

Medical Device Patenting Trends in India

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Abstract: *The patenting trends of global medical device industry are very promising but in India the patenting trends in the Indian medical device industry still at the budding stage because of the lesser degree of the innovation and technology adoption in this industry. But this provides a very good opportunity for the medical device industries to explore more and more in this Indian medical device market because India being the second largest populated country with diverse nature of patients. With the amendment of Indian patent law in march 2005 and the subsequent adoption of Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS), lead to the establishment of improved systematic statutory, administrative and judicial network to protect the IPRs, which opened up the avenue for the global and medical device companies to enter in India. This paper reviews the patent filing trends in general and medical device industry in the world and in India for a particular period of time.*

Keywords: Medical device industry, patents, patenting trends, patent filings

1. Introduction

When compared to the global medical device industry, which is very innovative, technology oriented and fast growing industry, the Indian medical device industry is still at the budding stage. The degree of innovation and technological adoption in the Indian medical device industry is very low. But this in turn provides very good opportunity for the many medical device industries both international and domestic companies to enter and develop this industry to a new level of high innovation and technology driven. India being the second largest populated country in the world, makes it one of the upcoming leading medical device market in the world. The medical device sector in India is growing at a considerable rate over the last few years. When comparing to the innovation in medical devices, Indian medical devices sector is still lacking behind. The data related to the amount of research and innovations done in this industry over the years are not clearly available. Further, the support from the Indian government for this industry is promising with the commitment to increase the expenditure on public health from 1.7% to 2.5% of GDP. The Indian medical device industry is still import oriented and it accounts only 1.7% of the world medical device market [1].

The factors which influence the medical device industry of a country are total health care expenditure, GDP, demand for treatment options linked with disease pattern of the people, awareness of people on treatment options, public spending on health care etc. [2]

Moreover the level of innovation in the medical device industry is also linked to the Intellectual Property Rights (IPR) rules and regulations or Patents Act of the country. The patent filing data is one of the measures which give an idea about the innovation or open innovation practices in India. A patent is a legal title granted to an inventor who has applied for the patent which prevents other people or parties to copy or exploit the invention without getting permission or authorization. [3]

A patent is applicable to a specific country or a group of countries for a specific period or duration of time. Generally, the period or duration of a new patent is for 20 years. The

types of patent that can be possible are utility patent, plant patent and design patent. The protection of patent differs from country to country. This makes the inventors to apply for patent protection in all those countries they are interested in. There is an option of international patent system also available which protect the intellectual property of the invention or innovation in many countries which abide these international patent systems [4]. This paper tries to review the patent filing trends in general and in medical device industry in the world and in India for a particular period of time

2. Literature Review

Medical Device Industry in India

The Indian health care industry is forecasted to touch USD 175 billion in 2020 from USD 100 billion in 2016, with the CAGR of 20%. In this health care industry, the medical device industry which was given an independent status in 2014 is valued at USD 6 billion in 2017 and estimated to reach USD 8.21 billion at the CAGR of 10 – 11%. Indian medical device industry is placed among the top 20 global medical device market and fourth largest medical device industry in Asia after Japan, China and South Korea. [5] The medical device industry in India is expected grow at a rapid pace in the upcoming years. The medical device industry in India is dominated by MNCs with 70 – 75% depends on imports and about 30% of the domestically manufactured devices are exported. 30% of import is mainly done from USA alone. [6] At present, the number of medical device manufactures in India is about 800 and many more international companies are looking forward to enter in to this segment.

Table 1: Medical devices market share percentage in India

S. No	Medical devices sub sector	Percentage
1	Equipments and instruments	53.75%
2	Consumables and disposables	16.0%
3	Patient aids	13.2%
4	Stents	8.85%
5	Implants	8.20%

Source: World bank, WHO

In the medical devices sector in India, out of total market share, the equipments and instruments has a market share of

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53.75%, followed by consumables and disposables has a market share of 16%, patient aids accounts has a market share of 13.2%, stents has a market share of 8.85% and implants has a market share of 8.2%. It is expected that patient aids sector will grow at a CAGR of 15% rate and equipments and instruments sector will grow at a CAGR of 10% in 2020.

