TAKSHASHILA INSTITUTION

India's Biotechnology Ecosystem: A SWOT analysis

Shambhavi Naik

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Biotechnology is going to be a key player in driving national economies and providing strategic advantages. This study analyses the current state of biotechnology in India and recommends increased funding, improved training and international cooperation as three important steps in India's ascent as a leading biotechnology power.

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Executive Summary

Biotechnology is recognised as critical for national growth and security. This study assesses biotechnology in India – its strengths, weakness, opportunities and threats. India's strengths include a dedicated governmental agency to promote biotechnology, a large workforce and ability to scale at affordable rates. Weaknesses include poor government and private investment in biotechnology, lack of fundamental research, weak regulatory ecosystem and lack of highly skilled labour. Based on this analysis, the study recommends three important steps for boosting the biotechnology sector – increase funding, enhance skill capacity, and boost international co-operation.

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Authors
Shambhavi Naik,
Chairperson,
Advanced Biology Programme,
The Takshashila Institution

I. Introduction

Biotechnology – the use of technology to harness biology - endows the ability to regulate cellular and molecular processes to develop products for human use. Examples of biotechnology-based applications include the production of synthetic insulin for treating diabetes, biofuels to reduce fossil fuel dependence, and drought-resistant crops to counter climate change effects. Thus, biotechnology can impact various aspects of human society – health, food security, environment, and economic growth.

In 1986, the Government of India established a Department of Biotechnology (DBT) within the Ministry of Science and Technology. DBT formulates policies to govern biotechnology, funds research and start-ups, and runs research institutes focused on critical biotechnology areas. The biotechnology sector in India has grown from US$1.1 billion in 2003 to a US$80.12 billion in 2022. The industry's year on year growth rate is 14.7 percent[1]. India has approximately a 3 percent share in the global biotechnology industry.

Within India, these are the percentage shares of biotechnology segments in India[2] — biopharmaceuticals, compromising diagnostics, therapeutics and vaccines account for 68 percent; bio-agriculture consisting of BT cotton, biofertilisers and related products account for 13 percent; bioindustry led by

Although controversial, there is a clear economic impact of cultivating BT cotton. Similar analyses of other genetically modified crops should also form part of the debate surrounding their adoption.

biofuels and enzymes account for 12 percent, and Bio IT and bio-services account for 7 percent. Figure 1 shows the detailed breakdown of market share per biotechnology segment.

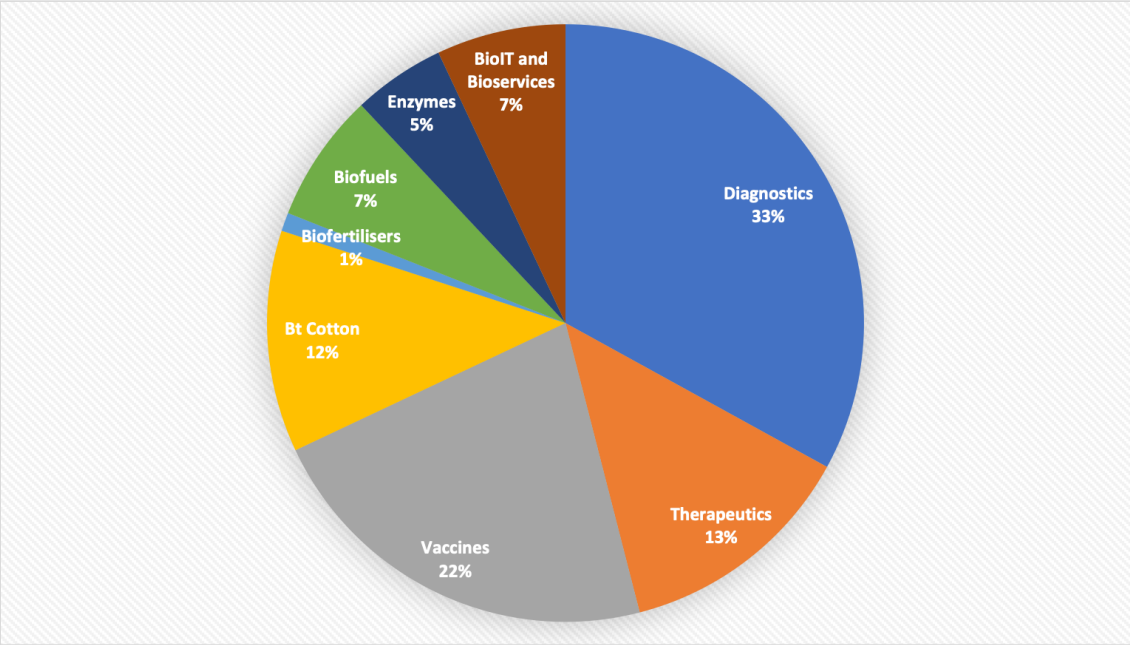

Figure 1: Percentage of Market share of key biotechnology segments[3]

When properly harnessed, biotechnology offers technological, strategic and economic advantages.

