

# ACCELERATING

FORGING  
INDIA'S  
BIOECONOMY



# GROWTH

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# FOREWARD



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The Biotechnology Industry Organization (BIO) and the Association of Biotechnology Led Enterprises (ABLE) are pleased to provide this white paper: *Accelerating Growth: Forging India's Bioeconomy*.

The Indian biotechnology industry is on the cusp of entering a new era when it can provide significant economic growth and development to the people of India and around the world. India already has many of the necessary ingredients needed in order to grow its bioeconomy, such as a talented and enthusiastic scientific workforce. However, not all the ingredients are in place in order for the country to reach the next level. In 2012, ABLE laid out an ambitious goal of growing the Indian bioeconomy from its present \$4.3 billion to more than \$100 billion by 2025. This call to action was quickly picked up by government officials and others who saw the potential benefits of a strong and vibrant biotechnology industry in meeting the needs of Indians in regards to medicine, food, fuel, and environment.

In order to reach this goal, the country needs a roadmap and this white paper is designed to provide such a guide. Biotechnology, like other industrial sectors, requires an ecosystem to nurture and sustain it. In the case of biotechnology, this ecosystem requires substantial input and assistance from the Government of India, at both the Central and State levels. Because biotechnology operates in a highly regulated environment, numerous government policies, rules and regulations are at play, influencing every single aspect of the industry, from research and development, through regulatory approvals, taxation and finance, all the way to government procurement. These policy concerns go well beyond the mandate of any one ministry or agency. Rather, multiple ministries need to work together towards a common goal.

In order to be as comprehensive as possible, the co-authors have examined India's emerging biotechnology industry from a variety of angles and perspectives, focusing attention on the various sub-sectors such as biopharmaceuticals and bio-agriculture, and as well various policy concerns such as taxation, infrastructure, regulation, and technology transfer. While biopharmaceuticals dominate in terms of market value—reflecting perhaps India's traditional strength in the pharmaceutical space—we should not neglect the tremendous benefits that could be generated in these other areas, particularly energy, agriculture and environmental remediation. These are all areas where India, and indeed the entire world, has significant unmet needs which could one day be provided by Indian scientists and entrepreneurs.

As Kiran Mazumdar-Shaw, the Chairman and Managing Director of Biocon, Ltd. and first President of ABLE recently noted, "India's contribution to affordable healthcare goes much beyond being a pharmacy to the world. ...Helped by a significantly lower cost base that supports a large talent pool of scientists and engineers, India's research engine is now driving a new model of innovation that adds the condition of affordability."

This raises another set of issues that are skillfully drawn out by the authors. As noted above, the current size of the biotechnology industry is approximately \$4 billion. In order to reach the stated goal of \$100 billion, there needs to be a dual focus on entrepreneurship and innovation. At the moment, there are only a handful of biotechnology companies in India. In order to reach its potential, India needs to encourage the



development of many more, by tearing down the barriers to new investment and improving the overall climate for business. About \$4 billion to \$5 billion in investment is needed on an annual basis for the next four years to realize the industry's goal for growth. Furthermore, the country needs to encourage more academic researchers to become entrepreneurs, taking their ideas from the laboratories to the factory floor, in the process creating new, high-paying jobs for many others.

Separately, India needs to re-emphasize its commitment to innovation and introduction of innovative biotechnology products. Significant resources are rightly focused on manufacturing biotechnology products, particularly biopharmaceuticals, at lower costs in order to ensure widespread affordability. While admirable, this is an extremely competitive space and will not likely bring in significant new revenues. An equal if not greater emphasis should be placed on developing new products for the global marketplace. By doing so, companies in India will be in a position to attract new investment capital and generate substantial amounts of new revenue. In such a manner, India will reach its goal of creating a \$100 billion industry.

We hope that this white paper will provide the new government in New Delhi and the various state capitals with thoughts on where they should focus their energies in the coming months and years. India is entering a new era of governance and regulation. Efficient and effective governance, coupled with a regulatory system anchored in global standards, is needed in order to provide the necessary underpinnings to allow Indian companies to compete on the global stage. In this manner, policymakers can help the Indian bioeconomy grow and thrive, in turn providing the economic, health and other benefits that India and its people richly deserve.

In closing, we agree with the authors that there is an incredible opportunity now for the country to claim its position as a global leader in biotechnology. The country is about to undergo a rapid transformation into a modern, integrated economy, one with opportunities for its citizens at all levels, regardless of income, social status, or geography. Biotechnology is one way that the country can deliver for its people, helping to feed, heal, and provide new, clean sources of energy.



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# INTRODUCTION: ACCELERATING GROWTH: FORGING INDIA'S BIOECONOMY

In 2012, the Association of Biotechnology Led Enterprises (ABLE) laid out a goal of growing India's bioeconomy to more than \$100 billion by 2025, a level that would place it on par with India's information technology industry today. India's biotechnology trade group noted that for nearly a decade the industry had generated a compounded annual growth rate of around 20 percent. It reasoned that if the government took steps to improve the business environment and worked with industry and academia to make a unified effort to capitalize on the nation's strengths in biotechnology, the industry in India could accelerate its average growth rate to about 30 percent a year and reach \$100 billion by 2025.

ABLE acknowledges that the goal is aspirational, but argues that such "stretch" goals have been effective in the past at catalyzing industry and driving growth. The vision is not only to transform India's biotechnology industry into a position of global leadership, but also to harness the technology to address the challenges the nation faces to feed its population, treat the growing health demands made by a rising incidence of chronic disease, and address environmental challenges the country faces while fueling its economy. In so doing, India has the opportunity to address global challenges, provide breakthroughs in the cost of technology to expand access and affordability to a global marketplace, create higher value-add products, better employment opportunities, and solidify its position in the global bioeconomy as a hub for both R&D and manufacturing. Doing so will drive foreign investment into India and help create high-paying jobs for a country where 1 million young people enter the job market every month.

The Biotechnology Industry Organization (BIO) and ABLE asked Burrill Media to provide an analysis of the biotechnology industry in India and make policy and other recommendations of changes that would allow it to accelerate its growth and realize its potential. In addition to secondary research, the authors conducted a series of interviews with leaders in industry, government, finance, academia, and others involved in India's biotechnology sector. The research for this study was launched with a full day workshop hosted by the Indian School of Business in Hyderabad in November, 2013 attended by more than 20 Indian thought leaders in biotechnology.

The Indian bioeconomy grew to \$4.3 billion at the end of fiscal 2013, up from \$530 million in fiscal 2003, according to BioSpectrum, a widely read trade publication on Indian biotechnology. (Note: All currency amounts in this report reference U.S. Dollars).

Though the industry is concentrated in Bangalore and Hyderabad, it extends across the country and includes more than 350 companies working not only in the area of vaccines and biopharmaceuticals, but also agricultural biotechnology, industrial biotechnology, bioservices, and bioinformatics. It includes homegrown enterprises that have demonstrated success on the global stage, as well as global multinationals attracted to India because of its location, costs, available talent, and market, which will become more attractive as prosperity in the country spreads.

But the biotechnology industry in India faces challenges that, like the country itself, are diverse and complex. There is evidence of slowing of growth in the sector tied directly to matters of policy and associated regulatory practices. In other cases, there are challenges posed by barriers that cannot be overcome through simple government mandates. While there are steps the government can take to speed the regulatory process, increase investment in the sector, attract multinational biotechnology companies, improve the business environment, and encourage innovation, tackling some of the issues will require leadership within government, coordination among agencies, public education, and steps to ensure government investments or policies are not stymied by leaden bureaucracy or the unintended consequences and costly delays of court rulings.

The question of what India could do to accelerate the growth of its industry is urgent. There is an opportunity now for the nation to stake a claim as a global leader in biotechnology and, in the process, transform its economy. But there are concerns that if proper steps are not taken to address problems that inhibit growth, slow innovation, and dissuade investment, the opportunity before it now could be lost. Nations are staking their claims in emerging areas that can drive growth of the industry. They are taking steps to capitalize on the convergence of information technology and biology, laying the groundwork for a thriving biosimilars industry, driving research and development of proprietary products in health-care and agriculture, and seizing opportunities to provide research and manufacturing services to the global industry that is looking to emerging markets for growth.

India is learning hard lessons from the success of competing nations that have taken aggressive steps to pursue new markets and attract companies to their shores. Today, the country and its biotechnology industry are at a crossroads, and what India does or does not do in the next few years will reverberate long into its future.



## SUMMARY OF RECOMMENDATIONS

The recommendations in this report are not presented in order of priority. Instead, they reflect a broad set of issues that need to be addressed for the entire ecosystem to flourish, although the authors feel the issues of regulation and intellectual property represent the most pressing issues for India's bioeconomy. For India to compete globally, attract investment, and enjoy the economic benefits that its strength in biotechnology can bring, it needs to align itself with global standards in these areas.

### REGULATION

- ☼ The Government of India should consolidate its regulatory agencies and reorganize them so they follow a similar structure to regulatory agencies in the markets into which India sells active pharmaceutical ingredients and finished products.

- ☼ India should empower an office within the drug review process to act as the single point of contact during a drug review, guide companies through the process, and resolve problems and conflicting instructions from different committees and agencies.

- ☼ The drug review process coordinator should have the mandate to require standard operating procedures and authority to create and enforce deadlines on a project-by project basis.

- ☼ The Drugs Controller-General should conduct ongoing quality and process control audits. India should have its own standards for such reviews and related reports, but the process should be cross-checked annually against foreign reviews of the same products.

- ☼ Inspections made by off-shore regulators of Indian facilities and clinical studies should be reviewed against reviews made by domestic agencies. Variances should be reported and they should be investigated as appropriate.

### AGRICULTURAL BIOTECHNOLOGY

- ☼ Leadership from the government and the biotech industry should find a way of conducting the national debate surrounding agricultural biotechnology based on a thorough social and scientific assessment of an appropriate incorporation of biotechnology into Indian and global food security.

- ☼ The government should take an active role in public education about biotechnology and its benefits, and to counteract the spread of misinformation.

- ☼ The Biotechnology Regulatory Authority of India (BRAI), first proposed in 2008, should be established to bring a more streamlined regulatory approach to agricultural biotechnology.

- ☼ Authority, transparency, and social and economic accountability of BRAI should be subject to on-going review.

### BIOSERVICES

- ☼ India should harmonize its regulatory processes and requirements with those of other countries.

- ☼ To promote greater use of Indian contract research organizations, India should make accumulated clinical data more useful for regulatory filings in other countries.

- ☼ In line with harmonization, India can also adapt the best practices for the oversight and regulation of contract research organizations in other countries, and modify them to India's specific circumstances.

### INDUSTRIAL BIOTECHNOLOGY

- ☼ The growth of the industrial biotechnology sector can be promoted at first by mandating use of products for needs that are currently unmet, particularly in energy and environmental remediation.

### BIOINFORMATICS

- ☼ India can take a global leadership role in formulating and promoting protection of personal data, especially for populations in the emerging markets.

### TECHNOLOGY TRANSFER

- ☼ India must address gaps in technology transfer quickly.

- ☼ It should follow developed countries to integrate the subject of translational research into academic coursework and offer training to faculty members as well.

- ☼ As is well known throughout India, the technology transfer enterprise in the United States was given its big boost with the passage of the Bayh-Dole Act in 1980. While there are imperfections in any mandated system of technology transfer, India should adopt *The Protection and Utilisation of Public Funded Intellectual Property* legislation first introduced in 2008. The failure to do so has a significant and ongoing cost to the biotechnology industry and the country in terms of lost opportunity and diminished competitive advantage as other countries rapidly develop their own technology transfer systems.

- ☼ Once mechanisms for technology transfer are in place at academic institutions, developing and maintaining professional staff will be a challenge. National training programs are in place in many countries and can serve as a model for professional development in India.



☼ Governments with active technology transfer programs do not track the performance of the programs or the outcomes associated with the technologies. India can take a leadership role in developing an information system for such tracking. Such a system will assist in the monitoring of progress and point to needed changes in policies and practices.

### **INTELLECTUAL PROPERTY**

☼ Using the patent system as a mechanism to control drug pricing forestalls making the difficult decisions about necessary investment in the healthcare system, but does not deal with the underlying issues. As politically challenging as it may be, there should be a reconsideration of the intent and application of Section 3(d) of the *Indian Patent Act*. The issue of access and affordability are clearly paramount, but as a matter of policy, the government must consider a broader array of solutions and allow its patent system to encourage needed innovation, particularly among domestic biotechnology companies. Moreover, multinational corporations say the use or threat of compulsory licensing dissuades them from investing in innovation in India.

