

ORIGINAL ARTICLE

Indian medical device sector: insights from patent filing trends

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ABSTRACT

In this study, patent application filing trends in India for the last decade (2005–2014) were analysed to understand the medical device patent filing profile. As India is the key emerging market with huge market potential, this study was also undertaken to identify the top medical device companies filing patents in India, the niche technology domains with maximum filings, key gaps in medical device innovation profile and scope for business opportunities. It was observed that patent application filings in the medical device sector during the last 5 years (2009–2013) contributed only to 2% of the total patent applications filed, which may be attributed to nascent medical device sector and lack of Intellectual Property (IP) awareness or funding support for IP filings. The analysis shows increasing trends in medical device patent applications in India, with major share of patent applications being filed from the USA. The Indian applications in this sector contributed only to 17% of the total patent application filings in the last decade. Although foreign players dominate the medical device sector, this study indicates that though at a small scale, Indian applicants are actively filing patents in all key domains of the medical device sector. With the enabling environment being provided by the Government of India with recent policy initiatives such as Startup India, Make in India, 100% Foreign Direct Investment (FDI) and so on and support to start-ups for IP filings, the Indian medical device industry is expected to witness aggressive IP filing and innovation trends and is poised to grow exponentially targeting US\$50 billion industry by 2025.

growth rates. The medical device and equipment market in India was valued at US\$6.36 billion in 2013, is experiencing an annual growth rate of 15% and has the potential to be a US\$50 billion industry by 2025. This fast growth can be attributed to factors such as improved healthcare infrastructure, increased healthcare spending, increased medical tourism, growing healthcare insurance and increased penetration of private sector.¹

The Indian medical device market, although small, is among the top 20 in the world by market size and fourth in Asia after Japan, China and South Korea. Concrete regulatory framework specific to medical devices is absent in India and the devices are currently regulated as drugs. The Indian medical device market is highly import dependent with 70%–75% of demand being met through imports.² India being an emerging market is evolving as a manufacturing hub for the key global medical device players and many medical device companies such as Philips, GE Medical systems, Start-up Bio-Ved (San Francisco), and so on, have set up their offices in India. Is India only a marketing hub for these medical device leaders or are these companies also developing innovation-driven medical devices backed by patents in India? An in-depth patent-based study was undertaken to draw inferences from their patent filing trends in India. There have been numerous initiatives in the past by industry bodies, consulting organisations, etc to study the gaps, market potential and opportunities in the Indian medical device sector; however, there is not much data available on patent filing trends in this sector, which is an important indicator of innovation and business interests of the companies.^{3–11}

It was, therefore felt, that a study, with respect to patent filing trends in the

INTRODUCTION

The Indian medical device sector, recognised as a sunrise sector by the Government of India, has huge market potential and is witnessing double-digit



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Table 1 Subclasses not included in the study

A61Q	Specific use of cosmetics or similar toilet preparations
A61P	Specific therapeutic activity of chemical compounds or medicinal preparations
A61D	Veterinary instruments, implements, tools or methods

medical device sector in India, is imperative to understand the sector more closely taking insights from the past and current trends in patent filing, identify major gaps in medical device innovation profile and unveil the scope for business opportunities. This paper provides a high-level overview of the overall patent filing trends in India for the past decade (2005–2014), identifies the countries and the key players which dominate the patent filings in India and reflects on patent filing trends across various technology sub-sectors. Such a study will be useful to understand the patent filing and innovation profile of the medical device sector in India and would assist the medical device stakeholders to draw inferences for evaluating the scope for innovation and opportunities for expansion.

EVALUATION STRATEGY/METHODOLOGY

For the purpose of this study, a well-planned strategy was devised. This was initiated by identifying the classes, subclasses and subgroups of the International Patent Classification (IPC) under which medical device patent applications are classified. A total of nine subclasses were identified under A61 from which only those subgroups that were relevant to medical devices were included in the study. The classes and subgroups related to methods, compositions, drugs and materials that fall under the purview of the IPC class A61 were not included in the study. Table 1 summarises the subclasses not included in the study.