Technological advantages

New techniques in synthetic biology, nanotechnology, gene editing, etc, confer technological advantages that can be used to improve health, create alternative sources of energy and revitalise the environment. Biotechnological progress can grant access to new therapies, cheaper food sources, and a more sustainable lifestyle.

Strategic advantages

During the pandemic, Government of India gifted over 14 million doses of COVID-19 vaccines to 98 countries.

Strengths in certain areas of biotechnology can provide strategic advantages. For example, COVID-19 demonstrated India's ability to scale both COVID-19 diagnostics and vaccines. India ably used its vaccine manufacturing ability to increase production to cater to domestic demand, and as a foreign policy tool, provided vaccines as aid through the Vaccine Maitri programme. Further, the indigenous development of Covaxin also allowed India to manufacture its own vaccine. This meant that India did not have to solely depend on foreign developers for its vaccine needs. Newer applications of biotechnology offer strategic advantages by allowing countries to do specific activities that other countries cannot, or limiting access to key materials. A hypothetical example is of biofuels – the country which makes a breakthrough in increasing efficiency of biofuels to match fossil fuels, will hold a strategic advantage over others. This is also true of other technological applications such as medical therapies or climate-resistant crops. For example,

the US had first access to mRNA COVID-19 vaccines, innovated by Moderna.

Economic advantages

Biomanufacturing is set to take over around 60 percent of industrial products, and becoming a major driver of the economy[4]. The US Bioeconomy is valued at US$1 trillion[5], while Japan's Bioeconomy Strategy aims to achieve 92 trillion yen (US$700 billion) market size by 2030[6]. Australia's life sciences industry is valued at over AU$100 billion[7]. India aims to achieve US$300 billion by 2030[8]. As demonstrated in Figure 2, apart from a brief downturn, the biotechnology sector has consistently grown across the world[9].

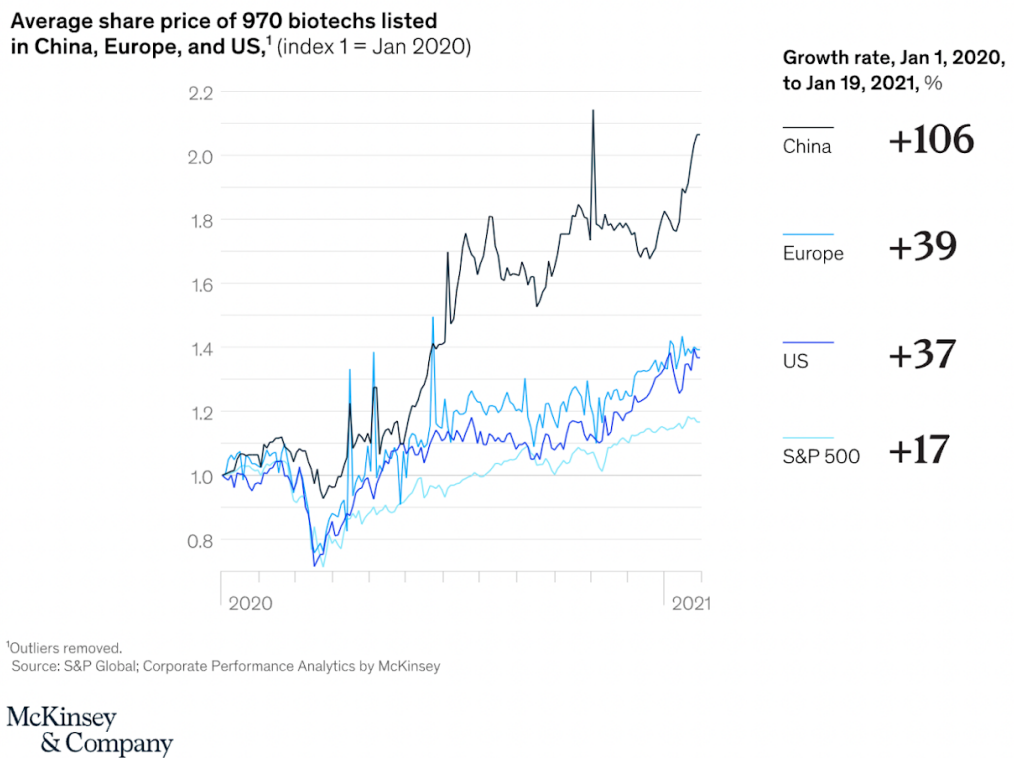

Figure 2: Average share price of 970 biotechs listed in China, Europe and US

Biotechnology is also an important job creator. A study by the United States Department of Agriculture reported that, in 2014, the biotechnology industry supported a total of 4.2 million American jobs through direct, indirect and induced contributions[10]. Thus, each biotechnology-based job generated 1.76 additional jobs in other sectors of the economy.

