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An Overview on Indian Patents on Biotechnology

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Abstract: ***Back ground:*** The application of biotechnology is a potential tool for mitigating the present and future fooding and clothing demands in developing countries like India. The commercialization of biotechnological products might benefiting the poor's in developing countries are unlikely to be developed. Biotechnology has the potential to provide a wide range of products and the existing production skills in the industrial, pharmaceuticals and the agricultural sector.

Methods: Ownership of the intellectual property rights is the key factors in determining the success of any technological invention, which was introduced in the market. It provides the means for technological progress to continue of the industry of the country. The new plans, animal varieties, new methods of treatments, new crops producing food articles as such are the inventions of biotechnology.

Result: Biotechnology is the result of the application of human intelligence and knowledge to the biological processes. Most of the tools of biotechnology have been developed, by companies, governments, research institutes and universities in developed nations. These human intellectual efforts deserve protection. India is a developing country with advance biotechnology based segments of pharmaceutical and agricultural industries. The Trade Related Intellectual Property Rights (TRIPS) is not likely to have a significant impact on incentives for innovation creation in the biotechnology sectors. In the recent years, the world has seen the biotechnology sector as one of greatest investment area through the Patent Law and will giving huge profit in future.

Conclusion: The Research and Development in the field of biotechnology should be encouraged for exploring new tools and improve the biological systems for interest of the common people. Priority should be given to generation, evaluation, protection and effective commercial utilization of tangible products of intellectual property in agriculture and pharmaceuticals. To support the future growth and development in the area of biotechnology and exchange of knowledge should be proper evaluate and secure through patent system.

Keywords: Biotechnology, India, IPR, Patent, Patent Laws, TRIPS.

1. INTRODUCTION

Biotechnology is a popular term for the generic technology of the 21st century. Recent technologies like genetic engineering and recombinant technology now included along with the old biotechnology concept. Earlier nobody thought that biotechnology could manipulate, plant, animal, microbes or human being. So no one thought of the need for evolving a comprehensive law and regulation for biotechnology product and process es. Now biotechnology has progressed in various generations and this field mandated a comprehensive legal framework for proper regulation. It is focusing on the manipulating of living or biological active materials at molecular level in scientific and commercial way. There are so many applications of modern biotechnology in the field of food, health, energy and environment. Research in biotechnology is extremely time consuming and requires huge investment. Granting of the Intellectual Property Rights (IPR) is an effective tool to protect the biotechnology inventions. Department of Biotechnology, Govt. of India survey the Indian patents in biotechnology during 1972–1988 and

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showed that patenting in biotechnology is foreign-dominated with nearly 75% of the patents owned by foreigners. Pharmaceutical patents covered the processes for the preparation of antibiotics, vitamins, enzymes, antibodies and vaccines. The agricultural sector covers plant growth regulators, veterinary vaccines, plant cells and tissue culture. In the food industry, dairy and fish products, yeast and food additives, starch products, glucose and fructose syrups are covered by the biotechnology patents [1].

Many Indian biotechnology companies have developed proprietary processes for manufacturing 'bio-generics' or 'bio-similar', derivative forms of first generation. A genetically engineered micro-organism was granted patent, in the field of biotechnology gained enormous significance on genetically engineered plant and human genetic material. The global adoption of the patent system started in Venice as the first patent law was enacted in 1494, which regarded as the foundation for the world's patent system. The requirements such as utility, novelty and non-obviousness are still the basis of modern patent law around the world. India is the one that has immense potential to utilize biotechnology to its advantage to solve some of its most intractable problems of productivity, health and environment.

The patentability of genes and other nucleic acid sequences is justified on the ground that they have been subject to a microbiological or non-biological process, *i.e.*, gene sequencing, which is itself a standard process patentable and patented under existing patent laws for invention. The patenting of genomes raises the question of the function of the genomes. The genome can do nothing by itself, while its function in the organism cannot be considered separately from the totality of the organism.

Patents have generally been recognized as a measure of innovative activity in different technological fields. Biotechnology patents are related to inventiveness; the area of genetic modification, however, poses a challenge to relate the raw patent data with commercial technology. Different aspects of research, like genetic constructs, transformation tools as well as utility patents of genetically modified organism contribute to this field. A clear understanding of the underlying facts and inputs in the innovation process in biotechnology sector is necessary to gain appropriate insight into the relationship between patents and other inputs within the framework of economic policies and regulatory processes leading to commercialisation of new technologies [2].

2. BIOTECHNOLOGY PATENT IN INDIA

A patent is an exclusive right granted by the government to an inventor for a limited period of time. It is granted by the patent office in which you wish to protect your valuable invention. It covers each and every area of technology such as pencil to helicopter [3]. The advent of biotechnology necessitated the law of patent should be suitably modified to match the needs of science and technology. The industries that utilise biotechnology are convinced that intellectual property protection should be obtainable for the inventions that stem from research and which have commercial value. The biotechnology research workers in academic institutions increasingly share this view because of their need for research funding which is in part conditional on patentability. But many people are not in favour of patents in biotechnology because they believe 'patenting life' is unethical in principle. Inventions relating to biotechnology have also been rather controversial in India.

The framing of a common law or rules for biotechnology patent is a complex process as the field biotechnology is divided into different sub fields. Those sub fields like genomics, tissue culture of plants and animals which have unique characteristics. The properties, applications, processes and products in different area of biotechnology are also different from each other.

The Biotechnology sector is being hailed as the sunrise sector of India. It has been making steady progress over the last few years and has the potential to emerge as a global leader in the biotech industry. During the year 2013-14, the total revenue generated in India from patent was Rs. 312.24 crore, which was 10.60% higher than that of the previous year, while total non-plan expenditure was Rs.39.63 crore leaving a revenue surplus of Rs.272.61 crores. The patent office generated a total revenue of Rs. 189.61 crore [4]. Major biotech companies India and global are given in Table **1**.

The Indian firms are not yet filing a significant number of patent applications in India. Companies generating significant biotechnology revenues in

Table 1. Major Indian & Global Biotech companies.

