse range of skills and experiences They become "hubs" of activity, with fairly rapid entry and exit of organizations and individuals". The cluster managers have a responsibility to promote this. They have to have a background of life sciences, should understand the theme of

the business being run by the cluster members, and should be able to mentor them, even sometime coach them. Such managers, in brief, must take up initiatives to identify funding opportunities for the cluster members, guide them to write application, help them to find partners and so on. This is exactly the job of the cluster managers in Germany, who are responsible to make their clusters successful. Clusters compete with each other to attract the highest research support from the state, federal or European funding agencies. In India too, a similar culture must evolve. Perhaps one may consider here ways and means to bring the German clusters managers closer to such managers in India, offering training and mentoring facilities that may help the cluster managers in India to be more effective. Here again policy makers from both Germany and India must consider ways and means to achieve this for Indian biotech clusters.

6.5 Exchange of information

"India offers excellent business opportunities for German enterprises. One of the constraints in a successful Indo-German business promotion is the lack of information flow, especially for the German Mittelstand (Midsized companies). The companies need detailed information about business development opportunities, financing, growth sectors and go-to-market strategies" says Yvonne Julia Metzger, General Manager , India Office BVMW e.V., the German Association for Small and Medium-sized Businesses. She is also founder and CEO of Markets and More, and official representative of BVMW e.V., in the metropolitan region Hamburg. This lack of information flow in both directions has to be overcome and efforts must be undertaken to make business relevant information available to Indian and German companies both in written and digital form. This also has been an important reason why the Consul General of Hamburg took this initiative to publish this booklet.

7. Conclusion

It is hoped that the information contained herein will be of benefit for both Indian and German Companies, policy makers and investors to take the cooperation between German and Indian Companies and academic institutions to the next level. It is obvious that Biotech sector in India offers attractive opportunities in Bio-Pharmaceutical sector, which in India is well established and relatively competitive. Bio-services with its strong

base in terms of skilled manpower and strong computational biology knowledge can be an interesting sector for investment from Germany. Agricultural biotechnology is an area where some German companies are already active in India, especially as market in Germany is almost nonexistent and research opportunities are limited too. Thus India can offer German companies excellent opportunities in this particular sector. India needs both investment and technology to move up the value chain. For this India needs to make its policies more transparent and logical to become an attractive destination for foreign direct investment.

8. About the Author

Dr. Amal Mukhopadhyay, Founder and Director of Elga Biotech, Hamburg, obtained his doctoral degree from the Institute of Medical Sciences, Banaras Hindu University in Biochemistry for his work in molecular biology in 1970. Following this, he was awarded a postdoctoral fellowship to carry out research work at the University Hospital at the University of Hamburg from 1975-1978. Dr. Mukhopadhyay has been active for over thirty years as a scientist and as an entrepreneur in the areas of healthcare, pharmaceuticals, biology and biotechnology. His strength lies in directing innovative research and development work, in promoting Business development, and in corporate leadership. He has over 100 research publications and has authored several books.

His earlier assignments include Co-founder and Managing Director of Agelab Pharma GmbH, Hamburg, Germany and Director, Institute of Hormone and Fertility Research at the University of Hamburg.

Currently he is a member of the Scientific Advisory Board of Polyclone Bioservices Ltd., Bangalore, India (www.polyclonebio.com), an overseas member of the Board of Scientific Advisory Committee of Yashraj Biotechnology Ltd., Mumbai (www.yashrajbio.com) and an Advisory Board member of Malkolak Institute of Life Sciences, Hyderabad (http://www.malkolak.in/).

He is convener of Hanseatic India Colloquium, a platform for networking between German and Indian companies and academic entities with an interest in biotechnology. He represents Hamburg Business Development Agency (HWF) for India in Life Sciences sector. He is currently Chairman of the executive board of an NGO, Hanseatic India Forum.

ELGA Biotech (www.elgabiotech.com) is a company that he has founded in 2004, with the purpose of building bridges between Germany and India especially in sectors of life sciences, biotechnology, pharmaceutical sciences. ELGA Biotech has strong roots both in India and Europe with wide ranging knowledge and expertise in business culture, business development, management, financing, R&D and marketing.

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Annexure

List of Associations and important contacts in the industry

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