Biotechnology sector consists of two chief areas –

i. **Research and Development (R&D)**
R&D is key to creating new products and services for use. Fundamental research increases human understanding of biology and allows scientists to harness the power of biology. Innovation is key to technological progress and has to be a thrust area in India's progress as a key biotechnology power.

ii. **Biomanufacturing**
Biomanufacturing includes mass manufacturing and scaling up of biotechnology products for consumption. This includes vaccines, enzymes, biofuels, etc.

A biotechnology leader has to have expertise in both these areas to maintain its lead on both innovation and manufacturing. The next section presents a SWOT analysis for biotechnology in India, including R&D and biomanufacturing.

II. SWOT

Strengths:

i. Dedicated regulatory department within Government of India

India was amongst the first countries to recognise the importance of biotechnology by carving out a separate department of biotechnology within the Ministry of Science and Technology. The DBT is led by a vision to *"Attain new heights in biotechnology research, shaping biotechnology into a premier precision tool of the future for creation of wealth and ensuring social justice – specially for the welfare of the poor."*

Its main functions include:

- Promote large scale use of Biotechnology
- Support R&D and manufacturing in Biology
- Responsibility for Autonomous Institutions
- Promote University and Industry Interaction
- Identify and Set up Centres of Excellence for R&D
- Integrated Programme for Human Resource Development
- Serve as Nodal Point for specific International Collaborations
- Establishment of Infrastructure Facilities to support R&D and production

- Evolve Bio Safety Guidelines, manufacture and application of cell based vaccines
- Serve as Nodal Point for the collection and dissemination of Information relating to Biotechnology.

The presence of a dedicated nodal agency signals India's intent to harness biotechnology as a key tool for government action.

ii. Large semi-skilled workforce

India has a large semi-skilled workforce, trained in basic sciences and technology. Although data specific to biotechnology is not available, reports from the All India Survey on Higher Education shows that roughly 8.6 million students registered for undergraduate studies in science or technology (Table 1). There is also an increasing number of students enrolling in postgraduate education in these fields (Table 2). This large number of students are equipped with basic skills needed to conduct research or run operations in bio-based academic or industrial sectors.

Programme	2016-17	2017-18	2018-19	2019-20	2020-21
B.Sc.- Bachelor of Science	44,33,910	45,97,068	44,62,217	44,55,380	47,27,748
B.Tech.- Bachelor of Technology and B.E.- Bachelor of Engineering	40,85,321	39,40,080	39,40,080	36,44,045	36,63,685
B.Pharm.- Bachelor of Pharmacy	3,13,776	2,25,457	2,46,358	2,93,822	3,74,695

Table 1: Enrolment in relevant programmes at Under Graduate Level

Programme	2016-17	2017-18	2018-19	2019-20	2020-21
M.Sc.- Master of Science	5,62,896	6,05,682	6,23,114	6,75,217	7,60,394
M.Tech. - Master of Technology	1,60,895	1,42,081	1,35,500	1,37,051	1,38,533
M.Phil.	43,267	34,109	30,692	23,934	16,744
Ph.D.	1,41,037	1,61,412	1,69,170	2,02,550	2,11,852

Table 2 Enrolment in relevant programmes at postgraduate level

iii. Cost-effective scaling

India can offer to scale biomanufacturing at price-competitive levels. Reports suggest that manufacturing in India may be up to 33% cheaper than manufacturing in the US[11]. India has already demonstrated this manufacturing capability by being a major provider for both vaccines and biosimilars to the world. Pre-COVID-19, the global vaccine market was valued at US$30 billion. Of this, the Indian vaccine market was valued at US$3 billion and roughly 2/3rd of the manufactured vaccines was for export purposes[12]. Similarly, more than 50 biosimilars from Indian companies have been approved for sale in India and various emerging markets.

Weakness:

i. Investment in Biotechnology R&D remains low

Indian investment in R&D is below 1% of GDP. Of that, its allocation to the Department of Biotechnology is less than 0.1% and has not increased substantially over the past five years (Figure 3).