Indian Company	Revenue (2013-14) (in million USD)	Global Company	Revenue (2013-14) (in million USD)
Serum Institute of India	437.1	Johnson & Johnson	74331
Biocon	344.5	Novartis AG	57996
Reliance Lifesciences	144.4	Bayer AG	56095
Nuziveedu seeds	143.2	Roche Holding AG	51895
NovoNordisk	131.1	Pfizer Inc	49605
Bharat Biotech	71.6	Sanofi SA	44848
Ankur Seeds	62.7	Merck & Co Inc	42237
Mahyco	45.3	GlaxoSmithKline PLC	37898
Rasi seeds	42.1	Sinopharm Group Co. Ltd.	32567
Panacea Biotec	32.1	Fresenius SE & Co. KGaA	57996

Source: http://www.ibef.org, http://www.statista.com [5, 6]

India; reveal that they filed only a handful of Indian patent applications during that period [3].

Patents are the strongest form of intellectual property protection in the sense that they allow the rights holder to exert the greatest control over the use of patented material. The concern patent protection to biotechnology- based research is that it could lead to patenting of research tools or the grant of broad patents that could potentially block further useful research. The Trade Related Intellectual Property Rights System (TRIPS), developing countries can choose to provide patents or develop a sui generis system to protect innovations in agriculture. Under Article 27.3 (b) of the TRIPS Agreement, members of the World Trade Organisation (WTO) may exclude from patentability plants and animals and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. In Indian patent law, the Patents (Amendment) Act, 2002 introduced significant changes with regard to the patentability of biotechnological inventions. By specifically allowing for the patentability of microorganisms, the law complied with the requirement of article 27.3(b) of the TRIPS Agreement. The (TRIPS) Agreement, to which India is a party as a member of the World Trade Organization (WTO), requires some level of protection of biotechnological inventions, including of plant varieties. India has to implement most of its TRIPS obligations by end of 1999 and is currently in the process of drafting revised legislation. The post-TRIPS regime has witnessed greater investment in research and development [7]. Within pharmaceutical research and development, there has been a significant increase in the focus on novel drug discovery [8] although new dosage forms remain dominant among product patents. The patent filing activity in the Indian Patent Office has increased dramatically in recent years (Table **2**).

The offices under the Controller General of Patents, Design and Trademarks (CGPDTM) have reported an overall increase of around 2.16% in filling of intellectual property applications during the reporting year 2013-14 (2, 51,564) compared to the previous year 2012-13 (2,46,251). During 2013-14, 42,951 patent applications ware filed. The office witnessed a marginal decrease of 1.65% in filing as compared to the previous year. The trends of last five years in respect of patent applications filed, examined, granted, refused and abandoned are given in Table **2**.

Table 2. Trends in patent application [9].

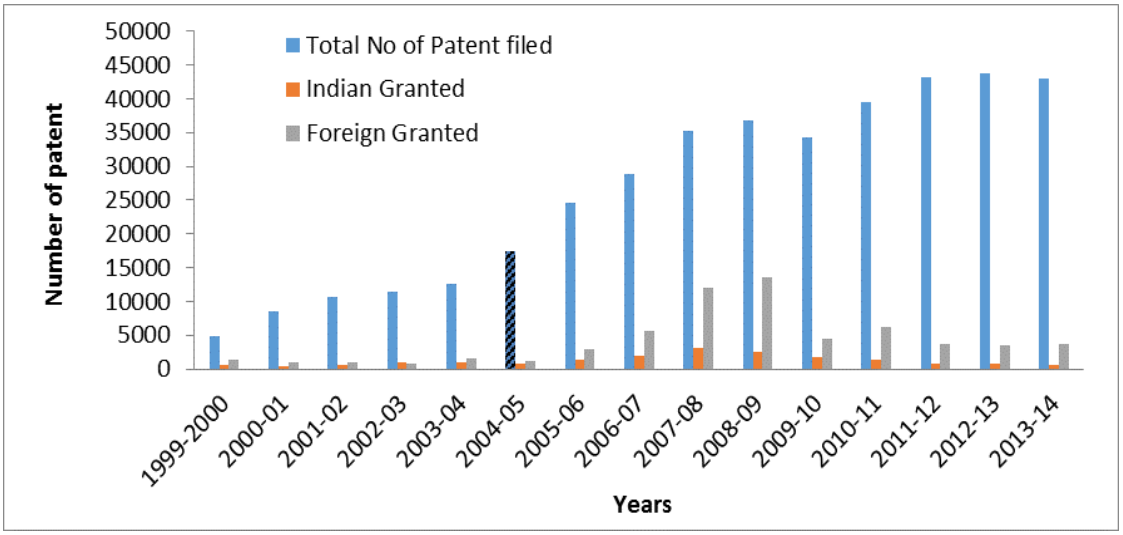
Year	2009-10	2010-11	2011-12	2012-13	2013-14
Filed	34,287	39,400	43,193	43,674	42,951
Granted	6,168	7,509	4,381	4,126	4,227

India, after becoming a member of the WTO, amended the 1970 Patent Amendment Act in 1999 so as to incorporate benefits for applications from industries such as drugs and agro-chemicals and

provisioning of exclusive marketing rights. The 2002 amendment to this Act made comprehensive changes to the legal regime, and brought in developments as a result of India's WTO and TRIPS related commitments. After an Ordinance in 2004 and the Patents Amendment Act 2005, the product patent was brought within Indian legal ambit. The establishment of the WTO and the requirements under TRIPS pushed the Indian IPR governance structure into introducing phased changes in the Patents Act 1970, so as to make the policy TRIPS compliant. Within the Indian patent regime, it has been seen that post WTO and between the period of 1995-2005, filing of patent application within India has increased at a very healthy rate of 15% with compound average grant rate of 11% (Fig. **1**). The selected patents on the biotechnological sector granted in India given in Table **3** and the trends of filed and granted patents in biotechnology shown in Fig. **2**.

