

# Patenting Biotechnological Innovations in India – Current Trends and Future Perspectives

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## Abstract

Innovations and inventions in the field of biotechnology and allied sciences has been increasing at a steady pace over the last several decades, with India moving up in rank in the global innovation index (GII) in the recent years. The stepping up of our ranks clearly point towards an increase in patenting in our country. According to the World Intellectual Property Indicators report, 2023 published by the WIPO (World Intellectual Property Organization) there is a 3.6 % increase in the number of patents filed globally, of which two-thirds are contributed by Asia alone. There has been a steady rise in the number of patents filed in India over the past decade. The field of biotechnology has been a significant contributor to this rise. In the current study, patenting trends especially in the area of biotechnology have been studied using published data. It has been observed that a 175% jump in the number of Indian Patent Applications filed in biotechnology and allied fields was registered in the year 2020-21. Despite an uptrend in the patenting activity, India significantly lags behind its closest contemporaries like China, Korea and Japan. The current study on Patenting Biotechnological Innovations in India, takes a closer look at India's progress in this field.

**Key words:** Patents, Intellectual property rights, Biotechnology, Innovation, Industry

India is a rapidly emerging biotechnology destination with players like Biocon, Serum Institute of India, Shantha Biotech, Reddy laboratories, Panacea Biotech and several others vying with each other as well as international competitors to develop new life-science based products. This is not to say that government-supported institutions engaged in biotechnology are far behind. In terms of innovation the last decade has seen a significant participation by India in the innovation arena. India has 4.65 lakh patents filed in the current decade (2014-2023), which is nearly 44% higher than those filed in the preceding decade (2004-2013) [11]. The economic leadership of the United States (US) and the European Union (EU) seems to be facing a challenge from Asian countries like China and India [5-6]. A major slice of this challenge will come from rapid technological advancements by both these nations. A number of factors which include improved intellectual property rights through the World Trade Organization's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights, ease of communication and travel around the globe as well as shorter pendency in patent processing can be said to have contributed to an overall boost to patenting in Asian countries [4], [19]. In the current paper, the study of the annual reports and data published by WIPO and IP India over the last decade clearly points to the fact that South Asia is a growing IP force and India is catching up on innovation. The numbers of biotechnology patents in India seem small as compared to China, Korea and Japan and the possible reasons are that India's investment in Research and Development activities remains low in comparison to developed countries. DBT (Department

of Biotechnology, Ministry of Science and Technology of India) approved Rs 1,315 crores in the country's 2022-23 budget as opposed to Rs 1,495 crores allocated in 2021-22. The lack of researchers, especially women researchers in an otherwise vast population, inadequate private investment in R & D and delays in approval of patents attribute to a lower than desired pace of research and development [20]. In its Status Report of 2023, JPO's (Japan Patent Office) patent system subcommittee discussed various measures to augment their patenting process, including digitalizing written procedures and improving user convenience [14]. The JPO has been aiming to achieve the "world's fastest and utmost quality patent examinations" in the near future. CNIPA (China National Intellectual Property Administration) has also been aiming at shorter processing time for patents [14]. India has been able to retain its 40<sup>th</sup> rank in the GI, 2023. It is ranked number one in 'Innovation Outperformers' [29]. This proves that the quality of scientific work in India is second to none. India only needs to now amplify its patenting regime. Instead of serving as a service provider for other foreign companies, time has now come when India should invest higher amounts in innovation and become self-reliant. The growth trajectory of India with reference to Biotechnology clearly indicates that we have entered a competitive phase of growth. With increasing impetus on schemes like Start up India, Aatma Nirbhar Bharat, make in India and growing Public-Private Partnership, it does seem likely that the next decade shall belong to India. The All-India Council for Technical Education (AICTE) and Office of Controller General of Patents, Designs Trade Marks

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(CGPDTM) have signed a Memorandum of Understanding to promote Intellectual Property Rights awareness in educational institutes across the country [11]. Friendly patent laws, quicker patent processing and generous funding shall go a long way in placing our efforts in the field of biotechnology, higher on the world map. India certainly does not want to be a bystander in the race to reap the benefits of the creativity of its inventors.