To get a broader insight into the trends in patent filing, ten (10) year data (2005–2014) on patent applications filed in India was analysed, which also includes the period wherein India adopted product patent regime. Patents filed under the selected classes and subclasses pertaining to the medical device sector were then extracted using Thomson Innovation database using IPC and keyword-based search. The data was also verified for conformance with data from Indian patent office available in their annual reports. Patent

search was limited to the first filed patent applications as an indicator of the country of origin for innovation/commercialisation. Number of patents was then plotted against time, medical device sub-sectors, foreign applicants to have deeper insights on medical device innovation trends in the country, preferred domain in medical device innovation, major foreign applicants in India, etc. For the purpose of this study and for a better understanding, the subclasses have been given names based on the broad medical device sub-sector for patents filed under them, details given in table 2.

For the purpose of deeper analysis, the data was further segregated to identify the major assignees (based on applicant country) and the key countries (based on priority country code) filing medical device patent applications in India. It may be noted that in this study, the data for the year 2014 may not be able to reflect the accurate/exact patent filing trends due to the pending 18 month publication period.

RESULTS AND DISCUSSION

Overall patent filing trends

When the patent filing trends for the last 10 years (2005 to 2014) were analysed, it was observed that the number of patent filings in the medical device domain has roughly doubled with 1104 filings in 2013, as compared to 640 filings in 2005 (figure 1a,b). The patent publication trends as per figure 1b confirm this observation. Long-term trends in patent filing in the medical device sector in India show a broad and overall increase in patent filings during 2005–2014 with exception during 2008–2010. This slowdown was also reflected in general patent filing trends in India across all sectors and may be considered as the impact of economic recession around this time.¹² The year-wise percentage increase in patent filing varies considerably with a significant drop in 2008 and 2010 and a 22% increase in patent filings in 2006. Year 2013 witnessed maximum patent filings in the field of medical devices in the last 10 years. There was on an average 8% increase in the patent filings in the last decade. This indicates the gradual and consistent IP awareness and innovation or strategies of the foreign companies to capitalise on the growing medical device market in India. Progress in innovation in this sector

Table 2 Title used for specific classes of medical devices

IPC class	IPC class description	Subsector title
A61M	Devices for introducing media into or onto the body; devices for transducing body media or for taking media from the body, for example syringes, inhalators, suction or pumping devices, probes, catheter, dilators and the like	Material delivery and collection
A61B	Devices for diagnostic, surgical instruments, auscultation and aids for medical examination	Diagnostic and surgical
A61N	Device for electrotherapy, magnetotherapy, radiation therapy, ultrasound therapy example laser therapy device	Therapy assistance
A61F	Prostheses, splints, bandages, devices for fomentation and treatment or protection of the eyes or ears	Implants and dressing
A61C	Dentistry devices, for example dental prosthesis, artificial teeth and the like	Dentistry

