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Finding Entrepreneurial Opportunities in India's Medical Device Sector through Patent Landscape Analysis

Anindya Roy Chowdhury and Purushotham Hanumanthu†

Centre for Intellectual Property Rights, Andhra University, Visakhapatnam - 530 003, Andhra Pradesh, India

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The present study explores the opportunities for entrepreneurs in the medical device sector in India using a systematic patent landscape analysis. Currently, India imports about 80 percent of its requirement of medical devices. Identifying entrepreneurial opportunities and promotingentrepreneurship is therefore an essential factor for India to become "*Atmanirbhar'' or self-reliant*in the medical device sector. There is an urgent need for entrepreneurship and innovation in this field.This study uses, for the first time, the patent landscaping as a tool to explore the potential entrepreneurial opportunities in medical devices. It further delves into themedical device market status in India, patentability and regulatory issues, government initiatives, etc.- giving a snapshot of the promising areasof medical devices for entrepreneurs to venture into.

Keywords: Entrepreneur, Entrepreneurship, Medical Device, Medical Technology, Patent, Landscape, LENS Database, Patent Data Retrieval Method, ipIndia Database, Startups IP Protection

Entrepreneurship is an important factor for economic stabilization of any country.[1] In the era of knowledge-based economy today, every country is actively working towards sci-tech resources and increased R&D innovation.[2] Government of India has also been facilitating various schemes and policies to encourage entrepreneurships. The medical device sector has grown significantly in the last decade, especially, in the era of COVID 19 as availability of reliable and affordable medical devices has become a key strategic management tool across the globe.

According to the World Health Organization, a "Medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings," for medical purposes.[3] Medical devices are essential tools for attaining global health stability. One of the essential components of the United Nations Sustainable Development Goals is to provide access to effective, innovative, and affordable medical devices, ensure healthy lives, and promote well-being for all at all ages.[4] Lack of access to quality and affordable medical devices in low and middle-income creates global health inequalities. The medical device industry requires constant innovation to deliver high quality and affordable devices. The COVID-19 pandemic showed the weakness in India's healthcare systems.Moreover, the medical device sector in India is mostly dependent on import. It is therefore important to understand what the technology areas where India needs to improve are.

R&D is the key for making an economy stronger particularly in medical devices. Patents are important in the area of biomedical engineering as it paves the road for competitive advantage. A patent, a type of intellectual property right, gives the owner the legal right to prevent third parties from exploiting his/her invention without authorization.[5] The owner can enjoy the patent right for a maximum period of 20 years subject to the payment of annual maintenance fee. Patent rights are territorial. One can obtain a patent only in the country where the application has been granted. Therefore, every country has their own Patent Law to deal with the practice. In addition, certain kinds of subject matters are not patentable. For example, in India, a medical process is not patentable.[6] However, surgical techniques, methods of medical treatment or diagnosis are patentable in the USA and Australia. In India, one can get a patent for a medical device that will carry out the process. It is therefore important to understand the worldwide patenting scenario and find out thegiants in the medical device sector. Studying the patenting trends in this sector will provide an insight into the research

†Corresponding author: Email: iprchair@andhrauniversity.edu.in

and development in different countries over time. Previous study has found out the patenting trend in medical technologies with an emphasis on Ireland.[7] Since this sector evolves fast, we are interested to understand the current scenario in medical device patents to help entrepreneurs explore the most promising opportunities in India.

The current study aims to explore entrepreneurial opportunities in the medical device sector in India. The study delves into the analysis of published patent data on medical devices to understand the current global scenario of medical device research. A special emphasis has been given on the Indian scenario including the medical device market in India and patentability criteria. The analysismay help entrepreneurs to understand important areas to venture. The primary methodology used to achieve the objective of the study is patent data search and analysis.

Patent Data Retrieval Method

Generally, an analysis of patent data over the last five years gives an overall idea about the technology trend. Therefore, the search has been carried out during 1st February 2016 to 8th February 2021.

LENS Database

At first, patent search has been conducted on the LENS Patent database by developing a structured keywords search strategy. LENS is an online patent search and analysis platform provided by an independent, international non-profit organization Cambia dedicated to democratizing innovation.[8] It has a collection of over 123.5 million patent records over 105 jurisdictions and 67.5 million patent families. At the time of data retrieval, the database was last updated on 28th January 2021. The query string used is [(Title: medical AND Claims: device) and Filters: Publication Date = (2016-02-01 - 2021-02-01)]. It is to be noted that while searching the patent database with this query string, the database will retrieve all the documents that have used the term 'medical' in their title. Claims are the legal fence around the invention. What is not claimed in an invention, remains unclaimed. Therefore, when a search has been performed with the query string using the Boolean operator 'AND', the database will also search the term 'device' used in claims, and return the documents that have used both 'medical' in their title and 'device' in their claim.Thus, it is confirmed that the resulting patent documents are on medical devices and not on medical methods. A total of 20,708 patents/patent applications have been obtained. After grouping down the patent families, the size has been collapsed to 10,943 documents.It is to be noted that using the same search parameters and limiting the jurisdiction to 'India', we could not find any patent/patent application in LENS database. Therefore, to fetch the medical device patents filed in India, we moved to the Indian Patent Office database ipIndia.