### **HUMAN RESOURCES DEVELOPMENT AND HIGHER EDUCATION**

☼ Indian universities should develop joint degree programs in such areas as information technology and biosciences and encourage projects that bring together students in different disciplines for common goals.

☼ The Indian Institutes of Technology and the Indian Institutes of Management should work together to develop joint degree programs to produce people with both scientific research and management skills.

☼ Programs should be established to train and encourage entrepreneurial researchers interested in commercializing technology to assist them with understanding issues around such things as intellectual property protections, capital formation, market analysis, and regulatory issues.

☼ India should develop programs and incentives to attract expatriates with deep industry and entrepreneurial experience to return to India as a valuable source of expertise to launch new companies or fill specific skills gaps.

### **INFRASTRUCTURE**

☼ India could create special zones that provide biotechnology companies with reliable water and power needed for their operations. These zones can have dedicated power plants and water purification, as well as sewage processing. The process of transferring specialized equipment from overseas sources should be expedited.

### **TAXATION**

☼ The investment tax credit in equipment that India provides high technology companies should be extended to biotechnology companies, as should the ten-year tax holiday afforded companies once they begin producing products.

☼ R&D tax credits extended to biopharmaceutical companies should be extended to contract research organizations and companies in other sectors of biotechnology.

☼ India should introduce accelerated appreciation for research and development expenditures, which could encourage generic drugmakers to invest in biologics and put India in line with China and Singapore, which both offer such incentives.

☼ India should offer tax holidays for R&D related income. In addition, India could incentivize the development of innovation through tax breaks for revenue derived by the sale of patented products.

☼ To incentivize investment in early-stage, privately held biotechnology companies, India should forgo taxes on gains from investments in these companies held for more than 10 years.

☼ India should consider the creation of tax favorable financing vehicles to allow the creation of off-balance sheet financing of R&D projects by private investors.

### **M&A AND PARTNERING**

☼ India should promote itself to biopharmaceutical companies as a gateway to Asia, provide forums that foster partnering opportunities, and take steps to quell concerns about the protection of intellectual property and other policies, laws, and business practices that impede partnering activity. M&A and partnering have been important mechanisms to access capital, technology, and new markets.

☼ Since access to innovation and markets are two reasons potential partners with Indian companies would seek to enter into a partnership, India will need to address issues that limit its development of innovative products or make its market unattractive to foreign companies despite its large and growing population.

### **FINANCE**

☼ Angel investing: There are limited interventions for public policy, but providing incentives through tax credits or other measures for angel investors could encourage the availability of capital for early-stage biotech.

☼ Incubator resources: Direct grants of investment capital to incubators may not be the most effective approach. A matching program to leverage government investment where the government provides funds on a 1:3 or 1:4 basis, and the incubator raises the larger portion of capital from private and local public and private sources, might be the best way to engage local communities and align interests.

☼ Government programs: The Department of Biotechnology program should preserve a meaningful role in capitalization in order to encourage work towards areas of strategic interest to India. A mechanism should be created to encourage Indian state governments to participate in funding.

☼ Venture capital: India should create matching programs similar to China's Emerging Industry Start-up Investment Scheme. An adaptation of this program could be a game changer for India.

☼ Public listing: As the Indian government accumulates experience with offshore listings, it could consider expanding the purposes for which Indian companies may list overseas.



## INDIA'S BIOTECHNOLOGY INDUSTRY TODAY

The goal of reaching a \$100 billion industry in India by 2025 provides an alluring target. It is obtainable, the reasoning goes, by increasing the industry's growth rate to around 30 percent. Such a back-of-the-envelope calculation provides a sense of the pace of growth that will be necessary to achieve that goal, but does not convey the significant changes that will be necessary in order to double the pace of growth in fiscal 2013. Given the time it takes to move biotechnology products from development to the market both because of their complexity and the necessary regulatory hurdles, some evidence of the industry's ability to meet those goals would need to be present in the pipelines and offerings of companies today. The intent of this paper is not to conduct an inventory of the industry's products and pipelines to test the likelihood of the industry achieving its growth goal of \$100 billion by 2025, but instead to look at the industry's strengths, weaknesses, opportunities, and threats to formulate a set of recommendations that would allow it to accelerate growth and realize its full potential.

India's biotechnology sector for the year ending March 31, 2013 reached sales of \$4.3 billion, according to the annual *BioSpectrum/ABLE* survey. Though it's grown over the past decade at a compounded annual average rate of about 20 percent, growth has slowed in recent years. In the fiscal year ending March 31, 2013, the industry as a whole grew at a rate of 15 percent. The biopharmaceutical sector (including vaccines, biosimilars, medical devices, and stem cells) is the Indian biotechnology industry's biggest source of revenues, generating more than 63 percent of the industry's total revenues in fiscal 2013. The biopharmaceutical sector with the related bioservices sector (including contract research, contract manufacturing, and outsourced clinical trials), together represent a combined 82 percent of the industry's total revenues in fiscal 2013.

India's biotechnology industry began in 1978 with the founding of Biocon, its first biotechnology company. Biocon today has more than 7,100 employees and \$344.5 million in revenue, 8 percent of all the revenue generated by the industry in fiscal 2013. In fact, 20 biotechnology companies in India generated almost half of the industry's total revenue in fiscal 2013, according to the India Brand Equity Foundation.

### BIOPHARMACEUTICALS DOMINATE

India's biopharmaceutical sector is a world leader in vaccines producing 60 percent of the world's supply. Some 15 companies produce more than 50 brands, according to the India Brand Equity Foundation. Vaccines represent the strongest generators of revenue within India's biopharmaceutical sector and the industry has shown its ability to both innovate and provide cost-competitive products to meet global demand. Today, India supplies more than half of all the vaccines to international organizations, such as the World Health Organization and the United Nations International Children's Emergency Fund. Leading companies in the area include the Serum Institute of India, Panacea Biotech, Bharat Biotech, Indian Immunologicals, and Shantha Biologics. Serum Institute of India is the nation's largest biotech with revenue of \$437.1 million.

India, long associated with its strengths in generic drug and active pharmaceutical ingredient manufacturing, is also demonstrating that it is capable of creating innovative biologics. In August, Biocon launched Alzumab, a first-in-class anti-CD6 antibody for the treatment of psoriasis in India. The global market for psoriasis drugs is expected to reach \$8 billion by 2016. The 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 bioeconomy. Consider that today, 2013 sales of Amgen's neutropenia therapy Neulasta roughly equaled India's entire bioeconomy and the seven top selling biologics *by themselves* each dwarfed the total revenues of India's biotechnology industry ranging from \$6.8 billion to \$10.7 billion in revenues a piece.

The emerging area of biosimilars promises to increase access and affordability to life-improving and life-savings medicines in India, as well as provide a global growth opportunity for Indian biopharmaceutical companies. Biosimilars are copies of innovative biologics no longer protected by patents. Unlike generic versions of small molecule drugs that are chemically synthesized, biologics are derived from living organisms. As a result, biosimilars can be functionally equivalent to, but not identical copies, of the innovator drug. The emerging market for biosimilars is attracting not only leading Indian biopharmaceutical companies, but generic drugmakers as well. Biocon, Serum Institute of India, Dr. Reddy's Lab, Intas, Shantha Biotech, Reliance Life Sciences, Wockhardt, and Cipla are among the Indian companies active in the area. Already Indian biopharmaceutical companies market more than 20 biosimilars in India.

In the United States, the Obama Administration's landmark healthcare reform law called for the creation of a regulatory pathway for biosimilars, but the U.S. Food and Drug Administration is still finalizing the rules for how it will review biosimilars seeking marketing approval. How fast and how big the market develops will depend to an extent on the FDA because the United States accounts for about half of global biologic sales. Market estimates vary widely, but a February 2013 report from McKinsey placed the range of estimates for the biosimilars market from \$2 billion to \$20 billion by 2020, a wide range sensitive to the pace and limitations of regulations in participating countries. Biosimilars are expected to provide greater access to biologics in emerging markets and be embraced in developed markets where there is increasing pressure to rein in healthcare spending, particularly on specialty pharmaceuticals that have been insulated against competition from generics. The pricing and global distribution of biosimilars, however, is still an open question. Biosimilars may face greater hurdles than small-molecule generics in crossing borders and their use in emerging markets may be limited by the degree of health services and financing available. Though these drugs will be able to command higher prices than generic small molecule drugs, it will be a competitive market and likely contribute less than 5 percent of the \$100 billion goal by 2025, suggesting innovation will be critical to driving growth.



Indian companies are also pushing into other emerging areas, such as regenerative medicine. The area of cell therapies in India is nascent in terms of revenue, but expected to grow rapidly. Already companies, such as Stempeutics and Reliance Life Sciences, are marketing products and there is a growing pipeline in development. The area has been hampered by the lack of a clear regulatory framework, but the country has been taking steps to address this. In March 2014, the *Economic Times* reported that India's Health Ministry had convened an expert panel that called for the establishment of licensing rules for stem cell banks, institutions running clinical trials of stem cell therapies, companies importing cell-based products, and companies manufacturing them within the country.

### GROWING OPPORTUNITIES

Beyond biopharmaceuticals, the bioservices sector represents an area of significant promise for India because of its skilled labor force, attractive costs, and access to major markets in Asia. India's bioservices sector includes global contract research organizations, such as Quintiles, as well as Indian companies including GVK Bio, Jubilant Biosys, and Advinus. These companies extend across the drug development continuum. Some offer a full range of services from target identification through human clinical trials. 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.

As the cost of bringing new molecules from discovery to market continues to rise, the global biopharmaceutical industry is seeking ways to improve efficiency. Though estimates vary widely, some studies suggest it now costs on average \$1.5 billion per new drug. Despite the rise in spending on research and development, the biopharmaceutical industry has not been able to improve its success rate. As a whole, the industry continues to produce an average of about 27 new molecular entities approved by the FDA each year. As pressure increases on cutting the time and cost to market, India has become attractive as a cost-effective place to conduct drug development. A 2011 study by the Boston Consulting Group suggests the cost of drug development in India is less than half of what it is in Europe and the United States. Though India's cost advantage is slowly shrinking, it is expected to remain significant for the next several years. Because of its large population and relative pharmaceutical naiveté, it has been able to recruit patients on average about four times faster than other global clinical trial sites, the study found. Current controversy over informed consent and compensation of participants, discussed below, has stalled this work and is jeopardizing India's position in this area.

Manufacturing is also an area where India is leveraging its cost-competitiveness. India has the opportunity to replicate in biologics the same type of success it has had with small molecule drugs. In 2009, Switzerland-based Lonza, a global biopharmaceutical contract manufacturer, announced plans to invest \$150 million in Hyderabad's Genome Valley in two phases. The first phase involved the establishment of R&D labs for more than 100 workers. The facility will include a range of services for biologics and bioinformatics. It includes a small-scale manufacturing plant for biopharmaceuticals and a small-scale biotherapeutic media manufacturing plant. The second phase, expected to be completed in 2015, will expand the manufacturing capacity, nearly double the R&D lab capacity, and

expand large-scale manufacturing for biopharmaceuticals. Lonza's efforts are seen as recognition that India could become a preferred destination for global biopharmaceuticals companies.

The convergence of the life sciences with information technology is creating a particular opportunity for India. The country has well-established strengths in the information technology area, and with the advent of low-cost, whole genome sequencing and the growing role of molecular diagnostics in both precision and preventive medicine, there is a proliferation of data creating demand for bioinformatic analysis. Though bioinformatics represents the smallest of India's biotechnology sectors having generated just a little more than 1 percent of the industry's revenues in fiscal 2013, it is an area of growing importance and opportunity. Bioinformatics companies developing innovative products and services include Strand Life Sciences and vLife, while service providers include Ocimum BioSolutions and Molecular Connections. Conventional information technology companies, including Cognizant and Infosys, have also waded into the arena.

### HEALTHCARE CHALLENGES

The challenges India's biopharmaceutical industry faces are made more complex by India's healthcare system. India spends 3.9 percent of its GDP on healthcare. That compares to 5.2 percent for China, 8.9 percent for Brazil, and 9.3 percent on average for member nations of the Organization for Economic Co-operation and Development. While the public sector dominates spending on healthcare in OECD member nations—on average governments account for 72 percent of spending—public sector spending on healthcare accounts for just 31 percent of total healthcare spending in India, leaving individuals to shoulder the bulk of spending with about half of those costs going to pay for drugs. Drug pricing and affordability has been a central concern of government healthcare policy, and a core issue in the evolution of India's drug-related intellectual property regime.