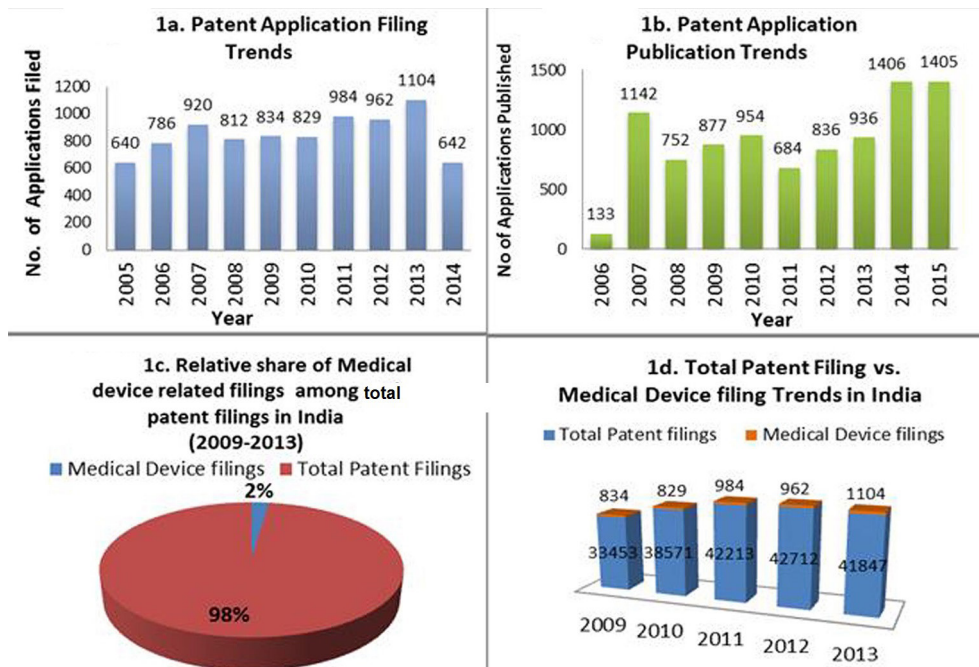


Figure 1 (a) Medical device patent application filing trends in India. The statistics shows slow yet steady increase in patent filings in India leading to almost doubling of the number of filings within the 10-year duration from 2005 to 2014. (b) Medical device patent application publication trends. The figure depicts a steady increase in publications over the 2005–2014 decade and supports the patent filing trends observed in (a) as innovations lead to patent filing and their publications thereafter. A surge in the publications during 2007 may be attributed to publication of applications filed under the mail box provision. (c) Relative share of medical device-related patent application filings against total patent filings during 2009–2013 period in India. (d) Total patent filing versus medical device filing trends in India. Patent filings in the medical device sector were only 2% of the total filings; however, a consistently increasing filing trend was observed.

is also supported by the success of some indigenous companies such as TTK Healthcare, Trivitron Healthcare, Aurolab and Appaswamy Associates, which have taken good advantage by developing innovative, indigenous low-cost medical devices. Some of the multi-national companies (MNCs) have been leveraging the Indian medical device market by tailoring their product portfolio as per Indian market needs. Transasia Biomedicals has developed an external fixator for the Indian market. Johnson & Johnson has developed a knee implant suitable for the Indian market as well as a reusable stapler for use in surgeries at price points, which are amenable to the Indian market. Roche Diagnostics has developed a screening device for cardiovascular diseases, which are suitable for use in rural settings.¹³ However, as this data represents overall patent applications in India including those filed by foreign applicants, it may not provide clear insights into indigenous innovation.

As per the annual report of the Indian Patent Office, during the last 5 years (2009–2013), a total of 2,03,509 patents were filed in India (figure 1c), out of which as per our analysis, 4713 patents (2% of the total filings) were filed in the medical device sector. Patent filings in this sector being only 2% of the total filings may be attributed to nascent medical device sector, lack of IP awareness and limited funding support for IP due diligence and/or

IP filing which is a cost-intensive process. Figure 1d shows trends in the total patent filings in India as compared with the number of patent application filings in the medical device sector in the last 5 years. The number of patent application filings in the medical device sector in India witnessed a consistent or increasing filing trend as compared with the total number of patent filings in India. It may be noted that total patent filings in the Indian Patent Office recorded a marginal decrease of around 2% in 2012–2013; however, the medical device sector witnessed around 14% increase in patent filings in this period indicating increasing IP awareness, innovation and market interests of applicants in this sector in India.

Global patent filing trends in India

Country-wise filings were then analysed to have a better understanding of the business interests of different countries in the Indian medical device market and also to evaluate patent applications filed by Indian applicants being a positive indicator of medical device innovation in India. In the last 10 years, around 80% of the patent applications filed in India in the medical device sector were filed by foreign institutes/companies. As per our analysis, patent applications in India by applicants of Indian origin in the medical device sector

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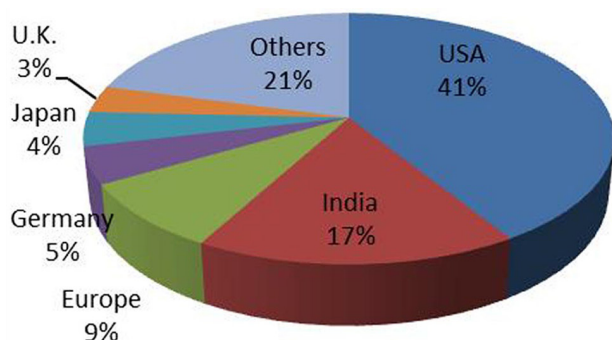


Figure 2 Country-wise patent filings in medical device sector in India for the period 2005–2014. The figure depicts dominant IP filings of about 80% of the total by foreign applicants.

accounted to only 17% minority share (figure 2). The Indian medical device sector is highly import dependent with 70%–75% of the demand being met through imports.¹⁴ The finding that about 80% of the patent applications filed in India are by foreign applicants correlates with the Indian medical device sector profile. Most of the foreign companies file patents in India for marketing medical devices in India but they do not have a manufacturing base in India.