Indian Patent Office database ipIndia

The Indian Patent Office database ipIndia has been used to find the patent applications filed at Indian Patent Office. This database provides options to search for bibliography data, e.g., title, application number, classification codes, etc. We searched the IpIndia database with the classification codes obtained from LENS. However, we could not find anything suitable. Therefore, the IPC codes database maintained by WIPO was searched to find a suitable IPC code that may be used to file patents on medical devices in India. It was found that the IPC code 'A61' is used for applications in 'Medical or Veterinary Science; Hygiene'. Therefore, we searched each subcodes under A61 (from A61B to A61Q) in ipIndia database to find relevant patents.[9]

Patent Landscape Analysis

Worldwide Patent Landscape of Medical Devices

An average of 4000 patent applications is being published yearly (Fig. 1). Among these documents, the ratio between published and granted patent is 4:3. The drooping in 2021 is due to the fact that it is only through 2 months in 2021.

The highest number of patents have been filed in the USA[Figure 2 (a)]. The next in line are the patent applications filed at World Intellectual Property Organization (WIPO) through the PCT route. Patent

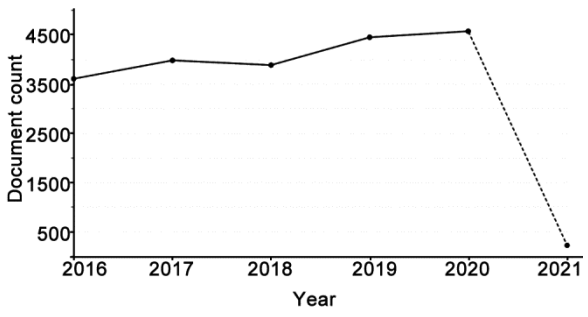

Fig. 1 — Number of patent applications published for medical device inventions

Offices worldwide use the patent classification codes to tag the applications under relevant subject area. There are two most used classification systems in the world, viz., Cooperative Patent Classification (CPC) and International Patent Classification (IPC). CPC is a modified version of the IPC and is managed by the European Patent Office and the US Patent and Trademark Office. Figure 2 (b) shows the top CPC codes and the corresponding subject matters for the patent/patent applications under study. Figure 3 shows the top applicants in this field. Medtronic is an American domiciled medical device company that generates the majority of its profits from the US healthcare system but its headquarter is located in the Republic of Ireland.[10]

Among the top 10 patent applicants, 6 are US-based organizations.

Figure 4 shows the top technology areas from the top two applicants.[11] Medtronic has been filing an average of 250 patent applications per year for assistive care devices. They are also filing a small number of applications for wearable medical devices.

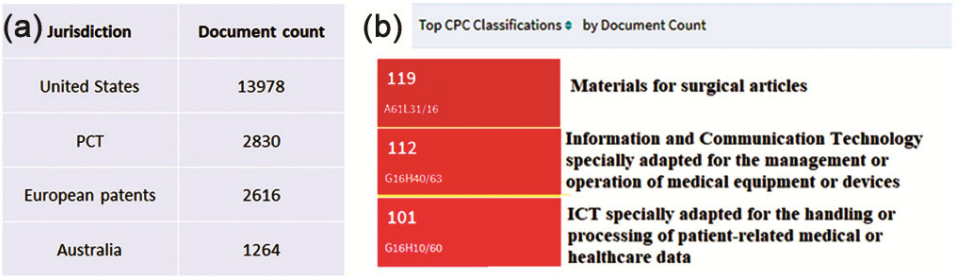

Fig. 2 — (a) Document published by different jurisdiction & (b) Top CPC codes used