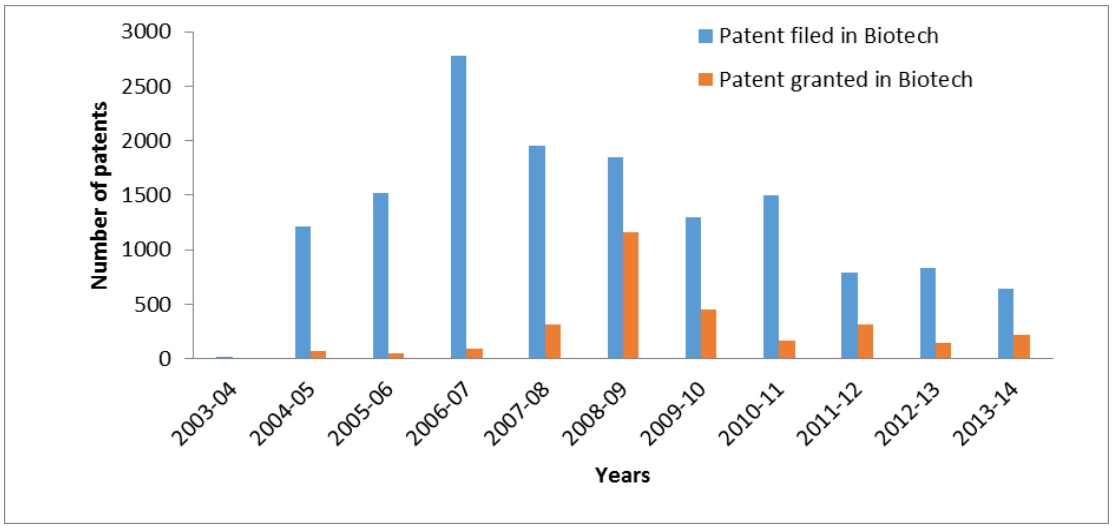
3. CHRONOLOGICAL DEVELOPMENT OF PATENTS IN INDIA

The history of Patent law in India starts from 1911 when the Indian Patents and Designs Act, 1911was enacted. The present Patents Act, 1970 came into



(Source: Compiled from CGPDTM Annual Reports, 2000-2014, http://www.ipindia.nic.in/)[9]

Fig. (1). Indian and Foreign Patent filed and granted (2000-2014).



(Source: Compiled from CGPDTM Annual Reports, 2004-2014, http://www.ipindia.nic.in/)[9]

Fig. (2). Patent filed and granted in India in the field of Biotechnology.

force in the year 1972, amending and consolidating the existing law relating to Patents in India. The Patents Act, 1970 was again amended by the Patents (Amendment) Act, 2005, wherein product patent was extended to all fields of technology including food, drugs, chemicals and micro organisms. An invention relating to a product or a process that is new, involving inventive step and capable of industrial application can be patented in India. However, it must not fall into the category of inventions that are non-patentable as provided under Section 3 and 4 of the (Indian) Patents Act, 1970. Patent application can be filed, either alone or jointly, by true and first inventor or his assignee in India [12].

In India, before 2002 patents were not allowed on living entities, biological materials, processes for production of living substances including nucleic acids but patents were granted for processes of producing non living substances by chemical processes, bioconversion and microbiological processes using microorganisms or biological processes [13].

Table 3. Selected patents granted in recent years in India [10, 11].

Sl. No.	Patent no. and year	Name of the patent	Name of the Patentee
Environmental			
1	165254, 1989	An improved rotating biological rope contactor for the treatment of biodegradable wastes	National Environmental Engineering Research Institute (NEERI), CSIR
2	175182, 1995	An improved anaerobic moving bed contactor for treatment of biodegradable moving bed contactor for treatment of biodegradable liquid wastes and biogas recovery	National Environmental Engineering Research Institute (NEERI), CSIR
3	185356, 2001	A biosensor for the determination of biological oxygen demand	Central Electrochemical Research Institute (CECRI), CSIR
4	185514, 2001	A device for the detection of faecal coliform bacteria in wastewater	National Environmental Engineering Research Institute (NEERI), CSIR
5	223945, 2008	A device for biological treatment of waste water and a process.	National Institute for Interdisciplinary Science and Technology (NIIST), CSIR
6	217114, 2008	An improved process for the biodegradation of industrial waste using a consortium of bacteria and fungus	National Chemical Laboratory (NCL), CSIR
7	216808, 2008	An improved process for the simultaneous production of biogas and fertilizer by high rate biomethanation of palm oil mill effluent	Institute of Genomics and Integrative Biology (IGIB), CSIR
8	236466, 2009	A process for the preparation of a bacterial consortium for the treatment of pulp and paper industrial waste water	Institute of Genomics & Integrative Biology (IGIB), CSIR
9	230551,2009	An improved anaerobic reactor useful for treatment of biodegradable waste water	National Environmental Engineering Research Institute (NEERI), CSIR
10	242196, 2010	A device for the biological treatment of wastewater containing biodegradable solids	National Institute for Interdisciplinary Science and Technology (NIIST), CSIR
11	241523, 2010	System and method for the Treatment of waste water	National Environmental Engineering Research Institute (NEERI), CSIR
12	245068, 2010	A process for bioremediation of p-nitrophenol contaminated soil	Institute of Microbial Technology (IMTECH), CSIR
13	242268, 2010	A process for the purification of water contaminated with *Escherichia coli* contaminated water for reusable option.	Central Leather Research Institute (CLRI), CSIR
14	257706, 2013	A novel catalyst useful for controlling microorganism in water and a process for the preparation.	Indian Institute of Chemical Technology (IICT), CSIR
Agricultural			
15	188337, 2003	A process for the preparation of an improved synergistic composition useful as growth medium for fungi and bacteria	Institute of Microbial Technology (IMTECH), CSIR

(Table 3) contd…..