Table 2: Medical devices domestic made and import percentage

S. No	Medical devices sub sector	Indian	Imports
1	Equipments and instruments	10%	90%
2	Consumables and disposables	60%	40%
3	Patient aids	20%	80%
4	Stents	40%	60%
5	Implants	25%	75%

Source: SKP research

In the medical devices sector in India, the equipments and instruments accounts for 90% of imports, followed by consumables and disposables accounts for 40% of imports, patient aids accounts for 80% of imports, stents accounts for 60% of imports and implants accounts for 75% of imports.

Table 3: Medical devices sub sector market value in 2017 and 2020

S. No	Medical devices sub sector	2017	2020	Increase in %
1	Equipments and instruments	3.23	4.34	34.4
2	Consumables and disposables	0.96	1.29	34.4
3	Patient aids	0.79	1.2	51.9
4	Stents	0.53	0.7	32.1
5	Implants	0.49	0.68	38.8

Patent Filing in Medical Devices

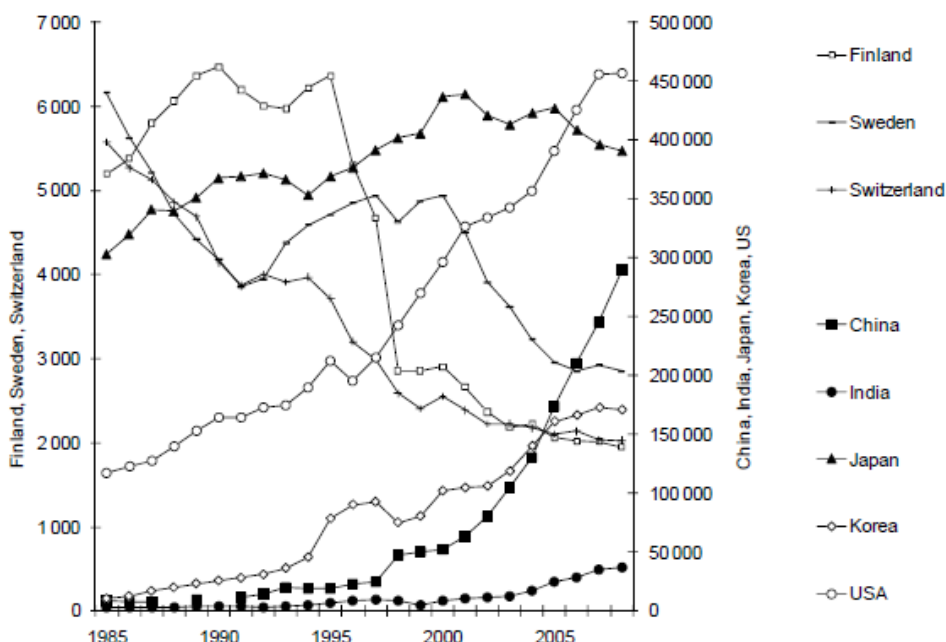
Patents are inseparable attendants of innovation and innovative products. Different countries focus on a wider but increasingly similar set of technologies that are patented which is increasing intra - national technology convergence. In addition intellectual property legal convergence takes place as newly industrialised countries have strengthened their IP regime in compliance with TRIPS and do to so in the context of their indigenous innovation practices [7].

The medical device industry is innovation oriented one which requires patent filings for the inventions and

innovations. There has been a increase in the innovations and patent filings in the medical device industries in the recent years. Increasing number of patent applications are filed each year on medical devices, which indicates the amount of innovation that is being taking place in this industry and also it shows the importance and value of the health care sector. Innovations in medical devices also depends on the multiple technologies like Information Technologies and the patenting also has to be taken either separately or combinely for these technologies also [8].