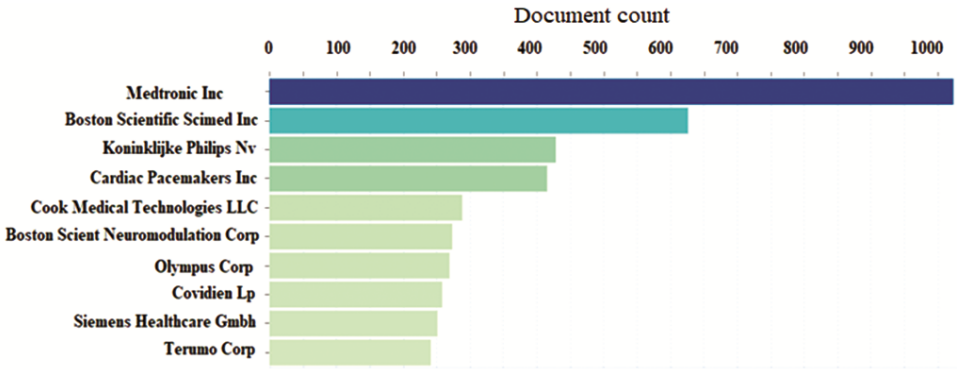

Fig. 3 — Top applicants in the medical field

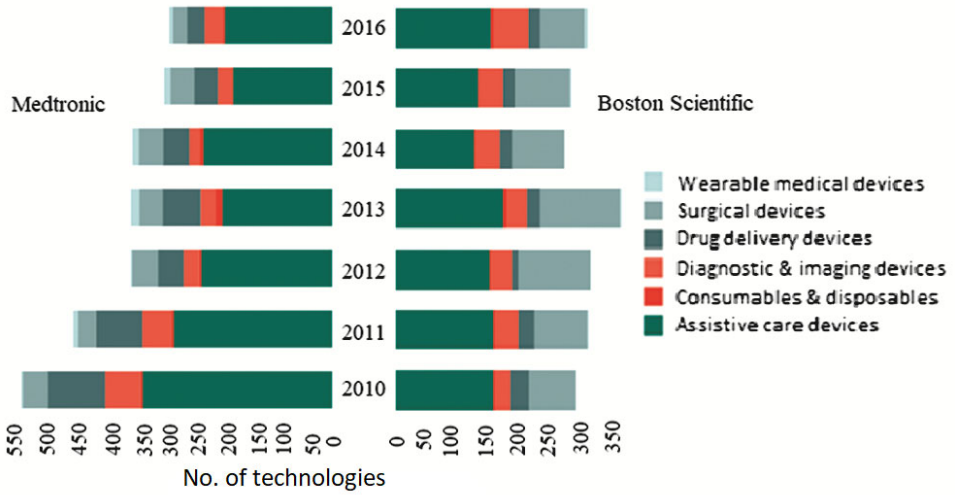

Fig. 4 — Top technology areas from the top two applicants namely, Medtronic and Boston Scientific

Boston Scientific files higher number of applications for surgical devices than Medtronic. Not much wearable medical devices can be seen for Boston Scientific. The top inventors are shown in the Figure 5. Further, search found that Keith Maile is an engineer working in Boston Scientific.

However, the scenario of the top 10 medical device companies of 2020, is a bit different.[12] It is interesting to see that the top patent applicants from Figure 3 are not sequentially represented in Figure 6.

Medtronic maintains its place at the top. However, the top companies in Figure 6 are the highest revenue generating companies. The revenue generated by a company is not directly proportional to the patent applications filed/published by it. It depends upon the amount of revenue it can generate by selling the medical devices or licensing out its patents or licensing in some of the patents filed by other companies. Basically, the revenue generated by a company from its patents will depend upon the quality of the patent not quantity. It also depends on commercialization and Technology Transfer Management. Interestingly, WIPO has shown that

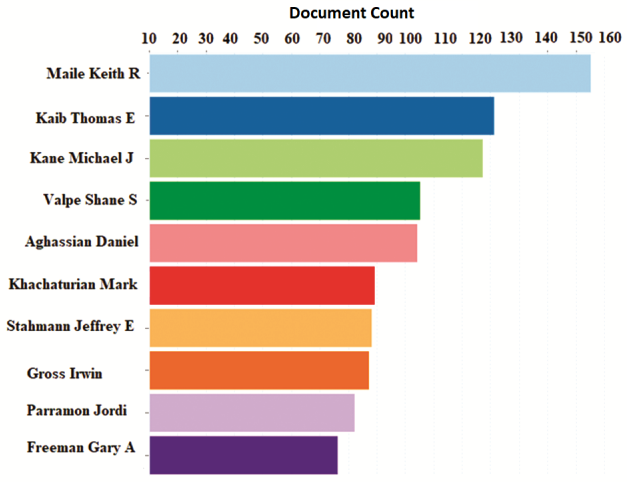

Fig. 5 — Top inventors

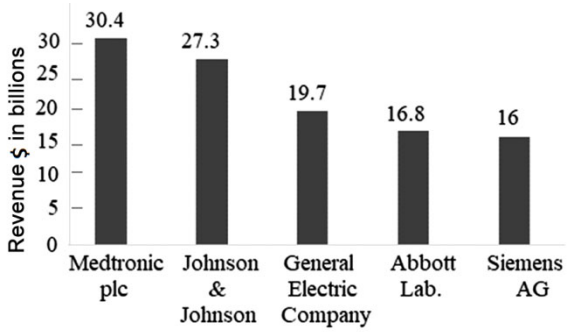

Fig. 6 — Top medical device companies in 2020

only 5-7% of all granted patents are ultimately commercialized.[13]

Medical Device Patenting in India

It is to be noted that using the same search parameters as described in the 'patent data retrieval method' section and limiting the jurisdiction to 'India', no patent/patent application was found in LENS database. Therefore, the search was performed on the Indian Patent Office database ipIndia. The ipIndia database does not provide keyword search options like LENS. Rather, it provides search options for bibliographic data. The classification codes obtained from Figure 2 (b) were used in Indian Patent Office's database. However, it did not result in anything suitable. Then, the IPC database maintained by WIPO was searched to find a suitable IPC code that may be used to file patents in India.[14] The IPC code 'A61' is used for applications in 'Medical or Veterinary Science; Hygiene'. Each subcode under A61 (from A61B to A61Q) was searched in ipIndia database to find relevant patents. Table 1 gives the titles of the patent applications that are published from 1st February 2016 to 1st February 2021 categorized under those IPC codes.