16	191748, 2003	A process for the preparation of novel insecticidal composition comprising extracts obtained form the plant *Albizia lebbeck* and delta endotoxin from *Bacillus thuringiensis*	Central Institute of Medicinal and Aromatic Plants(CIMAP), CSIR
17	194987, 2004	An improved process for the preparation of a growth medium useful for the growth of edible fungus	Central Food Technological Research Institute(CFTRI), ICAR
18	220746, 2008	A process for the production of blue green algal biofertilizer	Council of Scientific and Industrial Research, India [CSIR (SCH)]
19	215482, 2008	A process for the preparation of adhesive exopolysaccharide by *Bacillus* sp.	National Institute of Oceanography (NIO), CSIR
20	225394, 2008	Tissue culture method for marine algae cultivation	Central Salt & Marine Chemical Research Institute (CSMCRI), CSIR
21	217983, 2008	A process for the bioremediation of hexachlorocyclohexane-contaminated soils	Indian Institute of Toxicology Research, (IITR), CSIR
22	253983, 2012	An anti-bacterial composition	Central Institute of Medicinal and Aromatic Plants (CIMAP), CSIR
23	254416, 2012	A process for the preparation of heat resistant seeds	Central Food Technological Research Institute(CFTRI), CSIR
Biological			
24	6846666, 2005	Bacterial strain MTCC 5098 and a method of reducing total dissolved solids (TDS) from pulp and paper wastewater effluents using the said strain	Institute of Genomics & Integrative Biology (IGIB), CSIR
25	199828, 2007	An improved process for the production of ethanol using activated stable yeast crystals	Indian Institute of Chemical Technology (IICT), CSIR
26	216260, 2008	A biotechnological method for enhancing crude oil degradation	National Environmental Engineering Research Institute (NEERI), CSIR
27	215657, 2008	A biosensor device useful for the measurement of organic acids and their derivatives	Central Food Technological Research Institute(CFTRI), CSIR
28	232420, 2009	A process for the preparation of consortium of genetically modified bacteria useful for remediation of hazardous chemical wastes	National Environmental Engineering Research Institute (NEERI), CSIR
29	239741, 2010	A method for isolating a gene useful for the detection of pathogenic mycobacteria	Institute of Genomics & Integrative Biology (IGIB), CSIR
30	244344, 2010	A process for the estimation of accurate and reproducible biochemical oxygen demand of pulp and paper industrial waste water	Institute of Genomics & Integrative Biology (IGIB), CSIR
31	242406, 2010	A process for production of the biogas from briquettes of fruit and vegetable processing waste	Central Food Technological Research Institute(CFTRI), CSIR
32	254355, 2012	Antisense oligonucleotide of mycobacterial peptide deformylase	Institute of Microbial Technology (IMTECH), CSIR
33	250721, 2012	A process for microbial biotransformation of caffeine to theophylline	Central Food Technological Research Institute(CFTRI), CSIR
34	258982, 2014	Method for the preparation of stable and reusable biose sing granules	Indian Institute of Chemical Technology, (IICT) CSIR
35	258379, 2014	A set of novel oligonucleotide primers and the method for the detection of *Aspergillus ochraceus*	Central Food Technological Research Institute(CFTRI), CSIR
36	262695, 2014	Biosensor device for the determination of caffeine in food samples	Central Food Technological Research Institute (CFTRI), CSIR

In 15th January 2002, the Hon'ble Calcutta High Court given a landmark decision for the grant of patents to inventions where the final product of the claimed process contained living microorganisms in

a case filed by Dimminaco A.G. against the decision of the Controller General of Patents and Design. The Hon'ble court concluded that 'a new and useful art or process is an invention, and where the end product (even if it contains living organism) is a new article, the process leading to its manufacture is an invention'. The Court held that the word "manufacture" was not defined in the statute therefore, the dictionary meaning attributed to the word in the particular trade or business can be accepted if the end product is a commercial entity. India joined the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purposes of Patent Procedure on 17th December 2001 [13].

British rulers enacted the first ever patent law in India the Act VI of 1856 on protection of inventions based on the British patent law of 1852. After several modifications in 1859, 1872 and 1888, the consolidated Indian Patents and Designs Act, 1911was enacted and offered patent protection to the inventions. In the light of changing socio-politico scenarios in India there were moves to consolidate the patent law by bringing up a new legislation and the outcome is the enactment of Patents Act 1970. The Patents Act 1970 highlights the invention that satisfies the universally accepted requirements of patentability such as novelty, inventive step and industrial application. The Patents Act 1970 had undergone several amendments in 1999, 2002 and finally the Patents (Amendment) Act 2005 (hereinafter referred to as the Patents Act) with introduction of product patents on substances capable of use as medicine, drug, or food could be obtained when India completed implementation of TRIPS required amendments to its Act. Further considerable changes have been made in the patenting procedure through the introduction of Patent Rules, 2003 further amended in 2005 and 2006, resulting in new practice and procedure. The Patents Act does not specify which are patentable, but it illustrates subject matters that are not patentable. The Patents Act enacted in 1970 does not mention anything about biotechnology invention. The Judicial pronouncements in the US and EU and suitable intervention by judiciary led to amendments of patent laws in these countries. India's patent third laws were amended in 2002 to explicitly include biochemical, biotechnological, and microbiological processes within the definition of potentially patentable chemical processes. The formal bio-guidance is the need of the hour as biotechnology is gaining momentum in India.

4. BIOTECHNOLOGY PATENTING SYSTEM

Biotechnology patenting systems were developed in three major areas in Agricultural, Industrial and Pharmaceuticals.

4.1. Agricultural Patents

Most of the population relies on agriculture for its livelihood. India is self-sufficient in wheat and paddy, but deficient in other agricultural produce. Agriculture in developing countries is predominantly rural based. Majority of the poor people depend on this agriculture. The new technology will improve the yield or reduce the cost of production will also directly reduce poverty and indirectly help the poor by lowering the price of food and by creating more employment opportunities. The traditionally, technical changes have occurred as on-farm experimentation such as adapting different cropping pattern, and such improvements were kept out of intellectual property protection. During the Green Revolution (GR) period in India (1960s), many hybrid and high yielding varieties were introduced-particularly in rice and wheat. These were the types of seed variety that can be replanted each year, which made GR very successful.

In India biotechnology research and development (R &D) is in progress particularly in crop improvement. The most promising benefit from genetic engineering is the use of recombinant DNA techniques. Because it is possible to break through natural species barriers systematically by moving genes from one species to another that do not combine in nature. The genetically modified (GM) crops have been developed by using input traits (*e.g*. resistance to insect pests and plant diseases), output traits (*e.g*. delayed fruit ripening, better taste, nutritious, elimination of saturated fats in cooking oils, elimination of allergens, better delivery of necessary nutrients) agronomic traits (*e.g*. resistance to drought, salinity, acidity, flood, *etc*. and increase in crop yield) [14].