Though India has made great strides in healthcare since 1960, it still lags developed nations in measures such as life expectancy and infant mortality. Life expectancy grew to 65.5 years, more than a 20 year increase compared to 1960, but less than the OECD average of 80.1 years. Infant mortality since 1990 has been nearly halved to 47.2 deaths per 1,000 births but is ten-fold higher than the OECD average of 4.1 deaths per 1,000. Healthcare costs push 39 million Indians into poverty each year, according to the U.S. National Institutes of Health. There are great inequalities within India and those with the greatest need often have the most difficult access to care and are the least likely to have their health needs met, NIH says. Urbanization and Western lifestyles that have come with the growing economy have complicated India's healthcare landscape. Though communicable diseases remain a substantial threat in India, the prevalence of chronic diseases, such as cancer, diabetes, heart disease, and chronic obstructive pulmonary disease, are taking a growing toll on the population.

### BARRIERS ERECTED

Tension exists between India's goals of growing its biotechnology industry and the need to provide access to affordable care for its population. Within the Indian population there is suspicion towards multinational corporations and their motives. Against that

backdrop the industry has been involved in legal and policy battles that have slowed its growth, made India an outlier in its approach to intellectual property and clinical trials, and caused multinational biopharmaceutical companies to rethink their strategy and investment in the country.

In our interviews, multinational drug companies expressed concerns about inadequate legal machinery to stop infringement either before or after legal action is taken by a company. The interpretation of certain portions of the patent act can be abused by competitors. It can create a substantial challenge for innovators and create an environment in India where competitors seeking to delay entry of a new medicine that competes with an existing franchise have an unfair advantage. There is also the open-ended opportunity for pre-grant opposition that can be abused and lead to prolonged delays. Other provisions are viewed as arbitrary in nature and open to broad interpretation. Together, these may discourage multinational companies from fully participating in the Indian market.

Beyond the IP issue of allowance of patents is the matter of compulsory licensing. India's patent office in March 2012 ruled that the multinational pharmaceutical giant Bayer must license the intellectual property behind its kidney and liver cancer drug Nexavar to Natco Pharma, which makes an inexpensive generic version of the drug for the Indian market. The compulsory license was the first to be issued on a patented drug in India. In issuing the ruling, India joined Thailand and Brazil as part of the small group of nations that have enacted compulsory licensing on drugs for public health reasons. "The drug is exorbitantly priced and out of reach of most of the people," said India's Controller General of Patents, Designs, and Trademarks in the ruling, which relied on provisions in multilateral international trade agreements to support its conclusions. Natco sells the drug for about \$176 per month instead of the much higher price Bayer has charged in India, reported to be approximately \$5,500 per month. Under the terms of the license, Natco will pay Bayer a mandatory royalty of 7 percent of its net sales of the drug each quarter and, like Bayer, will supply the drug free of cost to patients unable to afford it. The decision has created uncertainty for potential investors. Moreover, critics point out that the significant drop in price has not led to as high an increase in use of the drug as anticipated, possibly suggesting the issue of access in India's healthcare system is more complicated than price alone.

The following month India's Supreme Court brought to an end a seven-year court battle when it ruled that a Novartis patent for its cancer drug Glivec was not valid. Novartis' new formulation of the drug, which the company says has better processing and storage properties, did not qualify for patent protection under the country's patent laws, which only allow for a new patent if the new formulation improves therapeutic efficacy. The decision allowed Indian drug-makers to continue making generic versions of the cancer drug. The older formulation of Glivec was not patent protected because at the time of invention, India did not recognize product patents.

While non-profit healthcare groups hailed the decision, the court's ruling triggered growing concern among multinational pharmaceutical companies about its impact on innovation and investment going forward. "We recognize the importance of generics

to the contribution of health once patents expire," said the former U.S.-India Business Council President Ron Somers, "but believe that in order for India to become the 'innovation nation of the 21st century,' it should reward and encourage innovation, including incremental innovation, by respecting the significant resources and costs associated with finding new and better cures to treat diseases."

There was a great divide in our interviews between innovators and those invested in weaker intellectual property systems, who felt the current interpretations, court decisions, and enforcement of intellectual property rights—including the compulsory licensing decision on the cancer drug, Nexavar, produced by Bayer—were appropriate and not needing change. Some went so far as to challenge the relevance of the questions stating that intellectual property matters are essentially resolved. Critics of India's policies on intellectual property say by limiting patents to inventions that enhance efficacy and other measures that revoke or reduce protections, India is discouraging important innovations that improve drug stability, bioavailability, and other areas that could benefit Indian patients. They say it is also contrary to the way India treats the patentability of inventions in other industries. The current standards of patent evaluation and approval can be counter-productive in the long run. As the research and development prowess of Indian companies advance, India's administration of patent law might actually inhibit the growth of the Indian industry. In order to reach the \$100 billion goal for India's biotechnology industry, the country will need the revenue brought in by innovative products created by Indian companies.

Furthermore, in our interviews, some multinational drug companies expressed concerns about inadequate legal machinery to discourage infringement either before or after legal action is taken by a company. Other provisions of the Patent Act that provide for compulsory licensing and the ability to revoke patents deemed as hurting the government or public are viewed as arbitrary and non-transparent in nature. Together, these work to discourage multinational companies and other investors from fully investing in R&D and manufacturing in India.

The perception of increasing hostility toward the innovative biopharmaceutical sector and growing obstacles and liabilities to operating in India extends beyond the intellectual property controversies. The Indian Supreme Court in 2013 also placed a hold on 162 clinical trials as a result of the health rights group Swasthya Adhikar Manch's filing of a public interest petition calling for a halt to illegal and unethical clinical trials. The group complained that pharmaceutical companies had exploited impoverished adults, children, and the mentally ill, who participated in clinical trials to get access to drugs without understanding the risk. The court also barred new trials from beginning until an adequate monitoring system could be put into place. In the wake of the ruling, India's Ministry of Health and Family Welfare is introducing new rules to, among other things, videotape the informed consent of clinical trial participants and require drugmakers to compensate clinical trials participants or their families who are harmed in a trial, even in cases where the drug being tested was not the cause of the injury or death.

Clinical trials play a critical role in bringing new drugs to market.



While no Indian government official has publicly questioned the value of clinical research, the lack of predictability in getting trials approved slows the drug development process, adds costs, and discourages investment. The decision and subsequent rules have had a sudden and significant impact on clinical trials activity as companies have responded by moving clinical trials to locations outside of India, including those sponsored by Indian companies.

## SEEDS OF GROWTH

India's agricultural sector employs more than half of India's working population. Nevertheless, as a contributor to India's economy, agriculture accounted for just 14.5 percent of the nation's GDP in fiscal 2012, down from 30 percent in fiscal 1991. The growth rate of the agriculture sector during the past decade has slowed to an average of 3 percent a year, far less than the 7 to 9 percent for the Indian economy as a whole as it continues to move away from its agrarian base and services drive a growing portion of economic growth. Despite the country's economic gains, chronic hunger persists with an estimated 240 million people in India unable to get the food they need. Worsening the problem for India is the fact that its population is growing faster than its food production. Per capita food production declined since the mid-1990s as rising incomes and changing lifestyles has created demand for fruits, vegetables, and meat. While demand has grown, the land available for cultivation has remained largely unchanged for more than 30 years.

The agricultural biotechnology sector includes both technology development companies and seed companies. These include multinationals, such as Monsanto, as well as indigenous companies, such as Nuziveedu Seeds, Rasi Seeds, and Mahayco. Agricultural biotechnology has grown significantly during the past decade and is now the third largest biotechnology sector within India accounting for nearly 14 percent of industry revenues in fiscal 2013. Agricultural biotechnology includes not only genetic modification of crops, but also the use of marker assisted selection to accelerate the breeding of desirable traits without the controversies surrounding genetically modified crops. India is also harnessing soil metagenomics to study microbes in soil in order to improve yields and decrease the use of pesticides and fertilizers.

The promise of agricultural biotechnology in India can be seen in the case of *Bt* cotton, a genetically modified seed that produces a protein that kills bollworm, a pest that attacks cotton crops. *Bt* crops contain an implanted gene for the production *Bacillus thuringiensis*, a bacterium in the soil that produces a protein that acts as a pesticide. The use of these seeds has dramatically reduced the use of pesticides and turned India from being an importer of cotton in 2001 to the second largest exporter of cotton today. *Bt* cotton now represents more than 90 percent of all of the cotton grown in India. Yields have increased 68 percent per hectare, farmers' incomes have grown 129 percent per hectare, and it has helped lift the fortunes of 7 million farmers who were living below the poverty line, according to a report from Accenture.

Rather than building on the success of *Bt* cotton and reproducing it with other crops, India's agricultural biotechnology industry has been crippled by protracted legal battles, public campaigns from activists groups fueling fear of biotech crops, and government

inaction on advancing legislation viewed as important by the industry, such as the Biotechnology Regulatory Authority of India Bill, which would establish a new regulatory body responsible for overseeing biotechnology products and research outside of therapeutic recombinant proteins. As a result, growth of the sector has been muted, advances have languished, investment has stalled, and opportunities have been lost.

Though many other GM crops have been in development, the move to the marketplace has been stymied by legal battles and regulatory actions. Regulators in 2009 approved genetically modified eggplant, but the Minister of Environment and Forests at the time instituted an indefinite moratorium on its cultivation. The crop has been the subject of litigation over whether it violates India's Biodiversity Act, which seeks to maintain the diversity of the complex of organisms within India's ecosystem. Matters grew worse for the industry in 2013, when an expert panel of scientists convened by India's Supreme Court recommended an indefinite moratorium on field trials of *Bt* food crops because of what it called "major gaps in the regulatory system." The court, however, was critical of the expert report.

The logjam may be clearing, at least for field testing. In March 2014, the Ministry of Environment and Forests Genetic Engineering Appraisal Committee approved field trials for 11 seeds and was expected to consider additional field trials at future meetings. ABLE expects to see resurgence in R&D spending by agriculture biotechnology companies in India in fiscal 2015 after the inability to conduct field trials brought R&D activity to a virtual standstill.

## FUELING THE FUTURE

India's industrial biotechnology sector includes companies working to use biological processes to produce enzymes for the food, pharmaceutical, and textile industries, as well as green chemicals. The sector also includes bioenergy companies and bioremediation companies developing biologic treatments for pollutants. Though it represented a little more than 3 percent of the total revenues generated by India's biotechnology industry in fiscal 2013, it is viewed as an area of great promise, in part because of the increasing demand for food and energy from growing populations and rising incomes in the developing world. The Danish biotech Novozymes is the largest industrial biotech in India, accounting for half of the country's industrial biotechnology revenues. Other key players in the country include Advanced Enzymes, Rossarri, Biotech Richcore, Zytex, Maps India, and Sea6 Energy.

The biotechnology sector is seen as an important potential contributor to solving India's growing energy problem and its need for energy security. India is a net importer of fossil fuels and its demand is expected to grow dramatically if it is to sustain its targeted rate of GDP growth of 7 to 9 percent. During the last decade, India's import of crude oil more than doubled to 140 million tons from 57.8 million tons at the end of fiscal 2000. During the next 25 years, demand for electricity in India is expected to increase five-fold. Today, India depends on coal to generate 60 percent of its electricity needs attaching an environment price to its surging demand.

India's National Biofuel Policy, put into place at the end of 2009, set a goal of replacing 20 percent of petroleum fuel consumption with

biofuels by the end of 2017. It is unlikely this goal will be realized. In 2012, the government set a target of 5 percent blending of ethanol with gasoline. It was expected to achieve a 2.9 percent blend in calendar 2013. Despite the aggressive goals, one significant constraint on production has been the lack of available feedstock despite a surplus of materials. India is without a feedstock biomass policy that would organize efforts for its collection, which is made challenging because of the need to gather it in rural areas from a complex of small farms.

Biomass materials used for power generation include bagasse (sugar cane), rice husk, straw, cotton stalk, coconut shells, soya husk, de-oiled cakes, coffee waste, jute wastes, groundnut shells, and saw dust. There is an estimated 500 million metric tons of available biomass a year and a surplus biomass availability of up to 150 metric tons a year covering agricultural and forestry residues corresponding to a potential of about 18,000 megawatts, according to India's Ministry of New and Renewable Energy. The large amount of biomass—as much as 150 million tons of surplus materials produced each year—could be converted into biofuels and chemicals. It also sees additional potential through bagasse-based cogeneration plants at the nation's sugar mills.