Although, none of these patents have yet been granted, it can be seen the number of patent applications filed by Indian applicants are increasing. Currently, foreign players dominate the medical device market in India.[15] It is probably due to the lack of IP awareness in India. Moreover, the foreign players have realised that India has huge market because of its population and potential.

Patentability Issues in India

Section 3(i) of the Indian Patents Act, 1970 prohibits the patenting of medical processes. However, there is no bar on patenting medical devices. Section 3(f) prohibits patenting inventions that are a mere arrangement or rearrangement of known devices, each functioning independently with their functions being already known. Thus, it is necessary to show that the medical device is more than a mere workshop improvement. India has one of the largest higher education systems in India.[16] There are around 200 engineering colleges in Indiaoffering courses on biomedical engineering. It is expected that soon we can see some improvements in the patent filing.

Medical Device Industry in India

The medical device industry of a country is influenced by several factors likecountry's

Table 1— Indian patents published from 1st February 2016 to 1st February 2021

IPC code	Title of the invention	Applicant	Inventor's State/Country	Filing year
A61B	A device for detection of kidney function	University of Petroleum and Energy Studies	Uttarakhand, India	2019
	Nutrition calculator and health condition based nutrient mapping for cooked food	Amity University	Uttar Pradesh, India	2018
	System and method for detecting retinopathy	Cognizant Technology Solutions India Pvt. Ltd.	Tamil Nadu, India	2017
	A kit for remote monitoring of cupping therapy and uses thereof	Dr. Rashid Hussain	Rajasthan, India	2016
	A device for automated diagnosis of epilepsy	IIT Delhi	Delhi, India	2016
	Salivary fluoride detection device and process of detection thereof	CSIR	West Bengal, India	2016
	Novel acetabular compression plate with dual cortical fixation and method of fixing thereof	Ramesh Kumar Sen	Punjab, India	2016
	Health tech machine	PikarHealthtechPvt.Ltd.	HR, India	2016
	Cancer detection system	AIIMS	Delhi, India	2016
	Infusion alarm system	GoverdhanDutt Puri	Punjab, India	2016
	A novel device for measuring pressure pulses based on applanation tonometry	AIIMS, IIT Delhi	Delhi, India	2016
	An improved procedure and a portable apparatus for diagnosis of seizures	Raja Aditya Kadambi	Karnataka, India	2016
	Device to predict past, present and futuristic human aura/emotion *via* bio-feedback	Chitkara University	Himachal Pradesh, India	2016
A61C	VIBRASP - a novel irrigant delivery, agitation and aspiration system	Dr.Tejesh Gupta Garlapati	Andhra Pradesh, India	2016
A61F	A prosthetic device and a method of operating the same	Sharda University	Uttar Pradesh, India	2019
	Spect-v for vision to the blind	Mr. Mukund Brhmarakshas, Vrinda Rajesh Bandishte	Maharashtra, India	2016
	A handheld control scanning aided reader-cum organizer for visually impaired	CSIR	Punjab, India	2016
	Orthopedic metallic implant for sustained drug release	IIT Roorkee	Uttarakhand, India	2017
A61H	Method and system for health monitoring and fault signature identification	TCS	Tamil Nadu, India	2017
A61J	Method and apparatus for contamination-free transfer of a hazardous drug	Plastmed Ltd.	Israel	2018
A61M	Fine needle aspiration syringe system	Dr. Ajeet Kumar Prajapati	Uttar Pradesh, India	2018
	Improved intravenous infusion set	Poly Medicure Limited	Haryana, India	2018
	Urea pump and urea supply system	Sejong Ind. Co. Ltd.	Republic of Korea	2018
A61N	An antenna for wireless power transfer in a cochlear implant	HCL Technologies Ltd.	Uttar Pradesh, India	2019

population, GDP, overall expenditure in healthcare, population's disease pattern, etc.[17]

Table 2 provides a comparison of the population and medical device market status in India, USA, and China. Among all the BRICS countries, India has the lowest per capital spend on medical devices.[15]India is the fourth largest medical device market in Asia after Japan, China and South Korea; and stands 20th in the world.[18] The medical device industry in India has both large multinationals and medium enterprises (SMEs).

Table 2 — Comparison of the population and medical device market status in 2020

	India	United States	China
Population	1,380,004,385	331,002,651	1,439,323,776
Size of medical device market ($)	11 billion	176.7 billion	12.5 billion

The market size in India is growing at 28% per annum and is expected to reach $11.86 billion in 2021-22and 50 billion in 2025.[18,19] Challenges for medical devices are custom duty, complex regulatory

Table 3 — List of initiatives by Government of India for medical device manufacturing

Area	Benefit
Domestic manufacturing	To boost domestic manufacturing of bulk drug and medical devices, GoI announced $2 billion
	Special incentives to first five manufacturers expressing interest for bulk production of raw materials
	Declared it as infrastructure industry for easy finance
	Viability gap funding with riders to generate jobs and boost export
Production-linked incentive	GoI announced $500 million of cumulative incentive scheme for device manufacturers
	Incentives to be provided at 5% of incremental sales for 6 years
	Category of manufacturer covered i) cancer care/radiotherapy, aesthetic & cardio-respiratory, radiology &nuclear medicine, all implants like cochlear and pacemaker
Medical device parks	GoI allocated $57 million for common infrastructure facilities in 4 medical device parks

approval processes. The medical tourism and luxury healthcare markets in India create huge demand for high-tech medical equipment.[20] Because of the huge gap between demand and supply of medical devices, there is an excellent opportunity for manufacturing devices in India. To strengthen the medical devices sector and boost the market, the Government of India has started various initiatives (Table 3) including enhanced focus on R&D and automatic 100% Foreign Direct Investment (FDI) for medical devices.[21]