The Indian Government, through its annual budget for 2005-06, has emphasized that the main thrust on agriculture sector would be to achieve further diversification in farm activities [15]. Agricultural biotechnology research is characterised by developing genetically engineered plants that have huge impact on global food production and seed

industry. Research in this sector consolidated since 1990s and attracted massive investments for R&D across several major private sector companies, public funded research laboratories and universities. Such a phenomenal technical change is not possible without path-breaking innovations at all levels evidenced by growing number of patents in agricultural biotechnology [2].

A small agricultural biotechnology (agri-biotech) company needs to establish a strong Intellectual Property (IP) portfolio. Such a portfolio provides a foundation for R&D, encourages outside investment and funding, and supports product commercialization. An important step in establishing an IP portfolio is in-licensing patent rights from third-party patent holders. Non exclusive licenses typically give a company freedom to operate and open up the possibility of creating commercializable products. Exclusive licenses give a company an exclusive position for commercialization under the patents in question. The agriculture patents constitute ~ 2% of the total Indian patents [16]. The total output of Indian patents on agriculture and food is given in Tables **4** & **5**.

Table 4. Indian patents on agriculture.

Year	Total no. of patents granted in India	Total no. of patents filed in agriculture in India	Total no. of patents granted in agriculture in India
2007-08	3173	66	53
2008-09	2541	29	04
2009-10	1725	40	04
2010-11	1273	20	01
2011-12	699	77	01
2012-13	716	103	03
2013-14	634	112	00

(Source: Compiled from CGPDTM Annual Reports, 2007-2014, http://www.ipindia.nic.in/)[9]

4.2. Industrial Patents

To encourage inventions by promoting the protection and utilization technologies, so the industries are developed, which contribute to the promotion of technological innovation and to the transfer and dissemination of technology. Biotechnology industries are largely dominated by companies serving both the pharmaceutical and biotechnology products. Out of 362 biotechnology firms in India, 54% of the revenue comes from the top 20 companies namely Biocon, serum institute of India, Panacea Biotec, Nuziveeedu seeds, Reliance Life Sciences, Rasi seeds, Mahyco, TRansasia, Ankur seeds, Syngene International, Bharat Biotech, Krishidhan Seeds, Shantha Biotech, Novozymes, Bharat serum, Jubiliant Life Science, Siro Clinpharma, Cadila, Indian Immunologicals, and Tulip Groups.

Table 5. Indian patents on Food.

Year	Total no. of patents filed in Food in India	Total no. of patents granted in Food in India	Percentage success
2000-01	96	72	75.00
2001-02	110	36	32.73
2002-03	199	67	33.67
2003-04	2125	110	5.18
2004-05	1079	67	6.21
2005-06	1274	140	10.99
2006-07	1271	244	19.20
2007-08	233	88	37.77
2008-09	340	97	28.53
2009-10	276	72	26.09
2010-11	315	84	26.67
2011-12	294	21	7.14
2012-13	452	37	8.19
2013-14	387	51	13.18

(Source: Compiled from CGPDTM Annual Reports, 2000-2014, http://www.ipindia.nic.in/)[9]

In recent years, the biotech industry is highly active in protection of its IP and doing extensive research and development to overcome the current competitive market force. The overview of this activity in terms of Indian patent filing trend and their product is shown in Table **6**.

4.3. Pharmaceutical Patents

India is an important manufacturer of globally recognised high quality pharmaceutical products and has become WTO/TRIPs compliant in post-GATT period. The trends of patent grants for Indi-

Table 6. Lead Indian Biotech Companies with their products and patent status (2010-11) [17].

Sl. No.	Company	*Products*	Patents	
			Published	Granted
1	Biocon	*Recombinant human insulin*	60	49
2	Serum Institute of India	*Recombinant Hep-B vaccine; Antisera*	31	9
3	Panacea Biotech	*Vaccine*	124	31
4	Reliance Life Sciences	*Plasma Protein &API*	70	3
5	Quintiles India	*Drug Development & clinical Trials*	1	-
6	Novo Nordisk	*Insulin*	283	76
7	Mahyco	*Bt cotton hybrid seeds*	7	1
8	Transasia	*Molecular Diagnostics*	31	1
9	Aventis Pharma	*Drugs*	229	127
10	Indian Immunologicals	Animal Vaccines	7	4
11	Bharat Serums	Drug, Vaccines, Biotech products	12	6
12	Advanced Enzyme Technologies	Nutrition & food processing	8	6
13	Life Care Innovations	NDDS, Lipid/Liposomal products for health care	10	3
14	Strand Life Sciences	Genomics and its Clinical Applications	3	-
15	*Nuziveedu seeds*	*Hybrid seeds*	-	-
16	*Rasi Seeds*	*Bt cotton hybrid seeds*	-	-

an pharmaceutical companies improved gradually but the numbers of companies having patents are very less compared to the total number pharmaceutical companies in India.

More than 90% of the Indian pharmaceutical industries are controlled by foreign multinationals. Drugs were manufactured outside India and imported for a higher cost. The drug prices were so high that in 1961, the US senate committee headed by Senator Estes Kefauver observed that India ranked among the highest priced nations in the world for drugs. Statistics of the first five year plan of India reveals that income from industries was as low as a mere 6.6% of the total national income. A mere 8% of the total labour force was working in industrial establishment. India was the largest reservoir epidemic diseases and it accounted for 5.1% of the total mortality. Around 50% of India's population were living under poverty and were unable to afford the cost of drugs. Consequently, life expectancy was very low and mortality rate due to diseases was very high. The central government under the Drugs Act of 1940 imported required drugs since India had local production of bulk drugs. India took significant steps to control the expenditure on drugs by signed an agreement with UNICEF to set up a factory for manufacturing of penicillin and antibiotics. This resulted in the establishment of Hindustan Antibiotic Limited in 1957 to manufacture drugs at a cheaper rate for the public. The government then appointed justice Rajagopala-Ayyangar Committee in 1957 to recommend revision to the patent law to suit industrial needs. The object of the committee was to ensure India developed a locally sustainable pharmaceutical market. The report submitted in 1959, that the patent legislation needed a clear directive. In recommending changes, the Ayyanger committee was bound by the provisions of the Indian constitution. Article 21 of the Indian constitution described right of life, which included the right to good health. The preamble of the Constitution requires policies to balance social and economic rights. Hence public health concerns need to be weighed with business interests in amending the patent legislation. The Ayyanger report argued that a patent policy vesting unrestrained monopoly would deny a vast section of India's population from access to medicines [18].