India has also pursued the use of jatropha to produce biodiesel. Jatropha is resistant to drought and pests, can be grown on wastelands, and produces seeds that are as much as 40 percent oil. But the crop takes several years to develop and farmers have been reluctant to plant it because of too many unknowns about its cultivation and the economics of growing it. Approaches to risk sharing with farmers by the Government could be beneficial in this regard. Energy-producing plants utilizing the feedstock have sold biodiesel but have been running at around 25 percent of capacity.

Though nearly 90 percent of India's crops go to the production of food, the food vs. fuel debate will impact India's choices of feedstocks and has led it to focus on cellulosic biofuels and the use of land not suitable for the growth of food crops. Nevertheless significant technical and logistical challenges remain as advanced biofuels will not be a practical part of India's energy solutions unless they can be made cost-competitive with fossil fuels. Growth of the industry is also expected to be limited by the availability of land and water.

The other major industrial opportunity for biotechnology lies in the production of enzymes. These provide a means of cutting the use of water, reducing energy consumption, and address environmental degradation from harsh chemical waste products that result from industrial processes. The use of enzymes to replace chemicals used in such areas as textiles, detergents, forestry products, feed, and other areas offers multiple benefits for India. But adoption is slow because of a lack of technical standards and government mandates that require the use of enzymes to benefit the environment, conserve resources, and drive demand.

### COMMON CONCERNS

Though each sector within India's biotechnology industry faces unique issues, there are also common sources of strength and common obstacles that threaten to stunt its growth. Problems with bureaucracy and corruption, the lack of transparency and predictability in regulatory agencies, weak connections between the academic and industrial sectors, a lack of available investment for

early-stage biotechnology companies, and a low-level of R&D spending hamper India's ability to realize its vision as an innovation-driven \$100 billion bioeconomy by 2025.

### EMBRACING BIOTECHNOLOGY

The Indian government has recognized the biotechnology industry as an important driver of future growth for its economy and has taken steps to invest in the industry and support its growth. It created the National Biotechnology Board in 1982, which later became the Department of Biotechnology, to help establish the infrastructure, regulatory and legal framework, and fertile ground for the industry to develop innovative products to build the nation's economy and address issues of health, agriculture, and the environment.

In 2007, India released its National Biotechnology Development Strategy, which recognized the industry as a "sunrise sector" in need of "focused attention." That policy called for greater coordination between ministries, funding for innovative R&D projects in small- and medium-sized companies, and efforts to enhance the strength of the life sciences within its academic institutions. In addition, it supported new centers of excellence for biotechnology, the development of new incubators and biotech parks, and testing and lab facilities. India has made a steadily growing investment in the sector through various mechanisms. It has also taken other steps to encourage investment and ease financial pressures on biotechnology companies, such as subsidies and tax breaks for R&D spending.

Much hope within the industry is being placed in the nation's new leadership. The expectation is that the new government will bring needed focus to address the needs of the industry, simplify and accelerate government processes, and create an atmosphere that is more focused on economic growth and supportive of the role the biotechnology industry will play as a driver of India's future economy. Companies engaged in business in India expressed that existing processes create obstacles to getting much needed products into the market.

Regulatory regimes are complex and agencies have overlapping authorities that sometimes leave companies in the no-win situation of receiving contradictory instructions. Though the industry has seen the creation of the National Biotechnology Regulatory Authority of India, first proposed in 2008, as a positive step in addressing some of these issues, its establishment has been stalled because of political disagreements over the new regulatory body. The lack of transparency and predictability surrounding regulation of the industry hurts its ability to attract both foreign direct investment and risk capital. Despite optimism about the new leadership, the political environment remains complex and biotechnology will have to contend for priority on a crowded agenda of pressing items the new government will face.

### COMPETITIVE LANDSCAPE

India exists within a global economy. Its rich human resource pool, large number of English speakers, skilled workforce, large number of graduates and post graduates in the biosciences, and relatively lower labor costs make it competitive. But India is not alone in trying to capitalize on the opportunities to build its bioeconomy. Many other Asian nations are embracing the same opportunities. This adds urgency to the task before India as other

emerging economies, seeing opportunities within the biotechnology arena, attract investment, lure companies into their borders, and strengthen efforts to build bioeconomies of their own. India will find it difficult to compete if it establishes regulatory or intellectual property regimes that are out of step with other countries, fails to address basic infrastructure needs, or ignores the financial and tax incentives others are using to attract and retain companies.

Consider that in 2010, Biocon began construction on a \$200 million manufacturing facility in Malaysia, citing the lack of reliable sources of power and water in its home country. Ranbaxy is building a second plant in Malaysia, and other biopharma companies already there include Dr. Reddy's Laboratories and Cipla Medpro. Malaysia not only boasts abundant power and water, but also offers significant incentives, such as a 10-year tax holiday and easy access to neighboring Asian markets. In part, this reflects companies pursuing new opportunities, but it also reflects concerns about unreliable infrastructure.

### A DEARTH OF PRIVATE FUNDING

Access to capital continues to hamper development of early-stage biotech companies in India. The long development times, and the lack of predictability with the country's regulatory and legal system makes it difficult for the sector to attract private investment. Uncertainty over such issues as clinical trials and intellectual property has turned investors cautious. In fact, the sector raised just \$24 million from private funds in 2012 and none in 2011, a sharp decline from the \$180 million raised in 2010, according to a report in Live Mint based on numbers from the Indian investment tracking service VCCEdge.

Early-stage funding is almost always led by the government, although there are instances of entrepreneurs funding their own ventures and the small but growing importance of angel capital to address this gap in funding. Adding to the difficulty of attracting private investment is a lack of expertise within Indian funds to evaluate investments in the biotech sector. Biotech companies must compete for investment with the information technology and Internet companies, which can provide quicker returns and entail less risk.

The Government of India has taken several steps to create funding for innovative biotechnology companies, particularly companies that are early-stage. India has made a growing investment in the sector through various mechanisms. In 2010, it took steps to create a government-backed venture capital fund to support drug discovery and research infrastructure. The government's Biotechnology Industry Research Assistance Council also offers so-called Biotechnology Ignition Grants to scientist entrepreneurs at research institutes, universities, or start-ups. The goal is to stimulate commercialization of discoveries by funding translational research. Grants are issued twice a year for as much as \$100,000 each. Some 18 grants have been issued for a total of \$1.6 million for projects that range from producing butanol from sea algae to aptamer-based detection of tuberculosis. While welcome, the funding represents a modest amount for a worldwide industry that raised \$96 billion globally in public and private financing in 2013.

Industry too is taking steps to improve the financial landscape. In 2013, ABLE's entrepreneurship committee took steps to establish an angel investment fund. The group is seeking wealthy individuals

with knowledge of the industry, such as expatriate scientists who are pharmaceutical industry veterans, to commit funding of \$1 million to \$2 million each, the *Business Standard* reported in April 2014.

### R&D SPENDING LAGS

Assuming India wants to build an innovation-based bioeconomy, adding to the challenges it faces is its relatively low levels of R&D investment. Overall R&D spending in India was just 0.85 percent of GDP in 2013, down from 0.9 percent of GDP in 2012, according to the 2014 Global R&D Funding Forecast from Battelle and R&D Magazine. That compares to 1.9 percent for China, 1.3 percent for Brazil, 1.5 percent for Russia, and 3.6 percent for South Korea. Though India's R&D spending is expected to return to 0.9 percent of GDP in 2014, the report notes that the increase represents just one-fifth of the expected increase in GDP. Within the biotechnology industry, R&D investment in India reached a total of \$2 billion in 2012, just \$400 million of which came from Indian government. That compares to a \$6 billion investment from South Korea and an \$8.4 billion investment from China, according to The New England Journal of Medicine. "It [India] has significant academic infrastructure, large population, and global connectivity, but social and political priorities draw investment away from R&D," the report said.

Though India's top universities are capable of world class research, interview subjects say there is a gulf between the top tier universities and other academic institutions both in terms of funding and the quality of research. They say there are weak ties between industry and academia, a poor understanding within academia of what it takes to commercialize promising inventions, and a lack of an entrepreneurial culture and understanding among research scientists.

### INNOVATION IS ESSENTIAL

Although India has experienced great success in leveraging its intellectual capital to become a leading provider of generic drugs and active pharmaceutical ingredients, a continued approach of building upon the discovery research of others will likely limit India's economic potential to become a global biotech powerhouse, thereby putting a virtual cap on growth in the industry. Extensive needs in healthcare, food, and energy, and the need to improve the environment and related resources, demand that India take its wellbeing in its own hands rather than rely on others to develop the solutions necessary to meet the needs of its growing population. Other nations that can provide low labor costs, access to strategic markets, and friendlier business climates will compete in those aspects of the global biotechnology sector that can be commoditized and where innovation is not a distinguishing factor. Biotechnology companies in the region will also need to see that India provides the necessary tools, such as patents and data protection, to promote investment in innovation by ensuring adequate opportunity for companies to recoup investment.

For India to realize its vision of reaching a \$100 billion bioeconomy by 2025, it must focus on high-value opportunities that are driven by innovation. To meet these ends, India must better connect its academic, industrial, and financial sectors, remove the barriers that inhibit their collaboration, and leverage its strengths in information technology and its skilled workforce to become a global leader in biotechnology.

## RECOMMENDATIONS

### BIOPHARMACEUTICALS REGULATION

#### ISSUES

The regulation of biopharmaceuticals in India is plodding, plagued with inefficiency, and complex because multiple agencies and committees share responsibility for the review and approval process. Companies have difficulty navigating the process and understanding regulators' mandates. This is made worse by the lack of a central coordinator to act as a single point of contact to guide companies through the process. Feedback from agencies during the application and review process is limited and adds to the opaqueness of the process and leaves it unpredictable and inconsistent. Interview subjects expressed a lack of confidence in scientific and clinical sophistication, as well as industry experience of regulators and review committees. Industry perceives agency staff as unwilling or unable to take ownership of the process and assume direct responsibility for project management.

India's lack of harmonization with the requirements of other countries harms companies' ability to capitalize on opportunities of Indian companies to expand into foreign markets. The limited post-approval monitoring of products and perceptions of compromised quality, fueled by inconsistent findings by U.S. FDA inspectors and their Indian counterparts, leaves a lack of confidence outside of India that Indian drugmakers are in compliance with Good Manufacturing Practices. There are also concerns over cases of alleged data falsification. India took a step towards addressing this in May 2014 when Drugs Controller General of India G.N. Singh announced plans to invest more than \$500 million over three years to double the number of regulators and create state-of-the-art testing labs at ports to ensure pharmaceutical exports meet global standards, *The Economic Times* reported.

#### IMPACT OF CURRENT PRACTICES

Concerns in foreign markets about lax regulatory oversight of small-molecule generics manufacturing will carry over to biosimilars produced in India and undermine one of the industry's most promising opportunities for growth. With respect to the generics industry itself, recent news of actions by the U.S. FDA have led American pharmacy benefits managers, the large groups that essentially control the purchase and distribution of drugs, to cease reimbursement of drugs sourced from India. Regulatory problems do not just provide consequences for the companies that wrestle with them. They also reverberate through the Indian economy as they increase the cost of drug development, impede the flow of new revenue streams, and slow the growth of the industry, jobs, and spending. Such barriers discourage innovation and product development that address the unique health needs of India and instead encourage companies to look for opportunities in other markets where regulation is transparent and predictable. They also diminish cost advantages India could have over competitors in foreign markets.

#### POTENTIAL INTERVENTIONS

The Government of India should consolidate its regulatory agencies, such as the Central Drugs Standard Control Organization (CDSCO) and the various state drug controllers, and reorganize them so they

follow a similar structure to regulatory agencies in the markets to which India sells active pharmaceutical and finished products.

While this report hesitates to make recommendations with respect to the restructuring of the Ministerial system, it must point out that there are at least three layers of bureaucracy between the Minister and the Drugs Controller General of India (DCGI). Consideration should be given to elevating the post, perhaps to a Secretary level, for direct reporting to the Minister. Alternatively, create an independent mandate similar to the Competition Commission of India. With such realignment, the DCGI would be better positioned to acquire the financial and human resources necessary for effective operation. South Korea, by way of example, recently made the equivalent post a Cabinet Minister position.