Currently, India has about 80% import dependency on medical devices, while exports are at US$2.1 billion in 2019 and is expected to reach US$10 billion in 2025.[15] Among the imported devices, 30% are imported from the USA alone.[22] Figure 7 shows the top five countries from where India imports most of its medical devices, and the year-on-year percentage growth rate of import from those countries.[23] Figure 8 further shows the import and export trend in India till 2015-2016 and segment wise import trend.[24,25] India is importing stethoscope, glucometers to MRI and CITI scan machines. To increase export of medical devices in the country, the Indian Ministry of Health and Family Welfare and Central Drugs Standard Control Organisation took various steps including implementing a draft guidance on good manufacturing practices and facility requirements, system for export labelling, clinical evaluation and adverse reporting clarification.

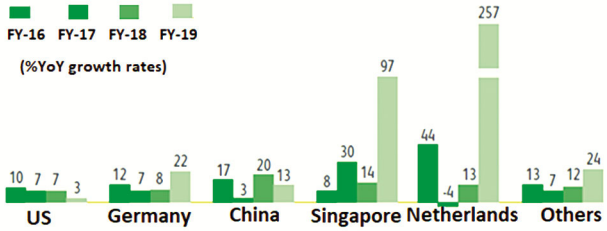

Fig. 7 — Top five medical device import countries Year-on-year percentage growth rates of import from these countries by India

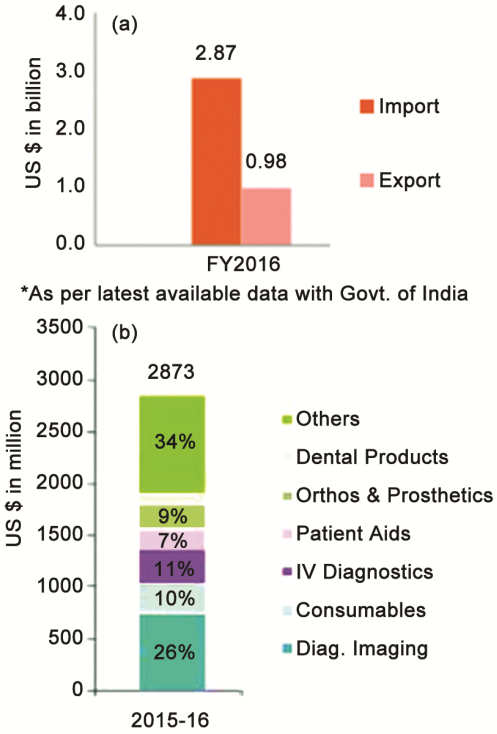

Fig. 8 — (a) Medical device import and export trend in 2016 & (b) Categories of medical device technologies imported

Atmanirbharta in MedTech Industry

To be *Atmanirbhar* in MedTech, we should be able to innovate in India and design in India.Three decades ago, the pharmaceutical industry in India was completely dependent on import. Now, India has a prominent presence in global pharmaceuticals.We can expect the same to happen in medical device sector if we implement reforms. With constant innovation and research work, medical devices will become more affordable and accessible.

The upcoming MedTech devices will be associated with AI robots. One can file patent in India or register the design of a medical device. Currently, only low-end medical devices are being manufactured in India; 90% of the high-end devices are being imported.[26] Figure 9 shows the medical device manufacturing