It was further observed that nearly 60% of the patent applications filed by foreign applicants/assignees in India in the medical device sector were from four countries viz. USA (41%), Europe (9%), Germany (5%) and Japan (4%). USA, which is the global leader in medical device innovation, is also the dominant player in Indian patent filings, as is evident from 41% patent application filings by USA-based applicants/assignees in India in the last decade. As

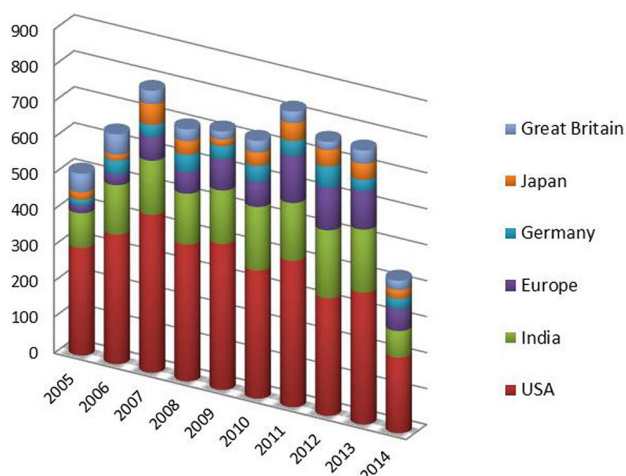


Figure 3 Top medical device patent filing year-wise trends of key countries. Declining trend in patenting activity is observed from USA since 2010, and similar trends were witnessed for Japan and Canada. However, European filings show a gradual rise in patent filing activity in India. The patent filings still remained dominated by foreign applicants, primarily USA, Japan, Europe and Canada.

evident from figure 3, during 2005–2014, India stood second to USA in patenting in the medical device sector. But this trend has changed in the last 5 years and USA is showing a relatively declining trend in patenting activity since 2010 and similar trends were witnessed for Japan and Canada; however, they still dominate patent filings in this sector in India. As per reports, multinational companies dominate the Indian medical device market in high-end innovation-driven products such as diagnostic equipment and instruments, which require stringent patent protection, and domestic players have a noticeable presence in the low-priced, high-volume segments based on off-patents or incremental innovations thereby contributing to less patents.¹⁴ This could be a reason for patent application dominance in India by USA, Europe and Japan applicants, which are the major suppliers of high-tech innovation-driven devices and equipment in India.

India, despite the growing domestic medical device manufacturing sector (growing at ~8% annually), has shown relatively less patenting activities in the past 10 years, as against other countries.

The foreign applicants/assignees in terms of patent filings in the medical device sector in the last 5 years (2010–2015) were then compared vis-à-vis 5 years post-implementation of product patent regime in India (2005–2009). We observed a decrease in the patent filings by US applicants/assignees by around 24%, UK by 40% in the years 2010–2015 vis-à-vis 2005–2009 and increased patent filings by European applicants by around 45% in the last 5 years as compared with earlier 5 year period (figure 4).

There was no change in percentage patent filings by Indian applicants within India, which remained constant to about 17% (figure 5a).

Top assignees for medical device patents in India

We then identified the top 10 applicants in India in terms of patent filings in the last decade (figure 6). Koninklijke Philips Electronics N.V. (Philips), Ethicon Endo-Surgery (Ethicon), a subsidiary of Johnson & Johnson, and Sanofi-Aventis Deutschland GmbH (Sanofi) are the top three applicants who have filed maximum patent applications in the medical device sector in India in the last decade. It is to be noted that the top 10 applicants in terms of patent filings remained foreign companies/multinationals who dominate the medical device market in India. Though Johnson & Johnson tops the global list of leading medical device companies, it is Philips (Dutch company) that tops the foreign applicant chart in India. The three main players in the medical device sector in the country are GE, Siemens and Philips. However, patent filing trends indicate that Philips seems to have a strategic plan for capturing the growing Indian medical device market.