We live in an era where inventions are being made at a dizzying pace in order to meet the burgeoning demands of mankind for innovations and economic growth. Not surprisingly, the bright minds that create novel ideas and products thereof need to protect their fruits of labor, which in turn has led to an increase in patent filing by innovators [2]. Today, intellectual property rights (IPRs) are assets that are considered more valuable than other tangible assets [23]. A patent can be described as the grant of an exclusive right, for a limited period, provided by the Government to the patentee, in exchange for full disclosure of their invention. Just as this patent bestows exclusive rights of making, using and selling to the inventor it implies that other parties do not enjoy any rights linked to that invention, for commercial gain [24].

Ideas arising from the intellect are naturally not limited to any one field, they encompass all subjects and areas. Much like innovations being made at an enormous pace in the realm of IT, mechanical engineering, chemistry, electronics, a lot is happening in the field of biotechnology, with biotechnological inventions and innovations changing the face of medicine, healthcare, forensic sciences and agriculture. Biotechnology innovations went from zero in the 1990s to the development of hundreds of GM cotton cultivars by 2008 [21]. Innovation developed around living organisms is an expensive, time-consuming and arduous task [10]. Such innovations are also impacted by several factors-social, economic and industrial, due to the inherent need of incorporation of investments in R&D to attain significant outcomes [17]. It is, therefore, crucial to safeguard the intellectual property of life-scientists and their parent organizations so that mankind continues to find solutions to rapidly-evolving problems with some promise of rewards. In the current study, an attempt has been made to understand the patenting regime in India, particularly in the context of biotechnology patents.

give credence to innovation, recognizing that the country can only progress if its people create and invent. “An India where Intellectual Property stimulates creativity and innovation for the benefit of all” is what India’s National IPR Policy advocates [18]. According to the World Intellectual Property Indicators report of 2023, published by the WIPO (World Intellectual Property Organization) there is a 3.6% increase in the number of patents filed globally [30]. A staggering two-thirds of the patent filing activity worldwide has taken place in Asia. Asia is rapidly evolving as a world leader in innovations and patent filing. Applications to the tune of 2.3 million were filed in the year 2021, representing a formidable 67.6% of the world’s total (Fig 1). China emerged as the hotspot of filings which accounted for 69% of all applications filed in the region in 2021. As compared to 1,585,663 applications filed in China, India had only 61,573 applications filed in 2021 (Table 1).

Table 1 2021- Patent applications at the Top-10 offices globally [30]

Country	Applications filed in 2021
China	1585663
US	591473
Japan	289200
Republic of Korea	237998
EPO	188778
India	61573
Germany	58569
Canada	37155
Australia	32409
Russian Federation	30977

Table 2 India's rank in the global innovation index [7]

Year	India’s rank in GII
2015	81
2016	66
2017	60
2018	57
2019	52
2020	48
2021	46
2022	40
2023	40

The patent law of a nation often reflects the industrial and scientific policies adopted by that nation. Patents are the tangible outcomes of research and development (R&D) efforts. While analyzing the technological progress of any country, a good parameter is the wealth of patents held by it. Along with R&D expenditure, it has been used as the primary indicator of industrial growth and development [16]. The framework of patent laws formulated by any country determines the course of development of its scientific and technological capabilities and also the growth of its domestic industries [9]. As per the Annual Report 2021-22 of the Department for Promotion of Industry and Internal Trade (DPIIT), Government of India, India’s rank in the Global Innovation Index (GII) has improved from the 81st rank in 2015 to the 40th rank in GII 2022 report (Table 2). India has retained its 40<sup>th</sup> rank in the year 2023 as well. In the last 10 years the number of patents filed and granted have consistently seen an uptrend (Table 3). In the past there has been a significant difference in the number of patents filed by the developed as well as developing countries. The developed nations have kept their innovations as a closely guarded secret and have transferred technology to the developing nations at a huge monetary cost. The time has come for innovators in developing countries like India, to jump on to the patenting