Considering the pharmaceuticals in Indian patent law the case of substances being used as food, drugs or medicines or produced by chemical processes, patents are granted only for the processes of manufacture of such substances and not for the substances themselves.

The Indian pharmaceutical industry remained import dependent till 1972, deeming most of the drugs unaffordable [19]. Political and policy developments in the early 1970's such as the new patent acts of 1972 and Drug Price Control Order (DPCO), 1970 laid the foundation for a strong pharmaceutical industry in India. Public sector focus on pharmaceutical industry and policies that curbed control of multinationals added to this conducive policy environment that led to the growth of domestic firms and establishment of India as a dominant supplier of pharmaceutical drugs across the world [20]. In the pre-TRIPs regime, the absence of product patents allowed local production of patented drugs at a fraction of the original cost while process patents encouraged generic companies to reduce the production costs of drugs. India's compliance with the TRIPS regime that became complete in 2005 has changed strategic options of Indian pharmaceutical firms. In the year 2013, the Indian pharmaceutical industry was the "third largest in the world in terms of volume" estimated to be worth $ 10 billion in 2010[21]. The Indian pharmaceutical industry remains pivotal in providing essential drugs at affordable prices. Patented drugs, on the other hand, comprise approximately 1% of the pharmaceutical market in the country [22].

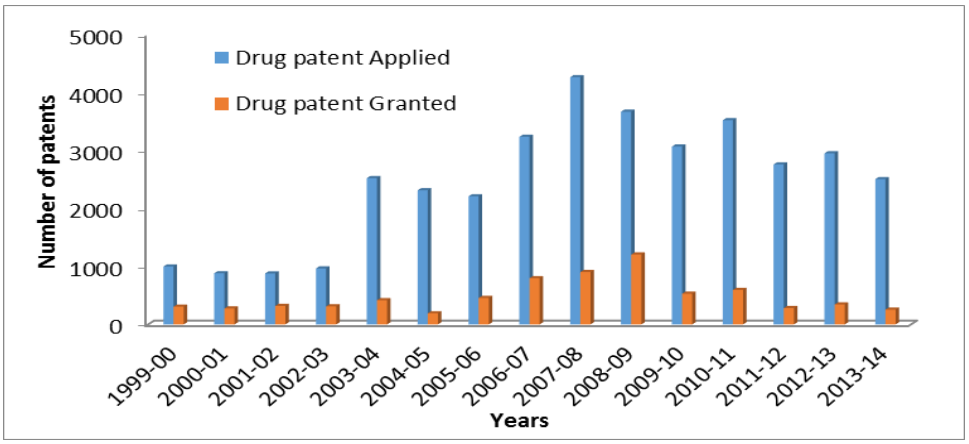
Biotechnology is used for pharmaceuticals and drugs manufacturing through biological processes. These are some of the best drugs used today and certainly among the most expensive. The Indian pharmaceutical industry is a successful, high-technology-based industry that has witnessed consistent growth over the past three decades. The current industry players comprise several privately owned Indian companies that have captured a substantial share in the domestic pharmaceutical market due to factors such as favourable government policies and limited competition from overseas [23]. India had a product patent regime for all inventions under the Patents and Designs Act 1911. However, in 1970, the government introduced the new Patents Act, which excluded pharmaceuticals and agrochemical products from eligibility for patents. This exclusion was introduced to break away India's dependence on imports for bulk drugs and formulations and provide for the development of a self reliant indigenous pharmaceutical industry (Table. **7**).

Patenting inventions is one parameter that enhances the strengths of a country economic. India has emerged as a manufacturing source for high quality pharmaceuticals which are recognized and accepted globally. There is a significant improvement in patent grants for Indian pharmaceutical companies, however the number of companies with patents is very less when compared to the total number of pharmaceutical companies in India

Table 7. Indian Companies in production of Biopharmaceuticals to Market.

Company	Products/technologies/services in the market
Advinus Theraputics	Metabolic disorders, inflammatory diseases, neglected diseases
Avestha	Agbiotech and transgenics, biosimilars
Bharat Biotech International	Recombinant drugs, cardiovascular diseases, vaccines
Bhat Bio-Tech India	Recombinant proteins, diagnostic markers
Bharat Serums and Vaccines	Plasma derivatives, monoclonals, hormones, serums.
Biocon	Industrial enzymes, recombinant protein therapeutic products and human growth hormone
Biological E.	Diagnostics, combination vaccines, antitetanus and antisnake venom sera
Dr Reddy's Laboratories	Infectious and parasitic diseases, oncology, immune disorders, endocrine, nutritional and metabolic diseases.
Gennova Biopharmaceuticals	Hi-tech molecules in nephrology, oncology and cardiology segment
Indian Immunologicals	Pediatric and childhood vaccines, DNA-based vaccines, animal- and human-health products

Source: Indian biotechnology database (http://www.indianbiotech.com/in/db/index.php[24]



(Source: Compiled from CGPDTM Annual Reports, 2000-2014, http://www.ipindia.nic.in/)[9]

Fig. (3). Trends of Drug patents in India.

(Fig. **3**) [9].

5. INDIAN PATENT ACT AND POLICY ISSUES

Patent Act in India was established in 1856 and has been modified several times. The major amendment was done in 1970 which satisfied the international norms of patentability such as novelty, inventive step and industrial application. The patent act 1970 had nothing specific about the biotechnology invention and protection. At the same time a significant number of biotech inventions and patent application were applied in the US and EU patent offices and courts as a result there was a need for the amendment of Indian patent act to introduce biotech patentability law. The amendment came in 2002 to explicitly include biochemical, biotechnological and microbiological processes within the definition of potentially patentable process [25].