In Medical Devices though there is a significant increase in the number of startup companies, only the big established companies are filing patent applications at large in this industry. These large companies have their own R&D infrastructure for their innovation practices and they also having partnering with high - tech companies for product offers which are more beneficial for consumers. These companies also have tie - up with academic institutions and universities which are having incubation centres for innovation in medical devices, to get licensing for more and more technologies [9].

The statistics of patent applications of various countries in the world from 1985 to 2008 shows that Japan was leading country in the patent applications per year ranging at about 3, 00, 000 applications from 1985 to about 4, 00, 000 applications in 2005. During that period USA stood second place from about 1, 00, 000 patent applications in 1985 to about 4, 00, 000 applications in 2005. In 2005, USA overtook Japan as the leading patent applications country in the world and in 2008, USA stood leading patent applications per year about 4, 50, 000 applications. Similarly Korea was the third leading country in the patent applications per year ranging at about 15, 000 applications from 1985 to about 1, 500, 000 applications in 2004. During that period China stood fourth place from about 10, 000 patent applications in 1985 to about 1, 500, 000 applications in 2005. In 2004, China overtook Korea as the third leading patent applications country in the world and in 2008, China stood third leading patent applications per year about 2, 90, 000 applications. In the case of India, during that period from about less than 10, 000 applications in 1985 to about 40, 000 applications in 2008 [10].



Source: Statistics from WIPO and national PTOs

Figure 1: National patent applications in selected countries per year from 1985 to 2008

Patents Act of 1970 under the support of patent rules 2003, provides the grant, revocation and regulations of patents in India. Under this act, patents can be given for the product and process for the period of 20 years, which include inventions of a new product or new process which can be applied in the industrial application except for some categories.

With the amendment of Indian patent law in march 2005 and the subsequent adoption of Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS), lead to the establishment of improved systematic statutory, administrative and judicial network to protect the IPRs, which opened up the avenue for the global and medical device companies to enter in India.

The Medical Device Regulation (MDR) under the Drugs and Cosmetics Act 1940, (DCA) describes the following categories of substances as medical devices [11]:

- a) Specific devices intended for external and internal use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings and animals which are notified by the government from time to time under the DCA.
- b) Specific substances intended to affect the structure or any function of the human body which are notified by the government under the DCA. At present the substances

notified are mechanical contraceptives (eg. Condoms, intra - uterine devices, tubal rings), insecticides and disinfectants.

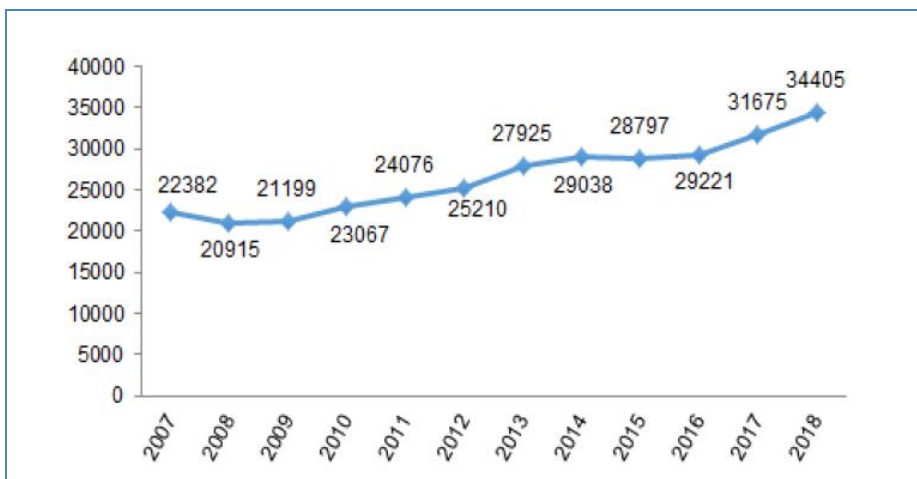
- c) Surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anti - coagulant
- d) Substances used for in vitro diagnosis

The patent filing in the medical devices in United State Patent and Trade Mark Office (USPTO) shows that from 2007 the number of filings was 22382 which have increased at the steady rate to reach 34405 in 2018 [12].