Table 3 shows top three assignees/applicants from top five jurisdictions including from India, USA,

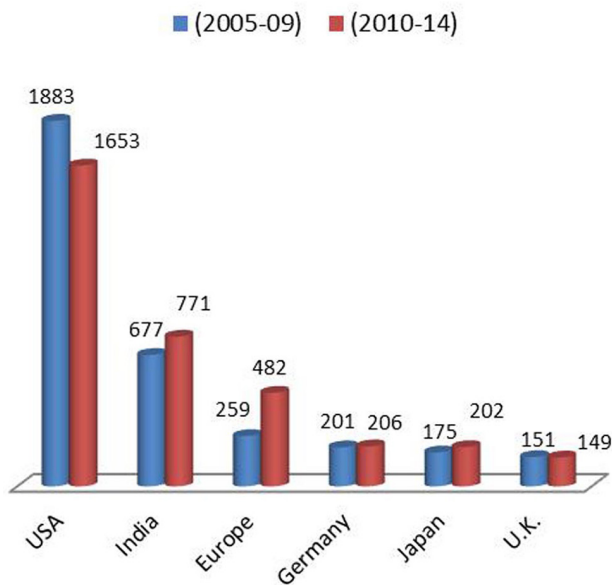


Figure 4 Comparative foreign patent filing trends in India for the period 2005–2009 vs 2010–2014. A decrease in the patent filings by US applicants/assignees was observed by around 24%, UK by 40% in the years 2010–2015 vis-à-vis 2005–2009 and increased patent filings by Europe applicants by around 45% in the last 5 years as compared with earlier 5 year period.

Europe, Germany and Japan, filing patent applications in India. The filing trends of top assignees/applicants in India for the last decade was also analysed as shown in figure 7. The IP filings by the top assignees show variable trends. Among the top assignees, Philips and Sanofi Aventis had filed maximum patent applications in the year 2011. Philips shows a steep rise in patent application filings with the exception in 2010. On the other hand, Ethicon shows a decline in patent filings. Sanofi Aventis emerged as a strong patent filing company since 2009 onwards. Becton Dickinson and Novo Nordisk maintained their IP filings to less than 30 applications annually. It can be inferred that Philips intends to increase its business in India; however, Johnson & Johnson seems to lose interest in the Indian medical device market. The decreasing trend in patent filing may also be attributed to focus on specific medical devices rather than diversified products.

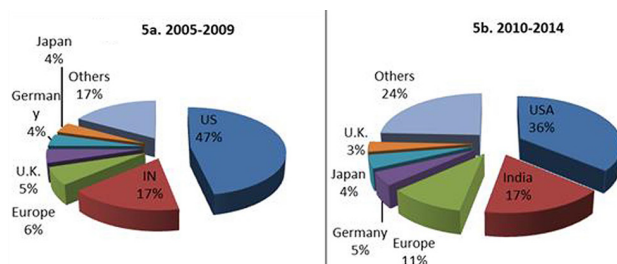


Figure 5 (a,b) Percentage share of patents in medical devices by different countries in India for the period 2005–2009 and 2010–2014, respectively.

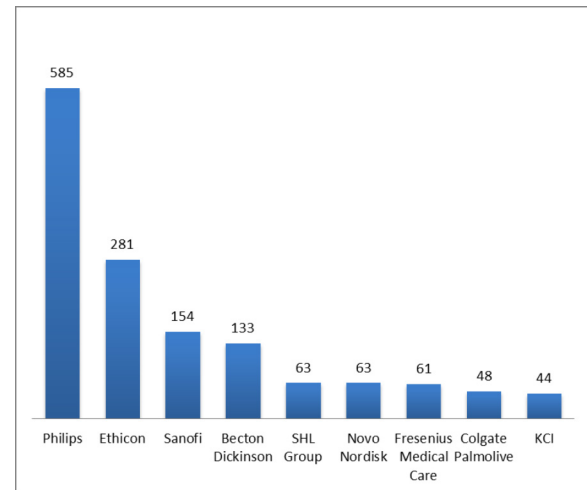


Figure 6 Top assignee/applicants based on patent application filings in India (2005–2014). The top 10 applicants are foreign companies/multinationals who dominate the medical device market in India.

Ethicon was very active in patent filings in India earlier between 2005 and 2009; however, 2010 onwards, Ethicon had significantly decreased patent filings in India in the medical device sector. Ethicon and Becton Dickinson and Company seem to revive their business interest in India as evident from the rising patent application filing trend in year 2013.

Domain (sub-sector) wise distribution of medical device patent applicants in India

We then evaluated the key medical device sub-sectors in which patent applications were filed to understand which sub-sectors are having prolific innovation and thereby also identify sub-sector-wise trends and gaps in innovation. We analysed that around 40% of patent application filings in India have been undertaken by Indian and foreign applicants in the field of medical delivery and collection devices (figure 8).