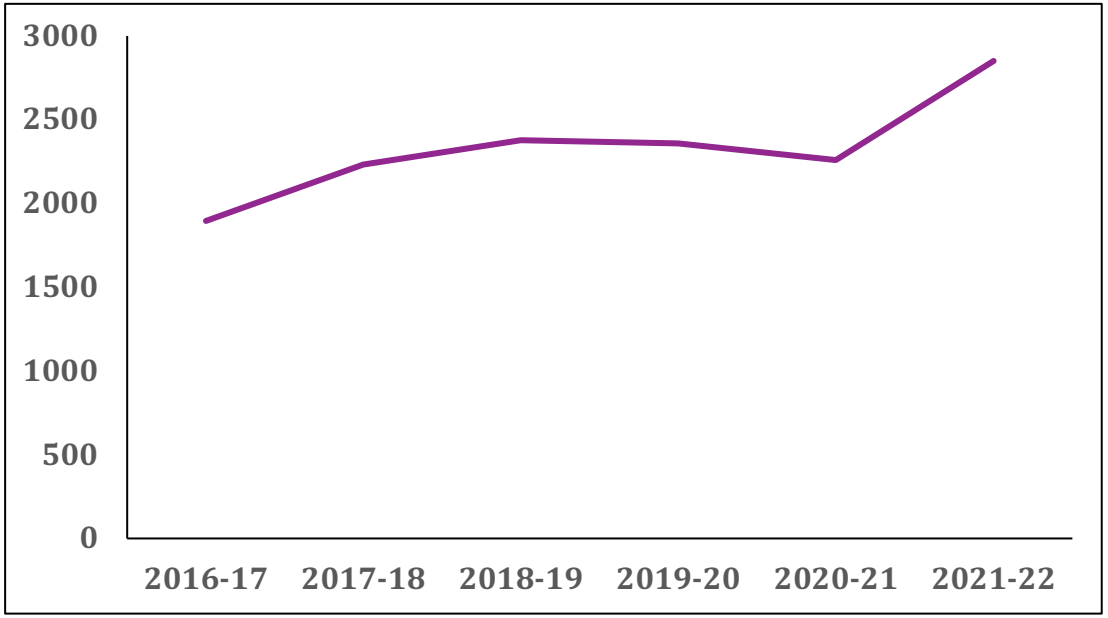

Figure 3: Allocation for DBT (Revised budgets) across designated years (in INR crores)

A rare spike in funding was observed during the onset of the COVID-19 pandemic, which facilitated efforts to create COVID-19 diagnostic kits and vaccines. However, in subsequent times, the allocation to DBT has again been reduced, despite the importance of biotechnology being made apparent in the fight against COVID-19 (Figure 4).

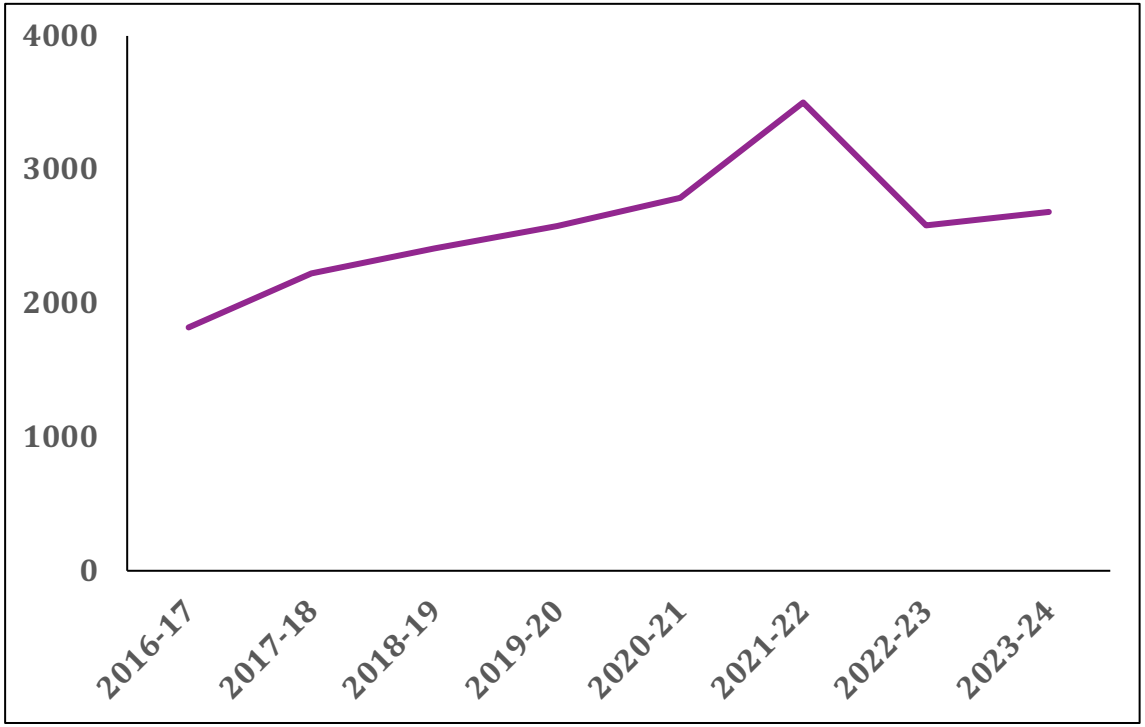

Figure 4: Allocation for DBT (budget estimates) across designated years (in INR crores)

In addition to poor government spending, private investment in biotechnology is low and no major biotechnology unicorns have emerged from India.