Table 4: Patent filing in medical devices in USPTO

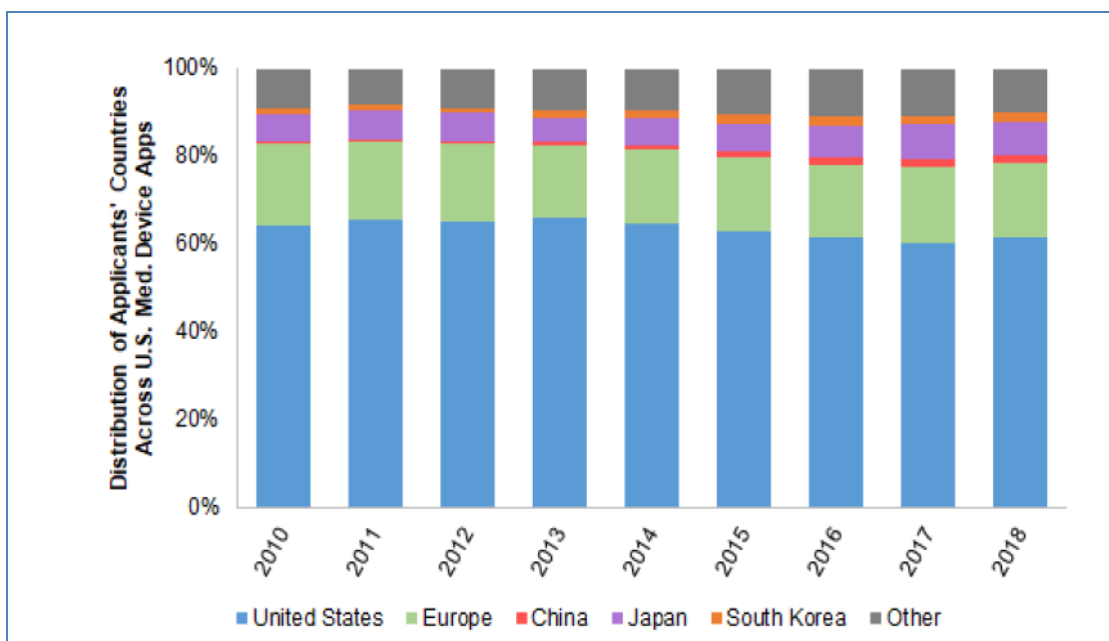
Year	Patent filing in Medical devices
2007	22382
2008	20915
2009	21199
2010	23067
2011	24076
2012	25210
2013	27925
2014	29038
2015	28797
2016	29221
2017	31675
2018	34405

Source: Kilpatrick Townsend



Source: Kilpatrick Townsend

Figure 2: Patent filing in medical devices in USPTO



Source: Kilpatrick Townsend

Figure 3: Distribution of Applicant's countries across U. S. Medical Device Applications

From the fig 3, it is observed that U. S patent filings dominate the patent filings all over the world and it remains almost stable around 60% of the world's patent filing in the last decade. After U. S, the Europe stands in second place in patent filings around 15% of the world's patent filing in the last decade. Japan stands in third place in patent filings and subsequently China and South Korea stands in the next positions with almost same percentage of contributions in the patent filings.

Patent protection Trends in US

Earlier the patent lawsuits in the US federal court were known to be more expensive and time - consuming. In 2012, Patent Trial and Appeal Board (PTAB) was formed to help the companies to appeal on the patents instead of registering lawsuits in the federal court, which helped medical device companies to challenge thousands of patents. Interestingly, a new analysis of data from PTAB shows that the number of PTAB filings in 2019 was 24% lesser than the year 2018. Also the institution PTAB filing rates were down to 62% in

2019 from 87% in 2013 and also the total filings during the period of 2015 to 2019 also decreased [13].