Table 3 Top assignees by country

USA	Philips Electronics N.V. (340) Ethicon Endo-Surgery (272) Becton Dickinson and Company (121)
India	Poly Medicure (39) Agrawal Pawan (27) Agarwal Zameer (27)
Europe	Philips Electronics N.V. (238) Sanofi-Aventis Deutschland GmbH (110) Novo Nordisk AS (44)
Germany	Fresenius Medical Care Deutschland GmbH Siemens (21) Robert Bosch GmbH (13)
Japan	Canon Kabushiki Kaisha (18) ACP Japan (17) Terumo Kabushiki Kaisha (16)

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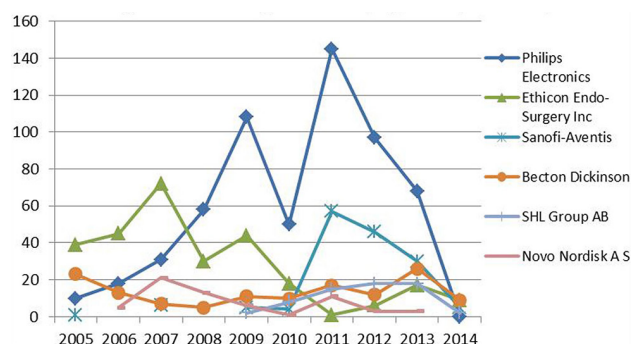


Figure 7 Patent filing trends of top applicants for the period 2005–2013 in India in the medical device sector. Philips, Sanofi Aventis, Becton Dickinson, Novo Nordisk, Ethicon and Siemens are some of the key medical device companies with active IP filings in this sector in India.

The patent applications filed in this domain included applications covering innovations in devices such as injections, medical syringes, cannulas, catheters, tubes, infusion devices, inhalers, pumping devices, blood collection sets, devices for local anaesthesia, hypothermia, etc. Data from Central Drugs Standard Control Organization (CDSCO), the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act, witnessed maximum registration in cardiology. CDSCO data suggests that overseas manufacturers are aggressively bringing their medical devices into the Indian market with cardiology on the top, followed by orthopaedic implants, vascular devices, syringes and needles, wound care and surgical dressings, ophthalmology, spine, urology and dental sector products.¹⁵ This correlates with the observation in the present study, with maximum filings in the medical delivery and collection devices. There has also been an increase in demand for dental and wound care

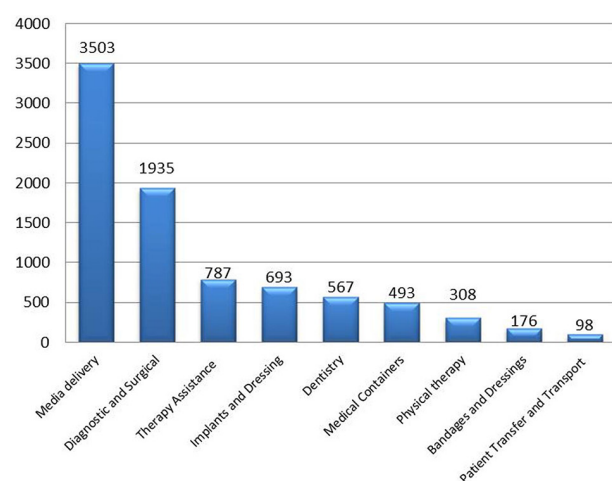


Figure 8 Patent applications filed in India in the various medical device sub-sectors in India. Maximum patent filings were observed in the field of medical delivery and collection devices, followed by patenting activity in the field of diagnostic and surgical instruments.

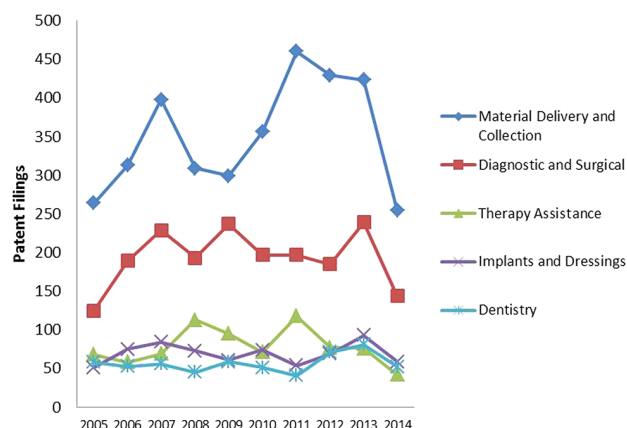


Figure 9 Domain-wise/sub-sector-wise patent filing trends.

products in the past 5 years. This contradiction may be attributed to regulation of only selected medical devices in India notified by the regulatory agencies. Most of the devices being unregulated need not be registered and therefore do not figure in CDSCO data.