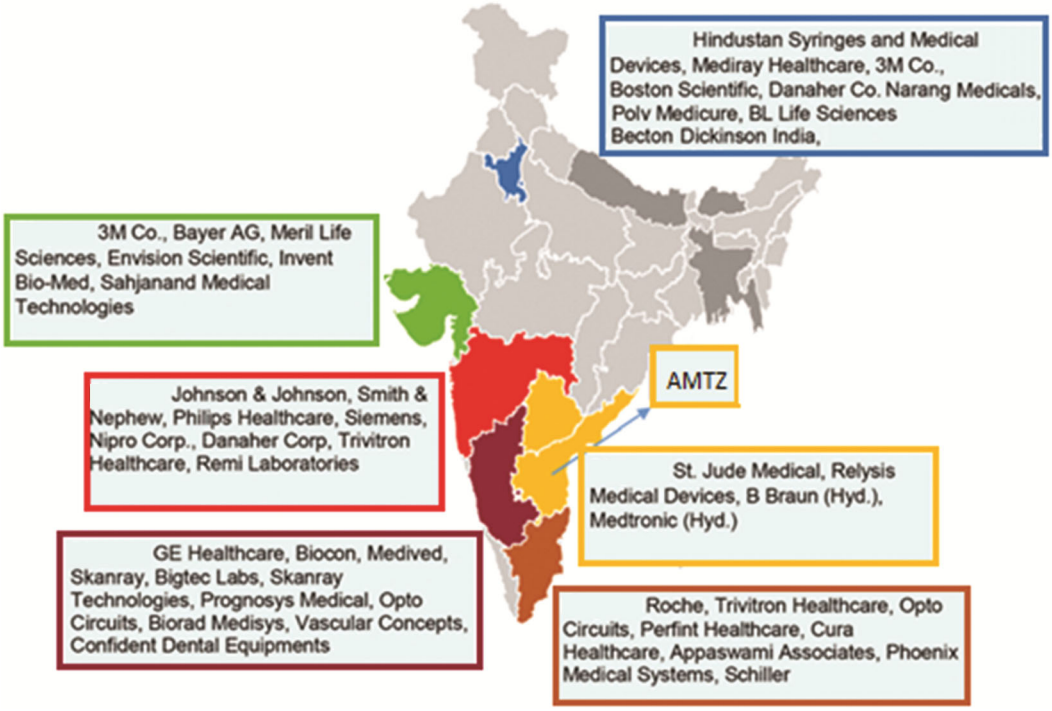

Fig. 9 — Medical device manufacturing clusters in India

clusters in India.[25] Top players from a state are shown in the same-colored box. Recently, Medtronic has announced investments of Rs 1200 crore over five years in its Hyderabad R&D centre, and *Siemens Healthineers* is investing Rs 1,300 crore in India by setting up an innovation hub in Bengaluru.[27,28] India is now waking up to the call for Make in India, Design in India and "Incubate in India". Several notable startups and SMEs working on innovative solutions or already made an impact in Indian context. The COVID-19 pandemic has presented a unique opportunity for India to emerge as the new manufacturing hub of the world. With India now taking centre stage in the fight against COVID by way of undertaking world's largest Covid-19 vaccination implementation program and supplying vaccine to about 40 countries in the world, India's MedTech sector is slated for a global presence which positions India as a global hub for medical devices. Post-COVID, the number of patent applications filed for ventilators has been doubled.[29,30]

The government is focusing on international harmonization of medical devices, policy framework, quality management system, and a creative conducive system for the manufacturer to make India a medical-device hub in the next decade. Table 3 lists the Govt. initiatives for manufacturers.[24]

Changes in Medical Device Regulation

A company must comply with the rules of the Drugs and Cosmetic Act of 1940, to legally register or import medical devices. The Medical Device Rule has been amended in 2020. According to the new rule, an appropriate license is required for newly notified devices. For Class A (low risk devices) and Class B (low to medium risk devices) the deadline to obtain the license is 11 August 2022 and for Class C (medium to high-risk devices) and Class D (high risk devices) is 11 August 2023.[31] Any violation of this Rule will result in criminal prosecution resulting in imprisonment and fine. In addition, any stock of medical device that is sold without registration or license can also be confiscated. There are 37 categories of medical devices that are already regulated or notified before the amendment, and therefore, it is not required to obtain registration for them.[31] These are Disposable Hypodermic Syringes, Needles, Perfusion set, cardiac stents, catheters, heart valves, Bone cements etc.

MedTech Innovation Status in Andhra Pradesh

Andhra Pradesh MedTech Zone Limited (AMTZ) is the world's first integrated Medical Device Manufacturing Ecosystem situated in Visakhapatnam.[32] It is also the first medical device

park in India. The objective behind such parks is to reduce the manufacturing cost and import dependencies. The facilities include Electro Magnetic Interference/Electro Magnetic Compatibility Testing Lab, Biomaterial testing Lab, 3D Design, Prototyping and Rapid Tooling facility, Gamma Irradiation Lab, X-Ray/CT Scan Tube Manufacturing, and a novelty assessment certificate.There are two incubator systems, viz., *MediValley* and *BioValley*. The *MediValley* incubator is funded by *Niti Ayog* through *Atal Innovation Mission*.It is the only facility in the country focused on medical technology starting from ideation, prototyping, testing, validation, manufacturing, and market access. The *BioValley* incubator nurtures entrepreneurship for scaling technologies is funded by DBT and AMTZ. The office of controller general of Patents, Design, and Trademark is also working with Centre for Patents in Biomedical Engineering toexamine all biomedical patent application with the help of biomedical scientists and engineers at Kalam Institute of Health Technology. Also, Messe Frankfurt India will launch Medical Device Innovation Summit in this year.[33]

Opportunities for Entrepreneurs

As discussed, India has a huge dependency on imports for medical devices. It is therefore, an excellent opportunity for Indian entrepreneurs and investors to venture into the medical device sector.