Overall, R&D investment in India has declined from 0.8% of GDP in 2008-09 to 0.7% in 2017-18. This is lower than the other BRICS nations. Brazil, Russia, China and South Africa spend around 1.2%, 1.1%, above 2% and 0.8%

respectively. The US spends roughly 3%. The world average is around 1.8%[13].

ii. Lack of focus on fundamental research

India's focus on fundamental research is low as compared with other biotechnology leaders. Publications in peer-reviewed journals is an indicator of research activity. An analysis of data of biological (Figure 5) or health-related (Figure 6) publications from various countries between 1996 and 2020 shows two important observations:

2020 has marked an uptick in biological and health related publications across all countries. This increase is most likely a response to COVID-19 .

A. There is a significant difference in the publication output between the three world leaders – US, EU and China – and other countries, including India.

B. China in particular had similar level of publication outputs as India in the mid 1990s. However, China has leapfrogged in this area, showing a steep increase in publication output, while India's pace of growth is much slower.

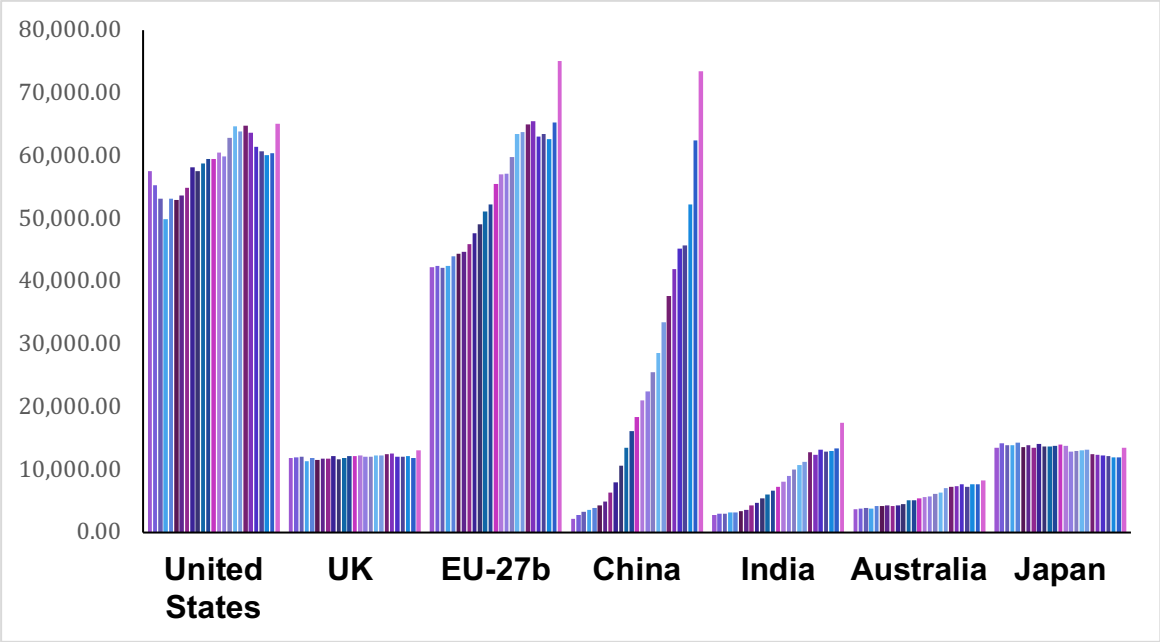

Figure 5: S&E articles in biological and biomedical sciences, fractional count, by region, country, or economy: Bars represent number of annual publications for the period 1996–2020