This was followed by patenting activity in the field of diagnostic and surgical instruments. This group constituted around 22% of the total patent filing activities in this sector in India. It was observed that around 9% of the total patent filings in India were undertaken in the field of therapy assistance devices such as devices for electrotherapy, magnetotherapy, radiation therapy, ultrasound therapy, etc. This was followed by about 8% filings in the field of implants and dressings followed by about 6% patent filings in the field of dentistry.

Then we analysed sub-sector-wise patent filing trends of the top five medical device domains (sub-sectors) based on IP filings in the last 10 years. It was observed that patent application filings depicting medical device innovation and interest of foreign companies for working/commercialising in India has increased predominantly in all medical device sub-sectors from 2011 to 2012 onwards (figure 9). Maximum patent application filings in the field of material delivery and collection devices and therapy assistance devices were observed in the year 2011. While for diagnostic and surgical devices, implants and dressings and dentistry devices, maximum patent filings were observed in the year 2013. There is no striking variation in filing trends in these medical device sub-sectors. Maximum patent filings were observed in the material delivery sector throughout the decade (2005–2014) and minimum applications in the dentistry sector. One reason for higher filings in the material delivery and collection devices may be due to the diversity of medical products covered under this class including syringes, inhalators, suction or pumping devices, probes, catheters, dilators and the like. Another reason may be due to the less stringent regulatory norms for devices under this class. Assuming that the regulatory norms are a major

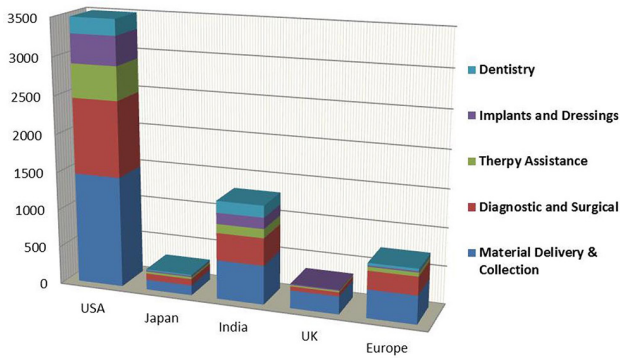


Figure 10 Percentage share of patents in medical device sub-sectors of top applicants in India.

hurdle for innovation and development of high-end medical devices in India, the stakeholder should take immediate steps for fully aligning India's medical device regulatory mechanism with that of global practices for promoting innovation of high-end medical devices in India. Appropriate policy measures are not only expected to boost country's US\$1 billion medical device exports but may also help multinational medical device firms that were hesitating to invest in India.

To understand medical device sub-sector-wise dominance of patent applications of different countries in India, we analysed the patent applications of the top countries in different device sub-sectors in India (figure 10). USA dominates almost all sub-sectors whether high-end, mid-range or simple technologies. It is also evident that the Indian medical device industry is also active in terms of patent filings in all sub-sectors, though at a small scale and particularly, in material delivery and collection devices, which comprises mostly disposable devices.

Table 4 summarises top three companies in each medical device sub-sector based on the number of patent application filings in India in the last decade. The data clearly

Material delivery and collection	Sanofi-Aventis Deutschland GmbH (146) Becton Dickinson and Company (127) Koninklijke Philips Electronics N.V. (117)
Diagnostics and surgical	Koninklijke Philips Electronics N.V. (321) Ethicon Endo-Surgery (215) Biosense Webster (30)
Therapeutic treatment	Koninklijke Philips Electronics N.V. (97) MEDTRONIC (17) Tomotherapy Incorporated (17)
Implants and dressings	Ethicon Endo-Surgery (32) KCI Licensing (16) BSN Medical (14)
Dentistry	Colgate-Palmolive Company (48) Koninklijke Philips Electronics N.V. (37) The Gillette Company (14)

indicates that few companies like Philips and Johnson & Johnson have diversified interest in the Indian medical device market whereas others have focused on specified sub-sectors such as implants or therapeutics.

CONCLUSIONS

This patent analysis provides key insights into patent filing, innovation trends, business interests and patenting activities in various technology sub-sectors of the medical device sector on a country-wise scale and highlights medical device companies across globe filing patent applications in India. As this study takes into account total filings in India including foreign filings, it reflects how the domestic market segment is positioned against the foreign segment in the Indian medical device market.