High-demand Technology Areas for Entrepreneurs

Figure 4 show that the largest number of patent applications from the top companies is from assistive care devices. However, that largely depends upon the country-wise requirement. The medical device market requirement in India is not necessarily the same as in the USA. According to a study conducted by *Deloitte* and *Nathealth*, the Indian Medical Device Industryhas four major segments, *viz*., consumables and implants, diagnostic imaging, instruments & appliances, and patient aids. Among these, the largest segment is instruments and appliances where ophthalmic, dental care, and therapeutic devices are in high demand.[34]Therefore, there is a huge opportunity for the entrepreneurs. On the other hand, India mostly imports the diagnostic and imaging devices (Fig. 8b). According to the statistical data from trade sources and industry, the most promising sub-sectors of medical equipment sector in India are: i) Medical Infrastructure, ii) Medical and Surgical Instruments, iii) Medical Imaging, iv) Electro Medical Equipment, v) Orthopedic and Prosthetic Appliances, vi) Cancer Diagnostics, vii) Ophthalmic Instruments and Appliances, viii) Orthodontic Equipment and Dental Implants, and ix) Point of Care Testing (POCT) Diagnostic devices.[22] Therefore, entrepreneurs can explore the above-said areas and keep in track of the patent/patent applications filed in India. Having filed a patent for a medical device in India will give the entrepreneur a competitive advantage over others.

Govt Initiatives for Entrepreneurship

The Govt of India has started a scheme for facilitating Startups IP Protection (SIPP).[35] It provides fast-track filingof Patents, Trademarks and Designs and expedited examination of patents filed by Startups. Such programs reduce time taken to obtain a patent. Startups are also eligible for 80% rebate in patent filing fees and 50% rebate in trademark filing fees. Govt of India is also facilitating women inventors, entrepreneurs, and MSMEs. MSMEs can file patent application in India at a discounted rate like Startups.

Initiatives for Women Entrepreneurs

Startup India is strengthening the women entrepreneurship ecosystem through policies and initiatives.[36] There are several active programs for women entrepreneurs like Lead HERs, Virtual Incubation Program, etc. Department of Science and Technology supports the Women Entrepreneurship and Empowerment Foundation with grants to women entrepreneurs.[37] A woman entrepreneur working in the area of Life Science/ Biotech/Pharma can apply for the WInER Award (Women In Entrepreneurial Research) by the Biotechnology Industry Research Assistance Council (BIRAC).[38] Indian Institute of Management at Bangalore and Visakhapatnam have also launched the Women Startup Program.[39] The funding opportunities specific for women entrepreneurs include i) BharatiyaMahila Bank Business Loan, ii) Mudra Yojana Scheme, iii) Dena Shakti Scheme, iv) Udyogini Scheme, v) Cent Kalyani Scheme, vi) MahilaUdyam Nidhi Scheme, and vii) Women Entrepreneurship Platform (WEP).[40] The WEP initiative by NITI Aayog offers support in incubation and acceleration, entrepreneurship skilling, marketing, funding and finance, compliances, and social entrepreneurship. Indian Patent Office is providing expedited examination route for women inventors in India. If the applicant is a natural person and one of them is a woman, then the patent application can opt for expedited examination so that a patent can be obtained faster.

Funding Opportunities for Entrepreneurs

An *Atmanirbhar Bharat* will put an emphasis on fostering entrepreneurship, nurturing innovation and creating an ecosystem for symbiotic rural-urban development as India recovers from COVID.[41]There are various funding opportunities available for entrepreneurs to start their journeys, *viz*., Startup India Initiative, Startup India Seed fund, BIRAC Seed fund, ASPIRE, MUDRA bank, ATAL Innovation Mission, NewGen Innovation and Entrepreneurship Development Centre (NewGen IEDC), Ministry of Skill Development and Entrepreneurship, PRISM'sTechnopreneur Promotion Program (TePP), Multiplier Grants Scheme (MGS), Zone Startups, Amity Innovation Incubator, Amrita TBI, etc.

Conclusion

Entrepreneurship is an important factor for economic development of any country. Since, India spends a large amount importing medical devices; wanted to find out the promising technology areas in this sector for entrepreneurial opportunities. The worldwide patenting scenario shows that the United States is the global hub of medical device R&D and innovation. Around 30% of medical devices imported into India are from the USA. Entrepreneurs in India are therefore encouraged to explore the field of medical device.The Govt of India is taking several initiatives to strengthen the medical device sector also. The Govt should also provide tax holiday for R&D-based companies to attract more investments and R&D infrastructure, and financial incentive for protection of IP internationally so that the Make-in-India dream can be true. The current study has explored the patent landscape of medical devices, technology areas that are in high demand in India, and the technologies that India is importing. Entrepreneurs therefore can develop technologies in those key areas and also own the technology by filing patent.With proper support from the Government and entrepreneurial ventures, it can be expected that in the near futureIndia will emerge as a medical device manufacturing hub.

References

1 Agarwal S, Ramadani V, Gerguri-Rashiti S, Agrawal V & Dixit J K, Inclusivity of entrepreneurship education on entrepreneurial attitude among young community: Evidence from India, *Journal of Enterprising Communities,* 14 (2020) 299.

2 LuoY, Hu Z& Yu K, The impact of the R&D expenditure and patent rights towards operating performance in Medical Device Industry – An empirical study, *Revista de Cercetare si Interventie Sociala,* 2018 187.

3 Medical devices, *World Health Organization,* https://www.who.int/medical_devices/full_deffinition/en/.

4 Ensure healthy lives and promote well-being for all at all ages, *United Nations,* https://sdgs.un.org/goals/goal3, 2021.