This is due because the IPR rules and standards have moved towards the way that would favour the patentees. This would be a favorable shift for the medical device companies when considering the validity of their patents. This makes the patentees less worried about IPR. Moreover, medical device companies while protecting their IP, should be aware of the shifting background of IPR practice in the recent PTAB decisions. Medical device companies should also understand the reasons behind the rejection of petitions by the PTAB panel and should leverage that fact into strategy while filing an IPR [13].

Patenting Trends in Medical Device Industry

The medical device industry is gradually becoming more dependent on small, young companies to provide innovations, but the early - stage medical technology companies are mostly relying on angel investors. It is also

more important than ever to protect intellectual property and mitigate exposure to litigation.

The following are the trends affecting innovation in the medical device industry [14]:

1) Innovation through acquisition

For the legacy medical device companies, there's less opportunity for big, game - changing, strategic acquisitions than there used to be. Instead, the focus is more on the smaller acquisitions that can add products to the companies' lineup. As the budgets are R&D getting economized, many medical device companies look for outsourcing of developmental technologies like that of pharmaceutical industry, where innovation is already mostly outsourced,

2) Partnering with academic institutions in a way that protects IP

Academic institutions are becoming a great source of inventions for medical device companies, but medical technology companies need to take care to protect their IP. It's a great way to get the foundational IP fast and some data behind it, but the medical device companies have to be careful with the license and agreements. That usually comes up during the due diligence i. e who owns what part of the IP and how important is the foundational IP. It is also to be noted that sometimes several academic research institutions do their research work together, so getting a license from one university may not be enough if several other institutions or universities involved in the research.

3) Venture Capital funding for more advanced companies

Venture capital organizations still appear to be focused on funding medical device companies that have already achieved a few milestones. These companies are interested in funding for Food and Drug Administration (FDA) approved devices. Much of the funding for early stage companies presently comes from angel investors and it is relatively easy to secure an investment in the \$1 million to \$3 million range.

4) Medical device litigation

Medical device companies apart from thinking about regulatory compliance they have to focus also on mitigating litigation risks. Media reports have impacted the public's perception of the medical device industry and acquired some attention from petitioner lawyers and that attention in turn has increased the potential for litigation.

5) Other Emerging trends

Medical Device industry will turn into a source of innovation and patenting because of several emerging trends related to aging population and technological advancement. The increasing aging population in the developed countries and the enhanced physical activities of aged level people in those countries provides an avenue for the growth of market opportunities for innovative medical devices [15]. Further, the advancement in technologies like increasing application of Artificial Intelligence (A. I) and robotics in medical environment have provided opportunities for innovation and patenting in medical device industry [16]. The personalisation of medical care including the emergence of health - related mobile applications may provide new

entrants to overcome the barriers to entry in to this medical devices industry. All of the above trends will tend to grow in coming years which will further enhance the rapid innovation and patenting practices in Medical Device Industry [17].

3. Materials and Methods

Markan S, and Verma Y, (2017) studied the patent application filing trends of medical devices in India for the period of 10 years from 2005 to 2014 and found that only 2% of medical device patents are filed among the total patents filed in India for the period of 2009 to 2013. The study also found that there was a increasing in percentage in the medical device patent filing trend and also foreign companies dominated the patent filing than the Indian companies [18].

Table 5 shows the patent applications filed and published details in India from the year 2005 to 2015. The average patent applications filed from 2005 to 2014 were 851.3 and the average patent applications published from 2006 to 2015 were 912.6. This shows that there was a increase in difference between the patent applications filled and published in India during the period of 2005 - 2015.