The patents and Designs Protection Act was introduced in 1872 and the Indian Patents and Designs Act in 1911. Later after independence the Patents bill was unsuccessfully introduced before the Parliament in 1949 & 1965 and finally the bill was passed into force on 20th April 1970. The Patent system in India is governed by the Patents Act, 1970 (No. 39 of 1970) and the Patents Rules, 2003. The patents act has been amended several times in 1974, 1985, 1999, 2002 and in 2005 and the rules have been amended in 2006.

According to the Indian Patent Act 1970 and subsequent Patent (Amendment) Act, 1999 and 2002, patents could be applied mainly for agricultural tools and machinery or the processes for the development of agricultural chemicals [26]. The Indian patents Act has been hailed as model legislation for developing countries. It seeks to balance both the need for granting rewards for inventors while ensuring that India's developmental needs are not ignored.

Patent rights in India ware introduced as early as 1856, and modified in 1859 along the lines of the English Patent act of 1852 “History of Indian patent system: [27]. The Patents Act provides for exclusive rights for a limited period of time for disclosure of inventions that are new, useful and non-obvious; an art, process, method or manner of manufacture; machine, apparatus or other article or a substance of manufacture. Non-Patentable inventions under the Patents Act include methods for agriculture or horticulture, medical, surgical, curative or prophylactic methods for treatment of human, animals or plants. For substances that could be used as food, drugs or medicine, only the process for the manufacturing of the substance could be Patented and not the substance itself. Under the Patents and Designs Act of 1911, product Patents ware available for all inventions. It was The Patents Act of 1970 that made product patents unavailable.

Recently the Indian Patent Office has published the Indian Patents (Amendment) Rules, 2014 which have come effective from 28th of February, 2014. The new amendments rules are subsequent to the previously published Patents (Amendment) Rules 2005, on 28th December 2004; The Patents (Amendment) Rules 2006, on 5th May 2006; The

Patent (Amendment) Rules, 2012 and Gazette Notification of Patent (Amendments) Rules 2013[28].

6. INTERNATIONAL PATENTS CONTROVERSY WITH INDIAN MATERIALS

The herbal products have a significant demand in developed and developing countries. The lead pharmaceutical companies emphasized on indigenous system of medicines acquired information from traditional healers of indigenous communities. Multi-national pharmaceutical companies interact with local communities in village level to identify plants and plant materials at their local and indigenous medicinal use.

Biopiracy of Indian traditional knowledge increases because this traditional information exists in different regional language in regionally published or unpublished format. The patent offices are unable to search this information prior to granting patents.

The treatments of human diseases from traditional knowledge are time-tested since they have been in practice for long ago. The reliability of the application of traditional medicine coupled with the absence of such information with patent offices provides an opportunity for the interlopers for getting patents on these therapeutic formulations of traditional medicines.

- **Basmati Rice (*Oryza sativa* Linn.)**

Rice Tec. Inc. company had applied for registration of a mark 'Texmati' before the UK Trade Mark Registry. Agricultural and Processed Food Exports Development Authority (APEDA) successfully opposed it. One of the documents relied upon by Rice Tec as evidence in support of the registration of the said mark was the US Patent 5,663,484 granted by US Patent Office to Rice Tec on September 2, 1997 and that is how this patent became an issue for contest. This US utility patent was unique in a way to claim a rice plant having characteristics similar to the traditional Indian Basmati Rice lines and with the geographical delimitation covering North, Central or South America or Caribbean Islands. The said patent covered 20 claims covering not only novel rice plant but also various rice lines; resulting plants and grains, seed deposit claims, method for selecting a rice plant for breeding and propagation. Its claims 15-17 were for a rice grain having characteristics similar to those from Indian Basmati rice lines. The said claims would have come in the way of Indian exports to US, if legally enforced.

Evidence from the IARI (Indian Agricultural Research Institute) bulletin was used against claims 15-17. The evidence was backed up by the germplasm collection of Directorate of Rice Research, Hyderabad since 1978. CFTRI (Central Food Technological Research Institute) scientists evaluated the various grain characteristics and accordingly the claims 15-17 were attacked on the basis of the declarations submitted by CFTRI scientists on grain characteristics. Eventually, a request for re-examination of this patent was filed on April 28, 2000.

Recently, Indian rice in the foreign markets witnessed tough challenge as a consequence of the decision of the US Patent and Trademark Office (USPTO) because this office granted permission on 2nd Sep 1997 under brand name 'Texmati' domestic and foreign markets with a label claiming the product to be superior or at least equivalent to Indian Basmati. Therefore Government of India filed a petition in the USPTO and subsequently Rice Tec Inc surrendered four claims in September 2000 and 11 more claims in August 2001. The Rice Tec Inc is presently selling basmati after developing its novel lines named BAS-867, RT-117, RT-112. The UK is allowing basmati only from India and Pakistan though it is patented as Texmati in the USA and as Jasmati in Thailand [28].

- **Neem (*Azadirachta indica* Juss.*)***

A tree legendary to India has been used as a biopesticide and medicine in India for century's. Ancient Indian Ayurvedic texts have described the Neem tree and it's medicinal properties as far back as 5000BC. The leaf extracts of Neem plant can be used for controling a lots of pests and fungal diseases. The Neem oil can be used as mixed in soap, flu control, relief from malaria, cure of skin disease and meningitis.

The European patent office granted a patent (EPO patent No.436257) in 1994 to the US Corporation W.R. Grace Company and US Department of Agriculture for a method for controlling fungi on plants by the aid of hydrophobic extracted Neem oil. In 1995, some international NGOs and

representatives of Indian farmers filed legal opposition against the patent of Neem oil. They submitted evidence that the fungicidal effect of extracts of Neem seeds had been known and used for centuries in Indian agriculture to protect crops, and therefore, it should not be patentable. In the year 1999, the European patent office decided that according to the evidence all features of the present claim were disclosed to the public prior to the patent application and the patent was not considered to involve an inventive step. The patent granted on Neem was revoked by the European patent office in May 2000. In March 2006 the European patent office rejected the challenge made by the USDA and the chemicals multinational, W. R. Grace to the previous decision to cancel their patent on the fungicidal properties of the Neem seeds extract [28].