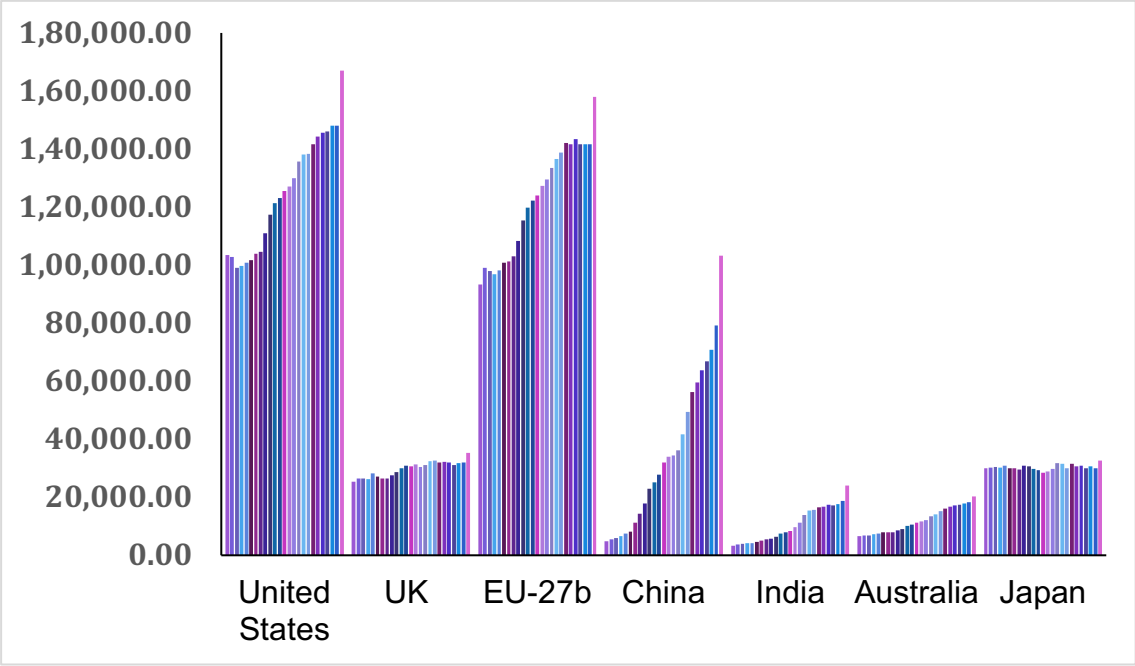

Figure 6: S&E articles in health sciences, fractional count, by region, country, or economy: Bars represent number of annual publications for the period of 1996–2020

These data show that Indian researchers are not on par with counterparts from other countries, when it comes to publishing novel research. Lack of access to funding as detailed in the earlier point, and other resources may be challenges that lead to this outcome. However, it is critical to boost fundamental research for India to become a biotechnology leader in its own right.

iii. Lack of highly-skilled labour

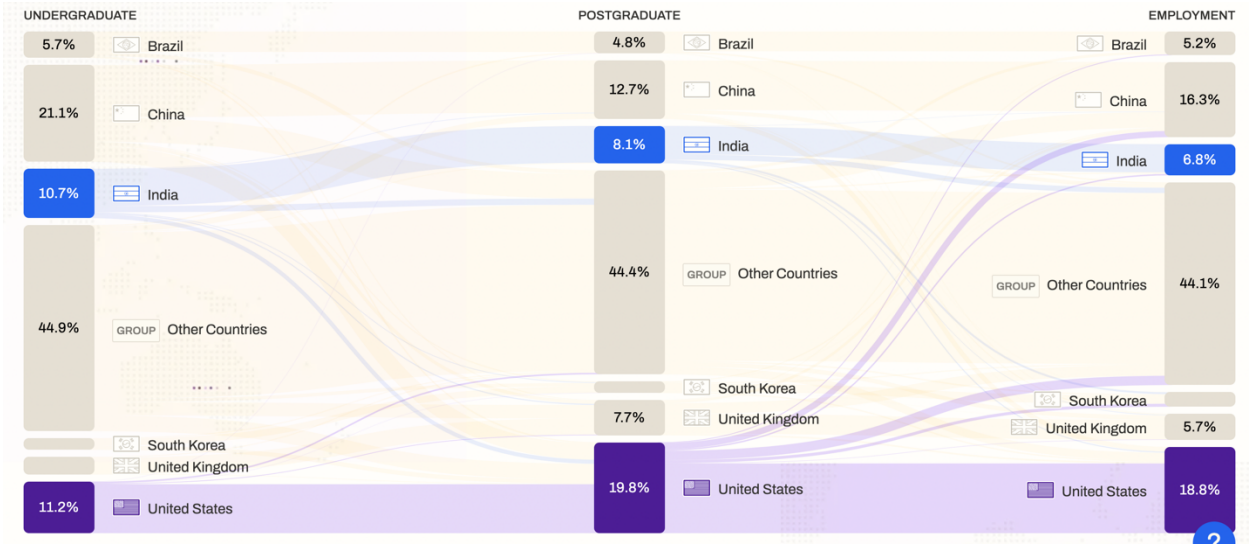

Figure 7: Mobilisation of workforce related to biomanufacturing. Data sourced from ASPI's Critical Technologies tracker.

As shown in Tables 1 and 2, India has a large semi-skilled workforce. However, to perform cutting edge research or scale up biomanufacturing, highly-skilled labour with precise biotechnology skills is required. Indian researchers and students are not exposed to the latest techniques or equipment. This results in mobilisation of the semi-skilled workforce to other countries for employment. This is evident in Figure 7 which shows mobilisation of labour in the biomanufacturing sector across countries. The movement of the workforce away from India at both the postgraduate and

employment levels suggests that though India is training personnel, it is unable to retain them in the country to build on the sector.

iv. Weak regulatory mechanisms

India's regulation of biotechnology products including pharmaceutical products is not transparent and of global standards. The opacity with which approvals for Bharat Biotech's Covaxin, Delhi University's GM mustard and the recent issues with throat syrups and eye drops raise serious concerns of using biotechnology made products in India. The Global BioLabs Report 2023 ranked India in the bottom 5 when it assessed 27 countries for biosafety, biosecurity and biorisk management regulation[14]. This perceived weakness can threaten foreign investment and co-operation.