Table 5: Medical devices Patents filed and published in India from 2005 - 2015

Year	Patent applications	
	Filed	Published
2005	640	-
2006	786	133
2007	920	1142
2008	812	752
2009	834	877
2010	829	954
2011	984	684
2012	962	836
2013	1104	936
2014	642	1406
2015	-	1406
Average	851.3	912.6

Source: Markan S and Verma Y, (2017)

Table 6 shows the total patent filed in India from all the industries and the patent filed from the medical devices industry in India from the year 2009 to 2013. The percentage data shows that there was an average of 2.27% of the medical device patent filled out of total patent filled in India from 2009 to 2013.

Table 6: Comparison of total patent filed and medical device patent filed in India from 2009 - 2013

Year	Total Patent Filed	Medical device patent filed	Percentage
2009	33453	834	2.49%
2010	38571	829	2.15%
2011	42213	984	2.33%
2012	42712	762	1.78%
2013	41847	1104	2.64%
Average	39759.2	902.6	2.27%

Source: Markan S and Verma Y, (2017)

Table 7 shows the country - wise patent filings in medical device sector in India for the period of 2005 to 2014, where the majority of the medical device patent in India was filed by USA (41%) and the medical device patent filed in India by Indian companies was 17%. Out of total, 83% of the medical device patent filed in India was by foreign countries. This shows that the patenting in medical device industry in India was dominated by foreign companies.

Table 7: Country - wise patent filings in medical device sector in India for the period 2005–2014

Country	Percentage
USA	41%
India	17%
Europe	9%
Germany	5%
Japan	4%
UK	3%
Other	21%

Source: Markan S and Verma Y, (2017)

Table 8 gives the detail about the country - wise and five year - wise comparison of patent filed in India in medical device industry in which there was a decrease in percentage - 12.21% for USA and - 1.32% for UK from the 2005 - 2009 five year term to 2010 - 2014 five year term was observed. For other countries there was a increase in the patent filing trend with Europe had high percentage of increase of 86.10% and on the other side Germany had 2.49%. The increase in percentage of India was 13.88%.

Table 8: Comparative foreign patent filing trends in India for the period 2005–2009 vs 2010–2014.

Country	2005 - 2009	2010 - 2014	Change %
USA	1883	1653	- 12.21%
India	677	771	13.88%
Europe	259	482	86.10%
Germany	201	206	2.49%
Japan	175	202	15.43%
UK	151	149	- 1.32%

Source: Markan S and Verma Y, (2017)

Table 9 shows the medical device sub - sector wise patents filed from 2005 to 2014, in which the medical delivery sector had high number of patents filed with 3503 patents accounting almost 41%, and the patient transfer & transport sector had lowest number of patents filed with 98 patents accounting for 1.14% of the total patents filed.

Table 9: Medical devices subsector wise patents filed from 2005 - 2014

S. No	Medical devices sub sector	Patents Filed	Percentage
1	Medical Delivery	3503	40.92%
2	Diagnostics and surgical	1935	22.61%
3	Therapy assistance	787	9.19%
4	Implants and dressing	693	8.10%
5	Dentistry	567	6.62%
6	Medical containers	493	5.76%
7	Physical therapy	308	3.60%
8	Bandages and dressing	176	2.06%
9	Patient transfer and transport	98	1.14%

Source: Markan S, Verma Y, 2017

4. Conclusion

Though the Indian medical device industry is growing, its growth will be mainly depend on the intensive innovation and technology adoption and its related patenting practices adopted by the medical device companies in India. In the world, USA remains the major contributor in the patent filings in the medical device industry followed by Germany, Japan, UK, Switzerland and Israel. An investigation of national trends over time present a summary of the performance of research and development of medical technology in the medical device industry in India. The medical device companies in India should adopt the strategy of benchmarking against the other high - patenting nations which would facilitate the national planning to ensure continued national competitive advantage. They also should focus on the increasing importance of mobile technology in medical devices which provides an opportunity for high tech companies to enter into medical device market. Still, innovation and technology adoption practices to be improved significantly in many subsectors of medical devices, so that more number of patent applications can be applied, which would make India among the list of top ranking countries in the medical device innovation and patent receiver.

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