Though India should be hesitant to add to existing layers of bureaucracy, it would benefit in the short-term from empowering an office within the review process to act as the single point of contact during a drug review, guide companies through the process, and resolve problems and conflicting instructions from different committees and agencies. This coordinator should be the first point-of-contact for companies in the regulatory process and serve as the project manager and overseer for the domestic and off-shore companies. The coordinator should have the mandate to require standard operating procedures and authority to create and enforce deadlines on a project-by-project basis.

To address quality concerns, the Drug Controller General should conduct ongoing quality and process control audits. India should have its own standards for such reviews and related reports, but the process should be cross-checked annually against foreign reviews of the same products. Cooperation with regulators in other countries to ensure appropriate development of standards and training for inspectors is strongly encouraged.

#### IMPLEMENTATION OF INTERVENTIONS

The potential interventions above should be implemented with a sense of urgency. Development of the product pipeline and its progress in regulatory review over the next two to three years is critical to approaching the growth goals of the industry.

#### POTENTIAL IMPACT OF INTERVENTIONS

A delay of just one or two years in improving and accelerating the regulatory review process will have disproportionate effects on India's ability to meet the targets for 2025. Each year of delay in regulatory approval can reduce revenue targets—cumulatively—by billions of dollars each year.

### AGRICULTURAL BIOTECHNOLOGY REGULATION

#### ISSUES

The issues surrounding agricultural biotechnology transcend industrial growth and include domestic and global food security, but the debate about the best approaches to addressing food security is ongo-

ing. Many groups advocate traditional farming methods combined with seed propagation and seed trading as the best way to achieve food security in a sustainable and economically equitable manner that does not impinge on the social and cultural fabric of Indian rural life. Others, who point to population growth and limitations to arable land and water, see the solution in the introduction and expansion of genetically modified crop technologies as a way to increase crop yields and reduce the need for water, pesticides, and fertilizers.

The debate in India—as elsewhere—is polarized. In India, it has moved from the public square to a protracted battle in the Indian Supreme Court. The Court assembled an expert committee to evaluate whether any risks existed with GM crops, but rather than resolve the question, it has left both sides charging members of the committee are either unqualified or biased, and their findings suspect.

### IMPACT OF CURRENT PRACTICES

The development of the regulatory system that governs the release of genetically modified crop technologies in India has been stymied. While *Bt* cotton has become a major crop in India, its use is not without controversy. The moratorium on approvals has prevented other GM cotton seed producers from entering the market, inhibiting price competition and exacerbating the impact on the very farmers that opponents of GM crops cite as concerns.

The debate over GM crops is not limited to India, but is being conducted throughout the world. It will perhaps be resolved in the next several years, at least in part. Once resolved, other countries in the region and elsewhere will increase production of crops in competition with India, and engage in research and development of new crop varieties limiting India's potential role in innovation and growth of its biotech sector.

### POTENTIAL INTERVENTIONS

Leadership from the government and the biotech industry should find a way of moving the national debate in a more constructive direction based on a thorough social and scientific assessment of an appropriate incorporation of biotechnology into Indian and global food security. It will be critical for the government to take an active role in public education about biotechnology and its benefits and to counteract the spread of misinformation.

The Biotechnology Regulatory Authority of India, first proposed in 2008, should be established to bring a more streamlined regulatory approach to agricultural biotechnology. The authority, transparency, and social and economic accountability of BRAI should be subject to ongoing review.

### IMPLEMENTATION OF INTERVENTIONS

Opposition to GM crops is not unique to India and has been a significant public issue in many countries. India alone will not resolve the underlying controversies, but can serve as a mediator for its own population on these issues by instituting policies based on scientific principles and a national consensus formulated on facts. The goal is to establish regulatory policies that are unambiguous and applied consistently.

### POTENTIAL IMPACTS OF INTERVENTIONS

Arrival of a functional set of consistently applied regulations related to

GM crops will provide a broad range of benefits. India can be the global leader in experimentation, modification, and development of GM crops for its own food security and for that of other countries with similar challenges by serving as a magnet country for collaboration with companies and research organizations worldwide.

As a leader of the developing world, India can set the global agenda for appropriate development of plant varieties, their pricing, distribution, and use in socially and culturally acceptable ways that may be foreign to Western ways of thinking. India can also benefit from the production of enhanced cash crops to make textiles, biofuels, and renewable chemicals, providing its companies with a competitive advantage.

### BIOSERVICES ISSUES

Bioservices encompasses major activities, such as clinical research organizations that are in the business of designing and conducting clinical trials for domestic and international biopharmaceutical companies. At one time, the bioservices sector enjoyed rapid growth and earmarked India as an important destination for clinical development due to the size of the Indian population, which facilitates patient recruitment for studies, and the available number of people not using multiple drugs that can interfere with clinical trials testing because of potential drug interactions. The development of contract research organizations in India is a critical step towards capacity building to create an innovative biopharmaceutical industry. In much the same way that the experience in the manufacture of generic drugs has laid production groundwork, contract research organizations established critical capability for domestic innovation. Moreover, a vibrant CRO industry brings public health benefits to a country by providing training opportunities to clinical staff and enabling access to new therapeutic modalities that address diseases that otherwise might have waited years for intervention.

The CRO sector, however, is particularly vulnerable to a bureaucratic and an unstable regulatory environment. The issues described above for biopharmaceutical companies apply to CROs, especially the multiple reporting to different committees and agencies, but there are additional regulations that affect the sector and can bring operations to a halt. For example, while it is perfectly reasonable and acceptable for patients in clinical trials to be compensated for injuries that result from negligence, current regulations require that patients be compensated even if the harm is caused by the comparator. If patients in the study die from the natural progression of their underlying disease, the sponsor of the trial is still liable for damages. This policy puts India out of step with countries that would likely serve as alternative sites for clinical trials and creates unnecessary risks for trial sponsors. Other requirements include that a drug successfully tested in India must be marketed in India, irrespective of whether there are clinical or commercial reasons to the contrary.

### IMPACT OF CURRENT PRACTICES

The current regulatory environment has had the impact of slowing the growth of the CRO sector itself, but has had the additional effect of driving clinical testing by Indian compa-



nies offshore. This has a profound, negative impact on the growth of biotech as an industry and the potential of denying the Indian people of the benefits of pharmaceutical products that serve public health. Finally, as drug discovery moves towards personalized and precision medicine based on genomic and population-specific drug development and away from one-size-fits-all solutions, the South Asian population will not reap the benefits of medicines developed for the unique genetic variations that may drive diseases in their population.

### POTENTIAL INTERVENTIONS

The bioservices sector represents a strategic sector for Indian biotechnology and the factors that will enable the growth of the sector should be fostered rather than impeded. India should reconsider the liability incurred by companies engaged in clinical trials while protecting patient rights. By the same token, provisions for protection of candidates for clinical trials should be better articulated and taught. Wider participation and representation in Independent Ethics Committees is a measure that might instill greater confidence by both the government and the public.

The recommendations made above for the biopharmaceutical industry as related to streamlining or centralizing the regulatory oversight of the process applies to CROs as well. Consideration of establishing an office for CROs to work in parallel with the central function for biopharmaceutical companies can also be an effective innovation.

Harmonization of Indian regulatory processes and requirements with those of other countries can also promote greater use of Indian CROs by making the accumulated data more useful for regulatory filings in other countries. In line with harmonization, India can also adapt the best practices for the oversight and regulation of CROs in other countries, and modify them to India's specific circumstances.

### IMPLEMENTATION OF INTERVENTIONS

The timetable for addressing the needs of the bioservices sector are urgent for the sector itself, for biotech more broadly, and for public health. The expansion of participation in institutional review boards is a measure that can be implemented quickly and at minimal expense. The role, findings, and activities of institutional review boards can be used to build confidence among patients, physicians, companies, and public officials.

Establishing regulations for CROs similar to the best practices in other countries can also be implemented over a period of one to two years. Efforts to streamline and centralize the regulatory process should be done in parallel with the same measures for the biopharmaceutical sector.

Finally, harmonization of Indian regulatory requirements with those of other countries will require a longer effort, but the process to promote harmonization can be mapped out in the short run, studies for purposes of comparisons can be done in the intermediate term, and full harmonization accomplished within four to five years.

### POTENTIAL IMPACT OF INTERVENTIONS

The impact of the above potential interventions will not be immediate, but steps taken now will begin to build confidence and can restore

the growth of bioservices to their earlier growth trajectory. Addressing the current set of circumstances will also encourage domestic biopharmaceutical companies to reverse the trend of going offshore for clinical development.

## INDUSTRIAL BIOTECHNOLOGY ISSUES

Industrial biotechnology includes a range of applications of biotechnology outside of healthcare and agriculture. It refers to the engineering of plants or cells to produce enzymes and industrial chemicals in an environmentally friendly way for multiple industrial uses, production of biofuels, or microbes for bioremediation. As specifically related to India industrial biotechnology is a means to tackle the real-world problems faced by most Indians on a daily basis, such as fresh water access, environmental remediation, and clean energy sources. As such, promotion of industrial biotechnology has the greatest potential of improving the welfare and quality of life for the average Indian.

Currently, Western Europe, the United States, and Canada hold dominant positions in this sector. There is, however, a significant economic opportunity for India that promises to generate substantial savings for other industries, as well as reducing the consumption of water, cutting the production of toxic byproducts, and repairing the environment.

The regulatory environment in India surrounding industrial biotechnology has not been restricting sector participants, but lack of government mandates have hurt the industry. The regulatory regime should drive other industries towards the use of industrial biotechnology products for use in the production of chemicals, textiles, forestry products, detergents, foods, pesticides, fertilizers, biofuels, and environmental remediation, particularly for water purification.

### IMPACT OF CURRENT PRACTICES

The current lack of mandates delays the development of the industrial biotechnology sector. This delay will represent lost opportunity in the short term. In the long term, India will find itself having to purchase the products from other countries that have accelerated programs underway. These are not limited to developed countries, but include Brazil and China. On the other hand, if industrial biotechnology becomes a focus in India, the ensuing technologies that emerge and are perfected in India will be available for production and export worldwide.

### POTENTIAL INTERVENTIONS

For government policymakers, there is a fine line between promoting replacement of existing chemicals and enzymes—especially when domestically produced—with biotech products. The growth of the industrial biotechnology sector can be promoted at first by mandating use of products for needs that are currently unmet, particularly in energy and environmental remediation.

### IMPLEMENTATION OF INTERVENTIONS

As domestic knowledge and capacity builds, regulations should be written to phase in and ultimately require the use of bio-enzymes across all industries where they are useful. Existing chemical companies should be incentivized to acquire technology, and

build capability and capacity so that they can be competitive participants in the sale of these products.

### POTENTIAL IMPACT OF INTERVENTIONS

The industrial biotechnology sector represents an opportunity to realize savings in the production of a wide variety of goods while at the same time enabling improvement of the environment. Additionally, it can contribute to water and food resources.

### BIOINFORMATICS

#### ISSUES

Bioinformatics, using digitized information to understand the characteristics of biological activity on a Big Data scale, can be thought of as a tool for either basic or industrial research. As a tool, it is also the basis for a business because it represents a body of products and services to sell to the research community. By virtue of the inherent value of the information and insights generated by bioinformatics, there is a second, potentially more valuable business, in selling or licensing the information for creating proprietary medicines, seeds or other products around the information. The proliferation of data from the arrival of next-generation sequencing, the advent of electronic health records, devices that provide real-time, continuous monitoring of patients, and other technologies are providing new opportunities to understand the underlying drivers of disease and move toward early interventions in individual patients, as well as monitor public health and the outbreak of infectious diseases.

In and of itself, bioinformatics is not vulnerable to regulation, at least not directly. Bioinformatics does, however, depend on the vibrancy of active academic research and biopharmaceutical drug discovery. These markets are international and can be served on a long distance basis, but domestic strength in both areas serves as a local base for experimentation, knowledge proliferation, and the creation of products and services. There is, however, an urgent need for regulation of bioinformatics as regards the safe and ethical use of personalized data on platforms accessible by multiple parties or even the public at large. The absence of a regulatory framework to control and monitor the access to genomic data can compromise use of the information and serve as a drag on the growth of the sector.

### IMPACT OF CURRENT PRACTICES

Currently, regulatory matters are not a high priority for bioinformatics, but the lack of a framework for protecting genomic information may delay development of the sector.

### POTENTIAL INTERVENTIONS

India can take a global leadership role in formulating and promoting protection of personal data, especially for populations in the emerging markets. In addition, a specific possibility is to use the Aadhar/Unique Identification Number initiative as a platform for indigenous open source research by different groups that leverage the UID and other Big Data resources.