Opportunity:

i. Increasing Domestic Expertise

Over the past few years, the Government of India has focussed its effort on repatriating scientists who have trained abroad. This effort is expected to reverse the impact of "brain drain" and bring scientists who have been exposed to the latest innovations to India. For example, 550 Indian biotechnologists have returned to India under the aegis of the Ramalingaswami Re-entry Fellowship, which was launched in 2006-07[15].

The Full Time Equivalent (FTE) for researchers has also increased in the past decade[16]. Data compiled from the UNESCO science report 2021 shows that that a dip in FTE in the early 2000s, there has been a significant rise in FTE since 2010 (Figure 8).

A full-time equivalent is based on the ratio of working hours actually spent on research and development (R&D) during a specific reference period (usually a calendar year) divided by the total number of hours conventionally worked in the same period by an individual or by a group. One FTE may be thought as one person-year. A person who normally spends 30% of their time on R&D and the rest on other activities (such as teaching, university administration and student counselling) should be considered as 0.3 FTE. Similarly, if a full-time R&D worker is employed at an R&D unit for only six months, this results in an FTE of 0.5.

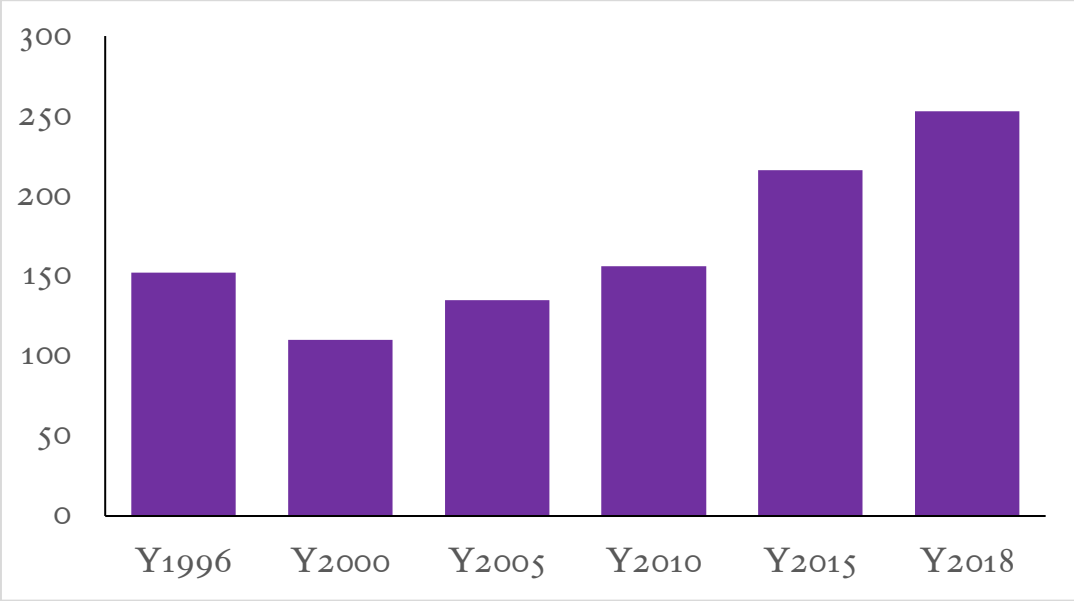

Figure 8: Number of FTE per million people in India across designated years.

ii. Increasing volume of drugs going off-patent

Indian biosimilars industry creates biosimilars to drugs which have gone off-patent and offers these as cost-effective alternatives. By 2030, approximately

10 major biologic drugs will be released from patent, and Indian manufacturers can vie to make biosimilars for this market[17]. The total market value for the top 15 drugs which would lose their patents in the 2020-2030 time period is approximately US$115 billion (Figure 9)[18].