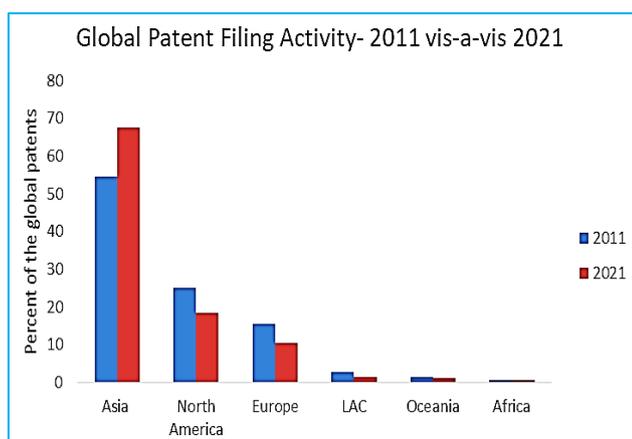


Fig 1 Graph showing the uptrend in the last 10 years in Patent filing globally. Two-thirds of the global patent filing comes from Asia [30]

## MATERIALS AND METHODS

### Patenting regime in Asia; Where India stands

Innovation is the key to any country's growth. The sustainable development goals set by the Government of India

bandwagon and be frontrunners. India's neighbor and a close contemporary, China, is significantly ahead in the patenting and innovation regime. With more awareness and focus on programs like Start-up India and Make-in-India, the day does not seem far when India will be stepping up its ranks further in the Global Innovation Index.

#### Turning the lens to biotechnological innovations

The term 'biotechnology' finds different ways of being defined. The United States Patent and Trademark office has from time to time sought to define 'Biotechnology'. According to one of the most widely accepted definitions of the USPTO, biotechnology means:

- (A) A process of genetically altering or otherwise inducing a single or multi-celled organism to
  - (i) express an exogenous nucleotide sequence
  - (ii) inhibit, eliminate, augment or alter expression of an endogenous nucleotide sequence
  - (iii) express a specific physiological characteristic not naturally associated with said organism
- (B) Cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody
- (C) A method of using a product produced by a process defined in (A) or (B) or combination of (A) and (B).

Article 2 of the Convention of Biological Diversity defines "Biotechnology" as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use". Thus, biotechnology can include cell biology, biochemistry, genetic engineering, immunology, microbiology etc.

There are three pillars on which the evolution of biotechnology in industrialized countries rests: (i) the scientific principle which makes the foundation of the biotechnological invention, (ii) companies engaged in biotechnological work and (iii) policies pertaining to research and development in this field, laid by the government [8]. India is among the top 12 biotechnology destinations in the world [25].

The transition of biosciences from molecular biology to genetic engineering has gathered momentum in the last couple of decades. In the current study, we aim to analyze the trend of biotechnology patents in India over the last decade.

## RESULTS AND DISCUSSION

### Patenting biotechnological innovations - An analytical review of India's performance over the last decade

As mentioned earlier, the number of patents filed in India in the last decade has consistently been on a rise (Fig 2, Table 3). In the years 2011-15, there was a narrow variation ranging from 0.4% to 1.6% in the number of patents filed. This saw a sudden uptrend in 2015-16, where an almost 9.6% jump in patent filings took place. This could be ascribed to an additional legal category called 'small entity' being introduced in India on 28th February, 2014. Defined in the Indian Patents Rules, (rule 2(fa)), an applicant may claim the status of a "Small Entity" if:

- (a) Investment in plant and machinery or equipment did not exceed INR 50 crore; or
- (b) Annual turnover did not exceed INR 250 crore.

This was also the year when electronic filing was introduced. These reasons could explain why there was an almost 10% rise in the number of patents filed in the country in 2015-16, over the previous year. Between the years 2016 and 2019 there was an insignificant variation in filing. 2019-20, however, witnessed an upsurge of 11%. The Government of India on 16<sup>th</sup> January, 2016 launched an initiative called Startup India. This was done with the vision to build a strong ecosystem for nurturing innovation and startups in the country. It included several benefits like reduced patent filing fees, fast-tracking of applications and tax exemption for three years [22]. The byproduct of such an initiative would naturally be increased economic growth that in turn would generate large scale employment for Indians. Not surprisingly, early December 2017 saw a total of 5350 startups as recognized by Department of Industrial Policy and Promotion (DIPP) [22]. It appears that the seed of rapidly rising startup culture that was sown in 2016, could be a factor that led to the development of innovative technologies, in the years that followed.