### IMPLEMENTATION OF INTERVENTIONS

India should convene a national commission to study the issues and formulate policies for confidentiality and perhaps compensation when personal data leads to the discovery of a product or service

with commercial value. Once India has a framework in place, it can promulgate its policies and systems to other countries.

### POTENTIAL IMPACT OF INTERVENTIONS

Tackling the protection of genetic information would be a proactive move and could put a spotlight on India's role in the bioinformatics revolution.

### TECHNOLOGY TRANSFER

#### ISSUES

As a term, technology transfer is used in a variety of contexts. It is the process of transferring skills, knowledge, technologies, methods of manufacturing, samples of manufacturing and facilities among corporations, governments or universities, and other institutions to ensure that scientific and technological developments are accessible to a wider range of users who can then further develop and exploit the technology to create new products, processes, applications, materials, or services. The process of conveyance varies widely. It typically involves licensing agreements or setting up joint ventures and partnerships to share both the risks and rewards of bringing new technologies to market.

Specifically, in this white paper technology transfer refers to the following:

- ✿ The collaboration between industry and universities, other academic institutions, or government laboratories resulting in the conveyance of intellectual property rights to the industrial concern for the development and sale of products based on the institutional intellectual property
- ✿ The conveyance of technology rights and know-how from one corporate entity to another for the purpose of realizing synergistic capabilities or market reach of the parties
- ✿ The exchange of technologies between governments in areas such as energy, agriculture and environmental management through national laboratories

Interviews conducted for this white paper were consistent in citing that the technology transfer process, particularly as managed by academic institutions, is poorly developed in India. These are the antecedent conditions for successful academic technology transfer:

- ✿ The technology transfer process presumes that there are worthwhile discoveries and inventions in the first place, and that the scientists behind the discoveries recognize the commercial potential of their own work and are appropriately incentivized to seek assistance for the protection and support of their work
- ✿ That academic institutional policies support the concept of commercialization of research
- ✿ That an appropriate investment has been made in initiating and funding an office of skilled professionals to manage the technology transfer process, and has also provided adequate financial resources to undertake the costs of IP protection
- ✿ That the technology transfer office has the sophistication and the reach to establish linkages with appropriate contacts at companies worldwide
- ✿ That industry is confident that IP rights will be attainable and enforceable under the laws of the country

☼ That the academic investigators will participate effectively in the conveyance of the knowledge central to the technology to the corporate partner

By and large, most of these conditions are not in place at Indian institutions of higher learning. National efforts to build an academic technology transfer infrastructure began in earnest at the Indian Institutes of Technology about seven years ago, but the endeavor has not moved rapidly enough to keep up with progress made in China, Brazil, Chile and other rapidly developing countries.

### IMPACT OF CURRENT PRACTICES

The significance of an immature technology transfer infrastructure in India's biotechnology ecosystem impedes the generation of new companies. In the United States, Europe, and Japan, the vast majority of companies—two-thirds or more in some studies—are built around technology sourced at a university. Increasingly, the universities take an active role in identifying those technologies that can form the basis for a start-up and then take steps to promote the creation and capitalization of a company to advance the technology. These start-ups provide platforms for faculty and students to transition into industry if they so desire. (It is noteworthy, that many of these academic start-ups establish operations in industrial or research parks, most of which are co-located with universities. In India, the research parks are often geographically discontinuous with leading universities and research institutions.)

India has likely lost untold opportunities for the creation of companies through the lack of investment in technology transfer capability. This is particularly unfortunate because India's national investment in life science R&D has been on a growth trajectory, but commercial translation has failed to keep pace.

### POTENTIAL INTERVENTIONS

There are gaps in technology transfer that India must address quickly. These go beyond the establishment of technology transfer offices with well-qualified staff. To wit:

☼ Throughout the United States, Canada, Europe, and Japan, doctoral programs in the life sciences have integrated the subject of translational research into their coursework and have offered training to faculty members as well. Translational research is the activity that aims to make findings from basic science useful for practical applications that enhance human health. It is practiced in fields, such as environmental and agricultural science, as well as the health, behavioral, and social sciences. For example, in medicine and nursing it aims to translate findings in basic research into medical and nursing practice and meaningful health outcomes. These translational research programs have become foundational to establishing commercial sensitivity and a sense of entrepreneurship among scientists. It is also prerequisite to effective technology transfer.

☼ As is well known throughout India, the technology transfer enterprise in the United States was given its big boost with the passage of the Bayh-Dole Act in 1980. While the Bayh-Dole Act is imperfect legislation, it has played a major role in the stimulation of university-industry relationships and has spawned the creation of thousands of companies in biotechnology and thousands of

license agreements with major corporations. In India, attempts to adopt a similar law were initiated in 2008 with introduction of *The Protection and Utilisation of Public Funded Intellectual Property*. As of the writing of this study, the legislation has not been passed by the Indian Parliament. There has been healthy debate about the implications of the law. India, of course, should adopt a law consistent with its national priorities and legal and cultural traditions, as well as addressing public health concerns related to access to medicines. There is, however, a significant cost to the biotech industry and the country in terms of lost opportunity and diminished competitive advantage as other countries rapidly develop their own technology transfer systems.

☼ It has been the experience of the dozen or more countries that have adopted a form of the U.S. Bayh-Dole Act that the commercial viability of research discoveries is never guaranteed. The process requires professional management and significant financial investment on the front-end of the process to build the pipeline between the laboratory and the marketplace or patient. Law makers and government officials, when debating and ultimately enacting legislation to address technology transfer, must also allow for the resources necessary to realize its potential.

☼ Once mechanisms for technology transfer are in place at academic institutions, developing and maintaining professional staff will be a challenge. National training programs are in place in many countries and can serve as a model for professional development in India.

☼ Governments with active technology transfer programs do not track the performance of the programs or the outcomes associated with the technologies. India can take a leadership role in developing an information system for such tracking. Such a system will assist in the monitoring of progress and point to needed changes in policies and practices.

### IMPLEMENTATION OF INTERVENTIONS

India has lost critical time in the development of technology transfer that cannot be regained. The recommendations made herein have equivalent priority and should be addressed without delay.

### POTENTIAL IMPACT OF INTERVENTIONS

A working technology transfer system will have an immediate impact on increasing patent activity, driving the creation of biotech start-ups, and forming strategic alliances among Indian institutions, Indian companies, and companies worldwide.

### INTELLECTUAL PROPERTY ISSUES

As the research and development prowess of Indian companies advance, India's administration of patent law threatens to inhibit the growth of the Indian industry. Application of the Indian Patent Act's Section 3(d)—a provision that has mainly been applied to innovative pharmaceuticals—is out of step with the rest of Indian patent law. Indian companies are among those developing numerous improvements to currently available drugs that provide significant new benefits to patients that are not directly related to therapeutic efficacy. For example, elimination of adverse reactions address safety problems and can represent a significant investment, but are not reflected in improved therapeutic or clinical efficacy per se.

Reformulation of vaccines to eliminate the cold chain for storage and transport would have inestimable public health benefits, but might not be patentable under Indian practices. The marriage of a pharmaceutical with a new delivery system can increase patient compliance, and hence efficacy, but currently would not be patentable under Indian practices. These types of advances are stepping stones for Indian companies to building a robust innovation-based bioeconomy that can attract inbound investment. However, these improvements will not reach patients or the marketplace without adequate patent protection.

### IMPACT OF CURRENT PRACTICES

The current approach to assessment of patentability in India, as well as the use of compulsory licensing, serves the short-term interests of the domestic generic biopharmaceutical industry, but may hurt it in the future. Of current consequence is the perception by multinational companies that India is not an environment friendly to research and development investment for the Indian market, either through investment in on-shore facilities and operations in India, or in focusing on products that may have a unique health benefit for the Indian population.

At the current time, investment in R&D activity in Indian facilities by just a handful of non-Indian companies can substantially supplement the expenditures of the public and private sectors.

R&D investment in India also accelerates the development of a sophisticated workforce for biotech, and can lead to the establishment of a base of entrepreneurs and managers that can propel the industry forward. China, Malaysia, Brazil and other countries are currently enjoying increasing investment in R&D on their shores by multi-national companies, and their domestic industries are reaping the benefits.

Of strategic importance to the Indian biopharmaceutical industry is the emergence of biosimilars. The intellectual property treatment of biosimilars will not be analogous to the treatment of small molecule generic drugs. All indications are that there will be significant competition from producers in many geographic markets. Biosimilars might well emerge as having patent protection in most producing countries, but not in India. That may leave the domestic Indian industry in the position of having to compete on price in its own market. This will be a huge obstacle for reaching the national bioeconomy goals by 2025.

### INTERVENTIONS

There are no simple solutions to bridging the divide between the preferences of India and its companies and the needs of international companies that seek to sell protected products within India. Section 3 (d) of the *Indian Patent Act* is designed to protect the population from high drug prices, but it is not the only means of assuring health equity, and not the best. It is not sustainable because before long, the pipeline of new medicines for intervention in diseases not yet addressed will falter. Using the patent system as a mechanism to control drug pricing forestalls making the difficult decisions about necessary investment in the health care system and does not deal with the underlying issues. Indian generic drugs often sell for lower prices outside of India—including in the United States—than in

India itself. There is a significant lack of access to unpatented medicines in India, suggesting that patents are not the problem.

As politically challenging as it may be, there should be a reconsideration of the intent and application of Section 3(d). The issue of access and affordability are clearly paramount, but as a matter of policy, the government, in concert with industry, academia, and community interest groups, should consider a broader array of solutions and allow patent practices to work towards encouraging needed innovation.

### IMPLEMENTATION OF INTERVENTIONS

There is an urgency to, at the very least, opening a reconsideration of Section 3(d). In order to build the biotech industry, India will have to send signals to international companies interested in the Indian market that they can expect treatment similar to that offered in other countries.

### POTENTIAL IMPACT OF INTERVENTIONS

A considerable amount of damage has already been done to India's image and it will take time to rebuild confidence. Over time, however, India can expect more offshore investment in its biotech industry in the form of creation of R&D facilities, clinical trials, and the development of medicines for the unique needs of the Indian population.

### HUMAN RESOURCES DEVELOPMENT AND HIGHER EDUCATION

The recommendations regarding human resource matters apply equally towards all five sectors: Biopharma, Bioinformatics, Bioservices, Agricultural Biotechnology and Industrial Biotechnology.

### ISSUES

One of India's great strengths and attractions to foreign companies is its skilled and educated workforce with a high level of English proficiency. The country has the third largest educational system in the world and is expected to boast the largest workforce by 2025. But while the biotechnology industry has for the most part been able to find the talent it needs to grow, there remain gaps in skills that need to be addressed for the industry to become innovation-driven, particularly in emerging areas of opportunity.

### IMPACT OF CURRENT PRACTICES

Though India's workforce remains a strength for the country, there is need for greater cross-disciplinary training to exploit new areas of opportunity, such as bioinformatics, to enhance the abilities of business leaders to manage research-driven enterprises, and to expand the business and entrepreneurial skills of scientists, who can drive the creation of a new generation of innovation-driven biotechnology companies. The existing Indian higher educational structure segregates disciplines both institutionally and geographically, except in the large, integrated universities.

### POTENTIAL INTERVENTIONS

Indian universities should develop joint degree programs in such areas as information technology and biosciences and encourage projects that bring together students in different disciplines for common goals. In addition, the Indian Institutes of Technology

and the Indian Institutes of Management should work together to develop joint degree programs to produce people with both scientific research and management skills.

Programs should be established to train and encourage entrepreneurial researchers interested in commercializing technology to assist them with understanding issues around such things as intellectual property protections, capital formation, market analysis, and regulatory issues.

In addition, India should develop programs and incentives to attract expatriates with deep industry and entrepreneurial experience to return to India as a valuable source of expertise to launch new companies or fill specific skills gaps.

### **IMPLEMENTATION OF INTERVENTIONS**

The Department of Biotechnology should coordinate an effort for academic institutions, government, and industry to work together to create these programs.

### **POTENTIAL IMPACT OF INTERVENTIONS**

Though gaps in skills are not an apparent stumbling block for the success of the industry, if India's biotechnology industry is to focus on innovation-driven products and services, skills in management and entrepreneurship, as well as greater availability of workers with interdisciplinary skill sets will become critical for India in its effort to accelerate the industry's growth.

### **INFRASTRUCTURE**

The recommendations regarding infrastructure matters apply equally towards three sectors: biopharmaceutical, agricultural biotechnology and industrial biotechnology. Bioinformatics and bioservices are minimally affected by infrastructure.