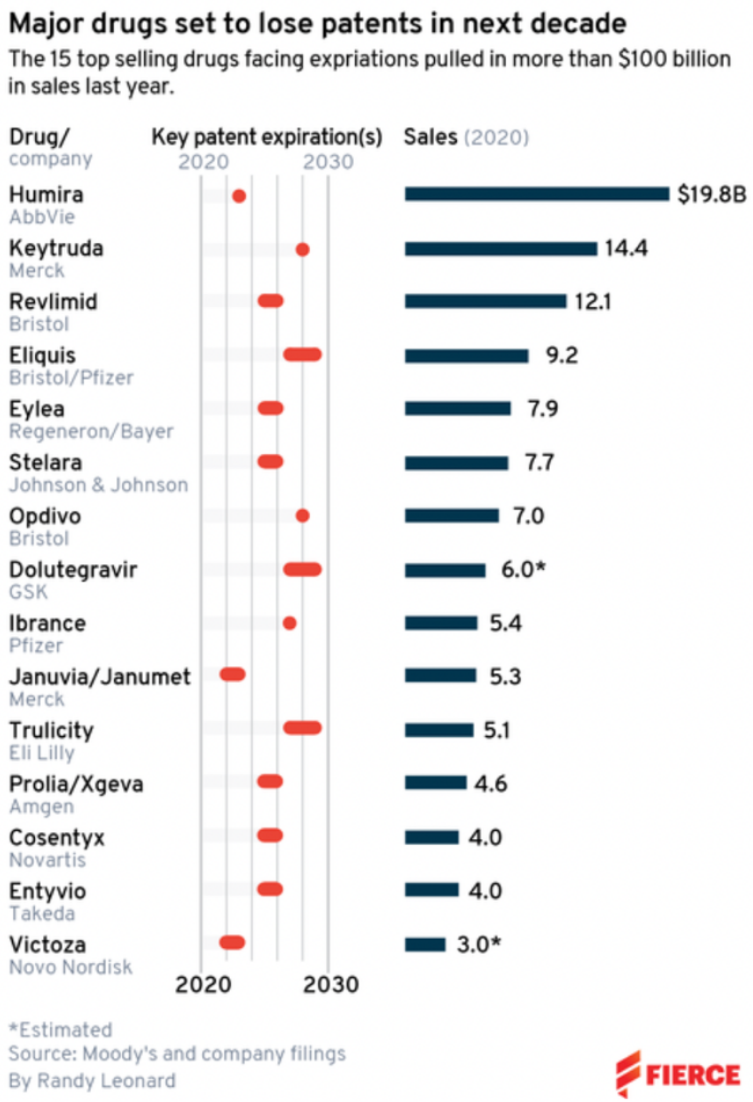

Figure 9: The top 15 drugs that will go off-patent in the 2020–30 decade

iii. Increasing foreign interest in collaborating with Indian biotechnology sector

Post COVID-19, there is increased attention to building supply chain resilience, particularly for biotechnology related products. For example, the Quad (US, India, Japan and Australia) has reiterated that monitoring biotechnology innovations and identifying opportunities for cooperation as a key action for the partnership[19]. Similarly, biotechnology is an important sector recognised the Indo-US Initiative on Critical and Emerging Technology (iCET). Additionally,, India has on-going bilateral co-operation initiatives with more than 13 countries in the field of biotechnology[20]. India should leverage these partnerships to attract funding, cross-training opportunities and market access for Indian biotechnology products and services.

Exact wording from the US Fact Sheet: Monitor Biotechnology Scanning: The Quad will monitor trends in critical and emerging technologies, starting with advanced biotechnologies, including synthetic biology, genome sequencing, and biomanufacturing. In the process, we will identify related opportunities for cooperation.

President Joe Biden and Prime Minister Narendra Modi announced the U.S.-India initiative on Critical and Emerging Technology (iCET) in May 2022 to elevate and expand strategic technology partnership and defense industrial cooperation between the governments, businesses, and academic institutions of the two countries.

Threats

- **Near shoring/friend shoring initiatives of countries**

While co-operation amongst like-minded countries is being encouraged, many are also focusing on enhancing domestic biotechnology capacity. For example, the US has announced its intention to invest US$1 billion in expanding its domestic bioindustrial manufacturing infrastructure over five years.

- **Risk-averse governance**

India needs to adopt emerging technologies to its advantage, irrespective of global support. Yet, India adopts new applications after their acceptance in other countries such as US. For example, there is currently a moratorium on the resesarch of stem cells or germline gene editing under certain conditions. Similarly, despite creating indigenous genetically modified crops, these are not approved for cultivation or use in India, citing fears about their impact. This risk-averse behaviour stymies innovation.

Section 8.3 of the National Guidelines of stem cells, 2017 pertains to prohibited areas of research. It reads "In the current state of scientific knowledge and understanding, stem cell research in the following areas is prohibited" This is ironical, without research there can be no improvement in the state of knowledge and understanding.

III. Recommendations

Based on this analysis, there are three major recommendations for uplifting India's biotechnology industry

1. **Increased investment in R&D**

The Indian government needs to invest more in fundamental R&D and create incentives to attract more private funding into biotechnology. This will promote innovation in India. This investment can be through design or deployment linked schemes, created on similar lines as those for semiconductor design and manufacturing. Investment can also be conditioned to increase private and public institution collaboration.

2. **Vocational courses**

Tailored training programmes that allow researchers to gain key skills for expanding biotechnology research and manufacturing.

3. **International co-operation**

There is significant global intent to diversify biotechnology supply chains away from China. India is an ideal alternative for substituting a selection

of these products. India should leverage this geopolitical situation to create conducive markets for its products and services. In addition, India can create opportunities that offer entrepreneurial opportunities to those of India origin but settled abroad to contribute to Indian science.

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