Table 3 Number of patent applications filed in India in the last decade [7]

S. No.	Year	Patent applications filed	% of biotech patents filed
1.	2011-12	43197	5.6%
2.	2012-13	43674 (+1.1%)	7.6%
3.	2013-14	42951 (-1.6%)	4.6%
4.	2014-15	42763 (-0.4%)	5.86%
5.	2015-16	46904 (+~9.6%)	5%
6.	2016-17	45444 (-3%)	5.75%
7.	2017-18	47854 (+5%)	5.54%
8.	2018-19	50659 (+5.8%)	6%
9.	2019-20	56267 (+11%)	2.75%
10.	2020-21	58503 (+~4%)	7.2%
11.	2021-22	66440 (+~13.6%)	6.7%

A closer look at 2020-21 data reveals an increase of 4% in the total patent filings as compared to the previous year but this year witnessed a staggering 175% increase in the biotechnology and allied field's patent filing (Table 3-4). This astounding increase in the number of filings could be vide Patents (Amendment) Rules, 2020, whereby, the statutory fee applicable for patent filings was subsidized for startups and small entities. In September, 2021, a rebate of 80% in patent

filing fees was introduced for educational institutions. This may have further incentivized patent filings by researchers in the educational institutions across the country (Table 5). While the subsidy would have had a positive impact on all areas of research, the filing of patents in Biotechnology was naturally in overdrive considering the world was reeling under the impact of the Covid-19 pandemic. According to IP-India Annual report 2021-22, CSIR has filed the maximum number of patents in the

year, followed by DRDO (Table 5) [12]. Two other factors which could have contributed to the upsurge in filing of Biotechnological patents are:

- In 2019, a total funding of 586.93 million USD was infused into the healthcare sector. This was 10% higher than the

funding received in the previous financial year. An increase in funding in R&D fructifies into better output, which is what has been witnessed.

- In 2020, in a landmark decision the Drugs Controller General of India (DCGI), reduced the time for testing the prototype of a medical device to 7 days from 30 days.

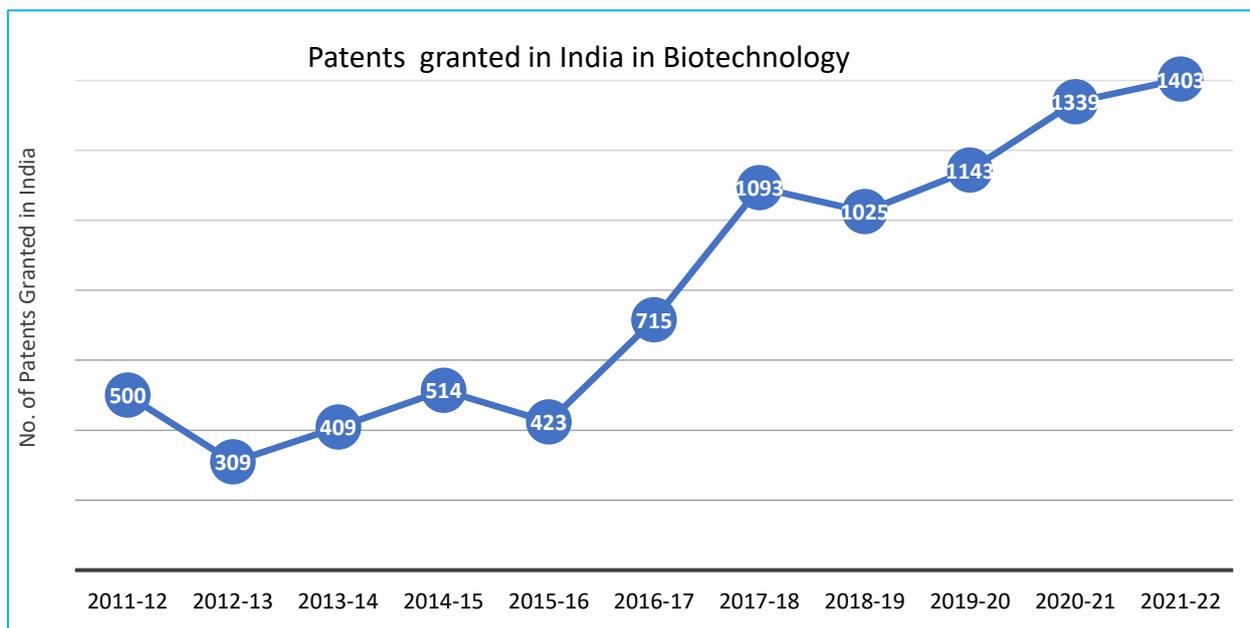


Fig 2 The trend of patents granted in biotechnology and allied fields in the last decade (Indian Patent Office Annual Reports)