### **ISSUES**

India faces great infrastructure challenges with water, power, land, and roadways that threaten to intensify as its population grows and its economy expands. Beyond the constraints infrastructure presents to the biotechnology industry, industry-specific infrastructure needs, such as bioreactors, fermenters, sequencers and analytic equipment are not manufactured in India. A specific example is concern raised by interviewees regarding the lack of vaccine-related cold chain facilities at ports and other strategic locations, as well as unpredictable supply chain systems and logistics. This is ironic given the enormous academic contribution that India has made to the supply chain management literature. Biotechnology can also help address some of this missing infrastructure, specifically new sources of fresh water and energy.

### **IMPACT OF CURRENT PRACTICES**

The general infrastructure issues faced in India have not only been a barrier to foreign direct investment in the biotechnology industry, but have also driven Indian companies to move off-shore with new manufacturing facilities. The lack of such things as large animal testing facilities in India has also caused Indian companies to send work offshore. The lack of industry-specific equipment manufacturing within India adds to cost and delays related to the process of clearing customs. Moreover, investors and multinational companies

certainly take notice of such deficiencies, as well as inefficient supply chain systems, when determining where to locate new manufacturing or R&D facilities.

### **POTENTIAL INTERVENTIONS**

India could create special zones that provide biotechnology companies with reliable water and power needed for their operations. These can have dedicated power plants and water purification, as well as sewage processing. The process of transferring specialized equipment should be expedited.

### **IMPLEMENTATION OF INTERVENTIONS**

State governments should work to identify appropriate zones for providing dedicated infrastructure needed by biotechnology companies. They should focus on existing biotechnology parks as the most obvious place to do this. India's Central Board of Excise and Customs should work with industry to identify critical equipment that is imported and develop an expedited means for bringing urgently needed equipment into the country.

### **POTENTIAL IMPACT OF INTERVENTIONS**

Addressing the general infrastructure needs can reverse the loss of biotechnology manufacturing to nearby competitors who can assure companies of reliable access to water and power. Expediting the importation of needed equipment can minimize delays often experienced by companies.

### **TAXATION ISSUES**

While taxes can create burdens for biotechnology companies, tax policy is a powerful tool in the government's arsenal to incentivize behavior, drive investment, and compete globally. The Indian government offers a number of tax incentives related to biotechnology, but its use is not as comprehensive as it could be and the biotechnology industry does not enjoy some of the same tax advantages extended to other industries. Bioservices companies should be viewed as information technology companies and afforded the same tax incentives as they enjoy.

### **IMPACT OF CURRENT PRACTICES**

Current tax incentives sometimes miss the mark by not being inclusive enough or large enough to achieve the desired goal of attracting investment into the sector and promoting growth and private investment in a sector where investors often feel risks are too high and returns too far off in the future.

### **POTENTIAL INTERVENTIONS**

The investment tax credit in equipment that India provides high technology companies should be extended to biotechnology companies, as should the ten-year tax holiday afforded companies once they begin producing products.

R&D tax credits extended to biopharmaceutical companies should be extended to contract research organizations. Introduction of accelerated appreciation for research and development expenditures could encourage generic drugmakers to invest in biologics and put India in line with China and Singapore, which both offer such incentives. In as much as strategic alliances and development con-



tracts characterize the working of the biopharmaceutical industry, it is counterproductive to tax development contract revenue. India should also offer tax holidays for R&D-related income. In addition, India could incentivize the development of innovation through tax breaks for revenue derived by the sale of patented products. Tax breaks extended to cover R&D expenses of Indian companies should include investment in R&D outside of India, as well as spending on the cost of patent filings, clinical development, drug discovery, and licensing.

India continues to be the primary funder of early-stage biotechnology companies. It can leverage its investment in the sector by attracting private capital through the use of tax incentives. To incentivize investment in early-stage, privately-held biotechnology companies, India should forgo taxes on gains from investments in these companies held for more than 10 years.

India should also consider the creation of tax favorable financing vehicles to allow the creation of off-balance sheet financing of R&D projects by private investors. These were used to great effect in the early years of the U.S. biotechnology industry and India should consider creating vehicles like these that are consistent with its own laws and practices as optional financing vehicles for biotechnology.

#### **IMPLEMENTATION OF INTERVENTIONS**

Several steps should be taken to increase the effectiveness of existing tax incentives. Government should review current incentives and determine if they are adequate to achieve what they set out to do. R&D tax credits available to biopharmaceutical companies should be extended to contract research organizations. India should take steps to ensure that its tax incentives are competitive with those offered by competing nations in Asia.

#### **POTENTIAL IMPACT OF INTERVENTIONS**

The high level of risk and the long path to revenue companies pursuing innovative biotechnology face make it challenging to attract capital. By expanding its use of tax policy as a tool to attract investment and incentivize innovation, India can accelerate the biotechnology industry's growth and the pace at which it generates benefits to the Indian economy, environment, and people.

#### **M&A AND PARTNERING ISSUES**

In India, much of the partnering and M&A activity has centered on generic drug makers. There has been some dealmaking in the biotechnology sector: Sanofi's 2009 acquisition of Shantha Biotech as well as a few landmark partnering transactions, such as Biocon's three major relationships with pharmaceutical companies, Glenmark and Sanofi, Novartis and Biological E, and Onconova/GVK Biosciences. Beyond these transactions, there is a lack of vibrant dealmaking activity that dissuades investment, impedes access to technology and expertise, and mutes growth. This problem should not be viewed in isolation, but must be understood in the context of concerns foreign companies have about the relative lack of predictability and transparency in regulations affecting these transactions, as well as taxation and profits repatriation. India's treatment of intellectual property and concerns about patent theft are also factors. Industrial interviewees also noted that the debate within the Health and Commerce Ministries regarding

possible curtailing of M&A activity in the biopharma sector has also caused hesitation in seeking opportunities.

#### **POTENTIAL INTERVENTIONS**

India should promote itself to biopharmaceutical companies as a gateway to Asia, provide forums that foster partnering opportunities, and take steps to quell concerns about the protection of intellectual property and other policies, laws, and business practices that impede partnering activity. Since access to innovation and markets are two reasons potential partners with Indian companies would seek to enter into a partnership, India will need to address issues that limit its development of innovative products or make its market unattractive to foreign companies despite its large and growing population.

#### **IMPLEMENTATION OF INTERVENTIONS**

The issue underlying the limited M&A and partnering activity for Indian biotechnology companies is complex and relates to a range of issues discussed elsewhere. In many ways this serves as a barometer for the Indian biotechnology environment. The Office of the Prime Minister or the Planning Commission should conduct a study specific to issues surrounding partnering and M&A, with reference to issues identified elsewhere in this report in order to diagnose the underlying reasons for the scarcity of partnering and M&A transactions, and ascertain specific policy measures that can reverse the current situation.

#### **FINANCE AND PUBLIC-PRIVATE PARTNERSHIPS ISSUES**

In many circles, biotech is synonymous with capital intensity. There is much truth to that association. During its nearly 40-year history, global biotech has absorbed approximately \$1 trillion of capital. The total costs of the development of a drug are beyond the resources of all but the major multinational corporations. Biopharmaceuticals are brought successfully to market only after a series of progressively larger capital infusions from a wide range of sources, such as angel investors, incubator funding and support, government programs, venture capitalists, strategic alliances, and proceeds from public offerings. In the case of therapeutics and vaccines for neglected tropical diseases, public-private partnerships often supplement the resources needed. The development of ROTAVAC and MenAfriVac are two recent examples. Even then, this accumulated capital is often just enough to bring products into the final phase of clinical trials, but not through to final approval in major regulated markets. A partnership with, or merger into a multinational is often necessary to fund the final stages of product approval. For better or for worse, this is the typical financing life cycle of biopharmaceuticals. Agricultural biotechnology and bioindustrial activities can be similarly capital intensive. Bioservices and bioinformatics have a somewhat lower financial barrier to entry because they are typically not involved in bringing a regulated product to market, but are also reliant on successive stages of capital from a variety of sources.

Throughout the worldwide history of biotechnology there has been an unreliable and inconsistent base of capital willing to undertake the risks associated with the industry. Consequently, there have been cycles of growth and decline in the biotechnology industry that have been unrelated to the progress of the science. In order to weather these cycles, the most skilled and experienced of entrepreneurs have had to

rely on diversified sources of capital and, in some cases, novel financial instruments, to bridge their companies to commercial success. In addition to offering research granting programs, those countries and local jurisdictions that have targeted biotech as a strategic industry have had to formulate programs to promote capital formation through government matching models, tax policies, and flexible securities regulations. In short, the capital ecosystem is a micro-climate within the larger ecosystem of biotechnology entrepreneurship. Each element has to be carefully nurtured and managed.

Public-private partnerships play a significant role in guiding the biotech industry towards meeting specific strategic goals for Indian biotechnology, as well as serving public health needs. They are a vehicle for attracting private participation—domestic and foreign—in meeting these goals and needs. They are an important adjunct to other sources of funding, but are less central to the problems of risk capital formation for biotechnology.

### IMPACT OF CURRENT PRACTICES

In the arena of providing capital resources, this report does not find that India is making errors in any of the areas of need, but it may be the case that in each of the potential sources of capital—angel investing, incubator funding and support, government programs, venture capital formation, strategic alliances, and public offerings—that India might not be doing enough to have the desired impacts. There are specific remedies and actions to pursue, but first the impact of the current circumstances should be explored.

### POTENTIAL INTERVENTIONS

**Angel investing:** There are limited interventions for public policy, but providing taxation incentives through tax credits or other measures for angel investors could encourage the availability of more capital for early-stage biotech.

**Incubator resources:** Direct grants of investment capital to incubators may not be the most effective approach. A matching program where the government will provide funds on a 1:3 or 1:4 basis (i.e., the government provides 25 to 33 percent of the capital), where the incubator raises capital locally from private sources or local governments, might be the best way to engage local communities and align interests.

**Government programs:** Continue the Department of Biotechnology Biotech Ignition Grants (BIG) program. Increase financial resources, especially in funding in other parts of the ecosystem, e.g. angels, venture capital, increases. In other words, the Department of Biotechnology program should preserve a meaningful role in capitalization in order to encourage work towards areas of strategic interest to India. A mechanism should be created to encourage Indian state governments to participate in funding.

**Venture capital:** India does have a venture capital industry, but its expansion and growth needs further encouragement. Here again, matching programs might be an appropriate approach. Adoption of a program similar to China's Emerging Industry Start-up Investment Scheme could be an effective measure to promote the formation of venture capital. In late-2009, the Ministry of Finance and National

Development and Reform Commission established the China Emerging Industry Start-up Investment Scheme to provide capital at the earliest stages of high-technology company creation and development. The Emerging Industry Start-up Investment Scheme has the specific task of promoting the creation and early-stage funding of companies in specific technologies identified as being strategic to the country, including: biotechnology and life-sciences, new energy, high-end manufacturing, information technology, advanced materials, energy-saving and clean technology. The Ministry of Finance is the overall manager of the Emerging Industry Start-up Investment Scheme and has allocated \$1.5 billion for the pilot phase of the program, with a required matching \$1.5 billion investment by local governments and the aim of another \$10 billion of capital from private sector sources in the pilot phase of 20 funds. Using the same formula, there are now more than 70 early-stage venture funds operating throughout China as part of the program. An adaptation of this program could be a game changer for India.

**Strategic alliances:** The role of strategic alliances in providing capital for the biotechnology industry is discussed in another section of this report's recommendations.

**Public listing:** As stated above, as the Indian government accumulates experience with off-shore listings, it could consider expanding the purposes for which Indian companies may list overseas. This report does not advocate creation of special rules for the listing of biotech companies on Indian exchanges.

### IMPLEMENTATION OF INTERVENTIONS

In the near term, India should address the recommended interventions for angel investing and the increase of incubator resources.

In the short to intermediate term, this report advocates that the recommended interventions for venture capital be studied and that steps be taken to promote the expansion of the venture capital industry through a national government sponsored matching program similar to the one underway in China.

Allocations for programs, such as grants issued by the Department of Biotechnology's BIG program, should at the very least keep pace with the expansion of capital from other sources so that the Department can influence the strategic direction of the biotech industry.

Changes in policies allowing Indian companies to list on foreign exchanges should evolve as more experience is accumulated, but generally off-shore listing should be encouraged.