5 Patents,*World Intellectual Property Organization,* https://www.wipo.int/patents/en/.

6 India I P, *The Patents Act, 1970*, 2015.

7 O'Cearbhaill R M, Murray T E & Lee M J, Medical device patents—A review of contemporary global trends with an Irish comparison, *The Irish Journal of Medical Science,* 188 (2019) 653.

8 LENS, www.LENS.org.

9 IpIndia Patent Search, https://ipindiaservices. gov.in/publicsearch.

10 Medtronic, *Wikipedia,* 2021.

11 Nidhi & Singh V, *Top Medical Device Companies: Research Activities and Patent Analytics*, https://www.greyb.com/top-medical-device-companies/, 2020.

12 Leading Medical Device Companies in 2020,*University Lab Partners,* https://www.universitylabpartners.org/blog/leading-medical-device-companies-2020#stryker, 2020.

13 Walker J, The real patent crisis is stifling innovation, *Forbes,* 2014.

14 International Patent Classification (IPC),*WIPO Documents,* https://www.wipo.int/classifications/ipc/en/, 2021.

15 Medical Devices Industry in India, *India Brand Equity Foundation,* https://www.ibef.org/industry/medical-devices.aspx, 2021.

16 India's system of higher education is the second largest in the world, https://www.studyinindia.gov.in/whyindia.

17 Dinesh P, View Point Indian Medical Device Industry-Current State & Opportunities for Growth, *Infosys View Point,* 2018.

18 Bajaj A, Medical Devices, https://www.investindia.gov.in/sector/medical-devices, 2021.

19 Indian pharma market expected to hit USD 130 billion by 2030: Sadananda Gowda, http://www.ficci.in/ficci-in-news-page.asp?nid=28718, 2021.

20 INDIA – Overview of medical device industry and healthcare statistics, *Emergo,* https://www.emergobyul.com/resources/market-india, 2019.

21 RBI formalizes automatic 100% FDI in medical devices sector, *Mint,* https://www.livemint.com/Industry/RFpbUUbDdYzkB6XmUMdJUN/RBI-formalizes-automatic-100-FDI-in-medical-devices-sector.html.

22 Healthcare Resource Guide: India, *Export Government,* https://2016.export.gov/industry/health/healthcareresourceguide/eg_main_108895.asp, 2019.

23 Top 5 countries for import and export of medical devices, *India Health,* https://www.indiahealth-exhibition.com/en/overview/industry-insights/Top-5-countries-for-import-and-export-of-medical-devices.html, 2020.

24 Kumar S & Garg A, India: Performance of Medical Devices Industry, *Tecnovaglobal* https://www.tecnovaglobal.com/pdf/India_Medical-Device-Industry-Snapshot_Jan-Mar 2020.pdf, 2020.

25 World Health Organization, Medical Device Manufacturing in India-A Sunrise,2017.

26 Emerging Opportunity for Medical Equipment Manufacturing in India, *ET Health World,* 2020.

27 Medtronic's Rs 1200-crore investment to turn Hyderabad into hub of medical devices, *New Indian Express,* 2020.

28 Siemens Healthineers to invest Rs 1,300 crore for innovation hub in Bengaluru, *Financial Express Bureau,* 2020.

29 Sengupta M & Hanumanthu P, Global Patent Landscape of COVID-19 Technologies, *Invention Intellegence,* 2020.

30 Sengupta M & Hanumanthu P, Severe Acute Respiratory Syndrome-Related Coronavirus: A Patent Based View, *Advanced Material Letters,* 11 (2020) 20.

31 All medical devices in India to be regulated as "drugs" – Medical Devices (Amendment) Rules, 2020, *Arogya Legal*, 2020.

32 Andhra Pradesh Medtech Zone Ltd, https://www.amtz.in/amtz/about-us/.

33 Medical Device Innovation Summit: India is poised to be a manufacturing hub for medical equipments and devices, *Express Healthcare,* 2020.

34 Medical Devices Making in India - A Leap for Indian Healthcare, *Deloitte Touche Tohmatsu India Private Limited,* 2016.

35 IPR Facilitation for Startups, *Journal of Intellectual property*, 2016.

36 Female Founders: Women Trailblazing innovations, *Startup India,* https://www.startupindia.gov.in/content/sih/en/women_entrepreneurs.html.

37 DST supported WEE foundation giving wings to women entrepreneurs, https://dst.gov.in/dst-supported-wee-foundation-giving-wings-women-entrepreneurs.

38 BIRAC TIE WINNER (Women in Entrepreneurial Research) AWARD, https://birac.nic.in/desc_new.php?id=818.

39 IIM-V launches second round of Women Startup Programme, https://www.thehindu.com/news/national/andhra-pradesh/iim-v-launches-second-round-of-women-startup-programme/article32280642.ece.

40 K N, 7 Indian Government initiatives to help women entrepreneurs, Smash The Glass Ceiling, *Vakil,* 2021.

41 Amjad I, What it will take for India to be truly 'Atmanirbhar', https://www.livemint.com/opinion/online-views/what-it-will-take-for-india-to-be-truly-atmanirbhar-11599652420913.html, 2020.