Table 4 Number of Indian patent applications filed in biotechnology and allied fields in the last decade (Source: Indian Patent Office Annual Reports)

S. No.	Year	Number of patents in biotechnology and allied fields
1.	2011-12	2418
2.	2012-13	3306 (+37%)
3.	2013-14	1984 (-40%)
4.	2014-15	2502 (+26%)
5.	2015-16	2332 (-6.8%)
6.	2016-17	1431 (-38.6%)
7.	2017-18	1620(+13.2%)
8.	2018-19	1465 (-9.6%)
9.	2019-20	1524 (4%)
10.	2020-21	4188(+175%)
11.	2021-22	4437 (+5.9%)
	Total	27,207

Table 5 top Indian applicants for patents from scientific research and development organizations in 2021-22 [12]

Name of organization*	Number of patents filed
Council of Scientific and Industrial Research	223
Chairman, Defence Research and Development Organization	117
Indian Council of Agricultural Research	66
Indian Council of Medical Research	37
Solara Active Pharma Sciences Ltd	10
Zydus Life Sciences	09
Sun Pharma Advanced Research Company Ltd	09

\*Although these organizations carry out research in other areas of science, they are actively engaged in biotechnological research

#### Analyzing the numbers

From 2011 to 2022, there has been a 53.8 % increase in the number of patents filed (Table 3). During the same assessment period, the number of patents filed in biotechnology and associated fields saw an increase of 83.5 %. The major change took place in the year 2020-21 (175%). Of the total 27,207 patent applications filed in the field of biotechnology

between 2011-22 (Table 4), about 8873 have been successful (Fig 2). This is 28.6% of the total applications, indicating the credibility and the quality of the patent applications that are received at the Indian Patent Office.

We can appreciate that a developing nation like the India can ill-afford the cost of imported products and so the major driver of India’s progress in healthcare has been lowering of

prices of some health products [26]. Indian biotechnologists have been encouraged by the positive changes in Indian patent laws and have obtained more and more patents for their work. This in turn has been instrumental in reducing the cost of production since they own the intellectual property. Biotechnological innovation is a major contributor to the rapidly evolving area of health industry in India [1].

Table 6 The number of biotechnology patents filed by India and Korea between 2018 and 2022 (Source: Ipo and Kipo)

	2018	2019	2020	2021	2022
India	1620	1465	1524	4188	4437
Korea	10033	10242	11096	11928	12287

#### *Biotechnology patents in India vis-à-vis China, Korea and Japan*

The IP index status of India shows that there is a positive relationship between IP Index and GDP [3]. In 2022, PCT filings rose to 278,100 - the highest number ever recorded in a single year. China continued to be the top originator of PCT applications filed with 70,015 applications - a modest growth of 0.6% from the previous year. Japan had 50,345 applications, with only a 0.1% rise in the number of applications as compared to the previous year. The Republic of Korea had 22,012 applications experiencing growth of an admirable 6.2% [28]. India on the other hand, recorded a staggering 25.4% growth in PCT filings. Data depicted in (Table 6) shows the number of Biotechnology patents filed by India and Korea over the last

few years. It throws light on how a developing country like India is showing a remarkable (close to 173%) increase in Biotechnology patents over a period of five years in comparison to a developed country like Korea, which is showing a modest 22% increase. While the number of patents being filed by the other Asian countries are significantly higher, the biotechnological patenting trajectory of India shows that it is blossoming and has a huge potential.

## CONCLUSION

The significant increase in patent filings, especially in biotechnology, highlights India's evolving landscape of innovation and intellectual property. The positive changes in patent laws and supportive government policies have not only enhanced the number of patents but also contributed to the reduction of healthcare costs and the overall advancement of the biotechnological industry. India's trajectory indicates a promising future, with continued growth and development in the field of biotechnological innovations.

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