- **Turmeric *(Curcuma longa* Linn.)**

In India the Turmeric(Haldi) has been traditionally used as medicine for centuries for the treatment of wound healing and common cold. It should not be patented in recent time for these properties of Turmeric. The rhizome of turmeric has the properties that make it an effective ingredient in medicines, cosmetics and dyes and also used as a important spice in Indian cooking. In 1995, two expatriate Indians at the University of Mississippi Medical Centre were granted a US patent (No.5, 401,504) on use of turmeric in wound healing. The Council of Scientific & Industrial Research (CSIR), India, New Delhi filed a complain with the US PTO challenging the patent on the grounds of existing of prior art. The CSIR argued that the medicinal use of Turmeric for healing wounds and rashes was not a novel invention as it has been used for thousands of years in India.Their claim was supported by documentary evidence of traditional knowledge, including ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association. Despite an appeal by the patent holders, the US PTO upheld the CSIR objections and cancelled the patent. The turmeric case was a landmark judgment as it was for the first time that a patent based on the traditional knowledge of a developing country was successfully challenged. The US Patent Office revoked this patent in 1997, after ascertaining that there was no novelty; the findings by innovators have been known in India for centuries [28].

7. CURRENT AND FUTURE DEVELOPMENT OF PATENTING IN INDIA

Recent changes in India's patent policy have led to some review of India's position on patents. The recent flow in patent applications in India provides important data for evaluating the potential for domestic sector to adjust to the new patent regime. In the last two decades, most reforms were implemented without any profound knowledge or thorough analyses of the societal and/or economic impact. The advancements in biotechnology and information technology have significant impact on patenting system.

It is difficult to judge whether the patent system benefits to the society. If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. It should be recognized that there is a striking correlation between wealth, economic performance and the scope of the patent system in all affluent countries. In recent years, the patent system has been both strengthened and expanded without any evidence of the benefits to society. Priority should be given to generation, evaluation, protection and effective commercial utilisation of tangible products of intellectual property in agriculture. The policy related to protection of IPR in different sectors of technologies, attention should be given to further liberalisation of its market, promotion of private sector investment and more efficient technology systems. The R&D in the field of biotechnology should be encouraged for exploring new tools and improve the biological systems for public interest. To support the future growth and welfare the development and exchange of knowledge should be properly evaluated and secured through patent system. By increasing the R&D and manufacturing sector the number of patent filling will grow in future.

8. CONCLUSION

The application of modern biotechnology for agricultural, ecological and pharmaceutical sectors has great hopes for the extent to which man can explore and exploit the biological resources. So it allows for the direct genetic modification of the life forms. The commercialization of genetic modified organisms has led to intense international and multicultural conflicts and debates. Using the advance technology to modify life forms is becoming

difficult for law and rules to protecting property right of biotechnological products. One of the significant developments in the patent laws has been in the Biotechnology sector. The biotechnology patents are the debating subjects that many countries consider these patents create future problems to access the patented life forms.

Most of the biotechnology processes have been invented in developed countries. Such technologies are yet to benefit the developing countries partly due to commercial reasons and also due to the fact that they may not always be applied in their present form. Development of appropriate biotechnology and their commercialization in developing countries is hindered by the array of existing patents. Such application will require the use of several patents with multiple owners. Moreover, such patents are owned by a few companies and institutions. Negotiating such 'patent thickets' poses serious challenges in development and application of biotechnology in developing countries. National and international initiatives should be taken for properly formulation of the intellectual property right law, and particularly patent law for patenting biotech products without depriving the interest of common peoples. India's domestic policy and international negotiations on one aspect of IPRs, patents, provides important lessons for formulating a comprehensive negotiating strategy on TRIPs. Support from developing countries, disunity among advanced nations and the role of NGOs were also factors that enabled India to promote its interests in the negotiations. In recent years a good number of patents are granted for all sorts of biotechnological inventions in India. The Research and Development in the field of biotechnology should be encouraged for exploring new tools and improve the biological systems for the interest of common people. Priority should be given to generation, evaluation, protection and effective commercialization of tangible products of intellectual property in agriculture, environment and medicine. Researchers in different Institutions must be aware of intellectual property issues in their research topics. The Intellectual property right has an impact on the social and economic development of a society. The policy related to protection of IPR in different sectors of technologies, attention should be given to further liberalization of its market, promotion of more efficient technology systems and private sector investments. The future growth and development in the sector of biotechnological research and exchange of knowledge should be encouraged through proper evaluation and secure patent system.

CONFLICT OF INTEREST

The author(s) confirm that this article content has no conflict of interest.

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ABBREVIATION

APEDA = Agricultural and Processed Food Exports Development Authority

AICRPE = All India Coordinated Research Project of Ethnobiology

CIMAP = Central Institute of Medicinal and Aromatic Plants

CFTRI = Central Food Technological Research Institute

CGPDTM = Controller General of Patents, Designs & Trade Marks

CSIR = Council of Scientific & Industrial Research

CECRI = Central Electrochemical Research Institute

CSMCRI = Central Salt & Marine Chemical Research Institute

CLRI = Central Leather Research Institute

DPCO = Drug Price Control Order

EPO = European Patent Office

GM = Genetically Modified

GR = Green Revolution

GATT = General Agreement on Tariffs and Trade

IPR = Intellectual Property Rights

IIPC = Indian Integrated Pharmaceuticals Company

IGIB = Institute of Genomics and Integrative Biology

IMTECH = Institute of Microbial Technology

IICT = Indian Institute of Chemical Technology

IITR = Indian Institute of Toxicology Research

IPO = Indian Patent Office

NIIST = National Institute for Interdisciplinary Science and Technology

NCL = National Chemical Laboratory

NDDS = Novel Drug Delivery System

NIO = National Institute of Oceanography

NEERI = National Environmental Engineering Research Institute

PVP = Plant variety protection

R &D = Research and Development

TRIPS = Trade Related Intellectual Property Rights

TBGRI = Tropical Botanical Garden Research Institute

UNICEF = United Nations Children's Fund

US = United States

USPTO = United States Patent and Trademark Office

WTO = World Trade Organisation

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