In this study, an increasing trend in the patent application filings in India was observed. An increasing trend in patent filing in the last decade and particularly in 2013–2014 may be taken as a positive indicator of increasing IP awareness in the country. The increased IP awareness and filings in this sector may also be attributed to the public private partnership schemes of the Government of India for supporting innovative ideas/technologies, for example, Biotech Industry Partnership Programme, Small Business Innovation Research Initiative, Biotechnology Ignition Grant Schemes, etc. Such funding schemes give weightage to those technologies that are focused on strong IP creation and have the potential to make the Indian medical device industry globally competitive. In these schemes, the technologies making the Indian industry globally competitive and focused on IP creation are given significant weightage for funding decisions. Such schemes serve as a major incentive for Indian research institutes and industries to innovate and file patent applications for attracting government funding. Other recent initiatives by the government including Make in India and release of National Medical Device Policy envisaging medical device regulation through autonomous National Medical Device Authority with an objective to make India a global hub for production and innovation in medical devices, may also have also contributed to positive environment in the country supporting innovation.¹⁶

A surge in this trend is expected in the coming years, considering the recent policy initiatives of the Government of India such as 100% FDI, support to start-ups through initiatives such as Start-up India in IP filings, etc. The medical device and equipment industry contributes to only 6% of India's US\$40 billion healthcare sector and about 2% to the total patent filings in India and therefore has a huge potential for growth through innovation, indigenous development or through partnerships with global Industry leaders.

India is one of the top 20 medical device markets globally and is the fourth largest in Asia after Japan,

China and South Korea.¹³ Indian medical device industry is highly import dependent wherein the requirements of high-end innovative products especially diagnostic equipments, implants and instruments are met by imports from USA, Europe, Japan, etc, while the domestic players have a noticeable presence in the low-price, high-volume segments. Lack of regulatory restrictions, with only 14 out of about 2000 medical devices being notified under The Drugs and Cosmetics Act, inverted duty structure favouring import of finished goods rather than raw materials/components and availability of low-cost labour are some key factors that attract MNCs to penetrate and dominate the Indian markets with imported products.

Patent filing trends in India by foreign applicants/assignees with around 40% filings by USA-based applicants and about 20% by Europe, Germany and Japan indicate that foreign companies with a well-devised IP strategy and market competitiveness are leveraging on this highly untapped market opportunity. One major example is Philips Electronics India which came up as the top applicant in terms of patent filings in the medical device sector in India. Philips has been firming up plans to make India a global production hub. In 2008, Philips made two healthcare acquisitions in India—Medtronics and Alpha X-Ray Technologies. By virtue of this, Philips acquired a footprint in manufacturing of medical equipment, with five plants that specialise in imaging devices and X-ray machines. The acquisitions also enabled Philips access to critical technology to develop value-segment products.¹⁷ The patent application filing trends observed in the present study support their IP strategy. Nearly all of the top 40 global medical device companies today have a presence in India and noticeable IP application base as can be seen in table 4. With changing economic and regulatory environment, the medical device industry is expected to grow significantly, fueled by a range of factors in the country. The share of multinational firms is around 40%–50% in consumables, instruments and appliances and 80%–90% in all other subsegments.¹⁸ In this study, we also noted that the applicants from multinational firms are having dominant IP filing share in high-end equipments and devices.

USA is known to be a global leader in medical devices with 17 US firms capturing half of the sales in the world market.¹⁹ It may be further noted that considering patenting activity as an indicator of market competitiveness, more than a quarter of the US patents are held by start-up companies. To raise competitiveness of the Indian medical device firms, India can take lessons from USA which provides a complete ecosystem for supporting innovation to commercialisation.

To tap the unmet market opportunity and gain market competitiveness, medical device manufacturers need to invest substantially in R&D and shift their innovation strategies from incremental innovation to breakthrough innovation. Increasing the number of innovation-based start-ups/medical device companies can also boost the medical device sector while adopting well-devised IP strategies.

To conclude, there is an immense potential and opportunity for the medical device sector to innovate across the value chain, to serve Indian and foreign consumers, and unlock the value of the Indian medical device market.

Contributors SM and YV contributed equally in the data extraction, analysis and interpretation. SM and YV contributed and approved the final version of the paper and are accountable for it.

Competing interests None declared.

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