### POTENTIAL IMPACT OF INTERVENTIONS

The goal is the formation of risk capital for biotech. Given the rapid progress in the building of biotech industries in other countries, there is an urgent need to increase capital resources dramatically. Realistically it will take a period of years. Once capital is available in greater supply, the pace of biotech growth will accelerate and gather momentum. Other recommendations in this report, if implemented, will also propel the expansion of the venture capital base because it will send signals to domestic and foreign sources of capital that India is a biotech friendly country prepared to take steps to drive rapid growth of the industry.

## CONCLUSION

India's biotechnology industry has the potential to become the jewel of the Indian economy and address the substantial healthcare, food, energy, and environmental issues that confront the Indian people. Rather than leverage its strengths and propel its biotechnology industry on the growth trajectory it had enjoyed for the millennial first decade, events and government actions in the last several years have restricted biotechnology's access to capital, discouraged foreign direct investment in the industry, and halted whole areas of research and development. There is now a threat of lasting harm to India's participation in the global bioeconomy when, at the same time, the West and many other emerging markets are racing towards removing obstacles and investing resources to advance their bioeconomies.

The biotechnology industry within India is too often viewed by its people as foreign as opposed to an opportunity that can be grown indigenously. The lens through which the industry is viewed sees exploitation rather than an economic force to address critical issues confronting the country: the nutrition and health of all Indians and a life in a more sustainable environment. Suspicions and misinformation have led to court battles that have stunted the growth of the Indian agricultural biotechnology industry, deprived Indians of the opportunity to participate in the development of new medicines through the institution of new rules that make clinical trials within the country undesirable and risky, and driven foreign and domestic companies that would likely partner, invest, and work within India to form partnerships and build facilities for research and production elsewhere.

The recommendations made in this report can address many of the fundamental issues that constrict the growth of India's biotechnology industry and help it to realize its potential. To do that, policymakers and the Indian people must accept that the biotechnology industry is not, as its critics say, the cause of social injustice and inequality. The people of India must come to understand that biotechnology is a powerful implement for addressing these same problems.





## SELECTED BIBLIOGRAPHY

Accenture. *Indian Biotech Agriculture Industry: Vision 2025*. <http://www.accenture.com/SiteCollectionDocuments/PDF/Accenture-Indian-Biotech-Agriculture-Industry-Vision-2025.pdf>; Accenture, 2013, <http://www.accenture.com/SiteCollectionDocuments/PDF/Accenture-Indian-Biotech-Agriculture-Industry-Vision-2025.pdf>.

Aradhey, Amit. *GAIN Report: India Biofuels Annual*. [http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Biofuels%20Annual\\_New%20Delhi\\_India\\_8-13-2013.pdf](http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Biofuels%20Annual_New%20Delhi_India_8-13-2013.pdf); Global Agricultural Information Network, USDA Foreign Agricultural Service, 2013.

Association of Biotechnology Led Enterprises. *Indian Biotechnology: The Roadmap to the Next Decade and Beyond*. [http://ableindia.in/admin/attachments/reports/The\\_Report.pdf](http://ableindia.in/admin/attachments/reports/The_Report.pdf); Association of Biotechnology Led Enterprises, 2012.

Balakrishnan, Reghu. "Biotech Industry Gives Birth to an Angel to Boost Investment for New Deals." *Business Standard*, April 26, 2014: [http://www.business-standard.com/article/companies/biotech-industry-gives-birth-to-an-angel-to-boost-investment-for-new-deals-113010900120\\_1.html](http://www.business-standard.com/article/companies/biotech-industry-gives-birth-to-an-angel-to-boost-investment-for-new-deals-113010900120_1.html).

Bergen, Mark. "Poor Infrastructure Hampers India's Export Chances in Downturn." *The New York Times*, September 5, 2013: [https://www.google.com/search?q=Poor+Infrastructure+Hampers+India%27s+Export+Chances+in+Downturn&oq=Poor+Infrastructure+Hampers+India%27s+Export+Chances+in+Downturn&aqs=chrome..69i57.911j0j4&sourceid=chrome&es\\_sm=122&ie=UTF-8](https://www.google.com/search?q=Poor+Infrastructure+Hampers+India%27s+Export+Chances+in+Downturn&oq=Poor+Infrastructure+Hampers+India%27s+Export+Chances+in+Downturn&aqs=chrome..69i57.911j0j4&sourceid=chrome&es_sm=122&ie=UTF-8).

BioSpectrum. *Survey Volume 1: Industry Insights*. [http://www.biospectrumindia.com/digital\\_assets/183/BSI\\_June-2013\\_Low-Res-PDF\\_Overview-and-Top20.pdf](http://www.biospectrumindia.com/digital_assets/183/BSI_June-2013_Low-Res-PDF_Overview-and-Top20.pdf); BioSpectrum, 2013.

Chakma, Justin, Gordon H Sun, Jeffrey D. Steinberg, Stephen M. Sammut, and Reshma Jagsi. "Asia's Ascent-Global Trend in Biomedical R&D Expenditures." *New England Journal of Medicine*, 2014: 3-6.

Chatterjee, Sumeet, and Aravidndan, Aradhana. "India Inc to Policymakers: Shape up or We'll Ship Out." *Reuters*, September 9, 2013: <http://www.reuters.com/article/2013/09/08/us-india-companies-economy-idUSBRE9870FZ20130908>.

Department of Biotechnology, Ministry of Sciences & Technology. *National Biotechnology Development Strategy-2014*. [https://www.google.com/search?q=National+Biotechnology+Development+Strategy-2014&oq=National+Biotechnology+Development+Strategy-2014&aqs=chrome..69i57j69i64.13399j0j4&sourceid=chrome&es\\_sm=122&ie=UTF-8](https://www.google.com/search?q=National+Biotechnology+Development+Strategy-2014&oq=National+Biotechnology+Development+Strategy-2014&aqs=chrome..69i57j69i64.13399j0j4&sourceid=chrome&es_sm=122&ie=UTF-8); Department of Biotechnology, Ministry of Sciences & Technology, 2014.

Dey, Sharmistha Mukherjee & Sushmi. "Indian Pharma Companies Make Malaysia a Hub to Tap Asean." *Business Standard*, January 6, 2013: [http://www.business-standard.com/article/companies/indian-pharma-companies-make-malaysia-a-hub-to-tap-asean-113010600032\\_1.html](http://www.business-standard.com/article/companies/indian-pharma-companies-make-malaysia-a-hub-to-tap-asean-113010600032_1.html).

Grueber, Martin, and Tim Studt. *2014 Global R&D Funding Forecast*. [http://www.battelle.org/docs/tpp/2014\\_global\\_rd\\_funding\\_forecast.pdf?sfvrsn=4](http://www.battelle.org/docs/tpp/2014_global_rd_funding_forecast.pdf?sfvrsn=4); Battelle and R&D Magazine, 2013.

Hirschler, Ben, and Siddiqui, Zeba. "Big Pharma Still Betting on "Messed Up" Indian Drugs Market." *Reuters*, March 12, 2014: <http://in.reuters.com/article/2014/03/12/india-bigpharma-patent-idINDEEA2B09220140312>.

India Brand Equity Foundation. *Sectorial Presentation: Biotechnology*. <http://www.ibef.org/download/Biotechnology-March-2014.pdf>; India Brand Equity Foundation, 2014.

Indian Brand Equity Foundation. *The Indian Biotechnology Sector: Investments, Growth and Prospects*. Indian Brand Equity Foundaton, January 2013.

Janssens, Bart, Simon Goodall, Sarwar Islam, and Kim Wagner. *Life Sciences R&D: Changing the Innovation Equation in India*. <http://www.bcg.com/documents/file80247.pdf>; The Boston Consulting Group, 2011.

Jha, Dilip Kumar. "Biotech Firms Smell Opportunity in GM Crop Move, Focus on R&D." *Business Standard*, March 25, 2014: [http://www.business-standard.com/article/markets/r-d-again-on-agenda-of-biotech-firms-114032500663\\_1.html](http://www.business-standard.com/article/markets/r-d-again-on-agenda-of-biotech-firms-114032500663_1.html).

Kulkarni, Narayan. "Approval Rate for Biologics Drop in India." *BioSpectrum*, January 13, 2013: <http://www.biospectrumasia.com/biospectrum/analysis/155256/approval-rate-biologics-drop-india>.

Kumar, J. Swatanter. "Aruna Rodrigues & Ors. vs. Union of India & Ors on 10 May, 2012." *Supreme Court of India Judgements*. May 10, 2012. <http://judis.nic.in/supremecourt/imgs1.aspx?filename=39314> (accessed April 28, 2014).

Miller, Henry I. "India's Genetic Engineering Dilemma." *Live Mint & The Wall Street Journal*, December 16, 2012: <http://www.livemint.com/Opinion/FTFuJAbFTXzAjL9bu4O19J/Indias-genetic-engineering-dilemma.html>.

Ministry of New & Renewable Energy. *National Policy on Biofuels*. [http://mnre.gov.in/file-manager/UserFiles/biofuel\\_policy.pdf](http://mnre.gov.in/file-manager/UserFiles/biofuel_policy.pdf), Accessed April 26, 2014; Government of India, Ministry of New & Renewable Energy, n.d.

Organization for Economic Co-operation and Development. *India: Sustaining High and Inclusive Growth*. OECD, 2012.



Palmer, Eric. "India's Economic Meltdown Pushes Biocon to Build Elsewhere." *Fierce Pharma Manufacturing*, September 9, 2013: <http://www.fiercepharmamanufacturing.com/story/indias-economic-meltdown-pushes-biocon-build-elsewhere/2013-09-09>.

—. "Malaysia's Location, Domestic Market Draw Ranbaxy, Cipla, Others." *Fierce Pharma Manufacturing*, January 7, 2013: <http://www.fiercepharmamanufacturing.com/story/malaysias-location-domestic-market-draw-ranbaxy-cipla-others/2013-01-07>.

Parameswaran Binod, Piyus Palkhiwala, Raghavendra Waikawaiwari, K Madhavan Nampoothiri, Arvind Duggal, Kakali Dey, Ashok Pandey. "Industrial Enzymes - Present Status and Future Perspectives for India." *Journal of Scientific & Industrial Research*, May 2013: 271-286.

Ramesh Chand, Ramesh Chand, S.S. Raju, Karl Rich. *Case Study: India - Biofuels and the Poor*. <http://biofuelsandthepoor.com/case-study-india/>: The Bill & Melinda Gates Foundation, 2011 .

Rao, Paul Wilson and Aarthi. *India's Role in Global Health R&D*. [http://www.genomicaybioeconomia.org/images/india%C2%B4s\\_role.pdf](http://www.genomicaybioeconomia.org/images/india%C2%B4s_role.pdf): Center for Global Health R&D Policy Assessment, 2012.

Roy, Subir. "How Biotechnology Lost Its Way." *Business Standard*, August 21, 2013: [http://www.business-standard.com/article/companies/how-biotechnology-lost-its-way-113082100040\\_1.html](http://www.business-standard.com/article/companies/how-biotechnology-lost-its-way-113082100040_1.html).

Sethi, Neha. "Veerappa Moily Approves Trials of Genetically Modified Crops." *Live Mint & The Wall Street Journal*, February 28, 2014: <http://www.livemint.com/Politics/xhXZNcGHVDq0wRz0ofR4CI/Veerappa-Moily-approves-trials-of-genetically-modified-crop.html>.

Seuba, Xavier, and Correa, Carolos. *Biotechnology in India: Its Policy and Normative Framework*. [http://www.clustercollaboration.eu/documents/2736637/2789253/Biotechnology+in+India\\_+Its+Policy+and+Normative+Framework.pdf/b07e1ec3-ce33-4efe-966e-8f64619cc731?version=1.0](http://www.clustercollaboration.eu/documents/2736637/2789253/Biotechnology+in+India_+Its+Policy+and+Normative+Framework.pdf/b07e1ec3-ce33-4efe-966e-8f64619cc731?version=1.0), Ministry of Innovation, Government of Catalonia, 2010.

Singh, Alok Kr. "Biotechnology: The New Horizon for Indian Leadership." *VSRD Technical & Non-Technical Journal*, 2011: 144-159.

Sudarshan Kumar, Shachi Trivedi. *A History of Biotechnology in India*. Association of Biotechnology Led Enterprises, 2013.

Unnikrishnan, C.H. "Private Investors, Banks Keep off India's Biotech Industry." *Live Mint & The Wall Street Journal*, January 2, 2013: <http://www.livemint.com/Companies/971fR7iNydWkwkbJNG2y2M/Private-investors-banks-keep-off-Indias-biotech-industry.html>.

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