

Current Status and Challenges of Medical Device Innovations- Indian Perspective

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Medical devices and diagnostics cater an integral component of the health care system with a mandate of 'access and equity'. Medical device is an instrument which is applied for diagnosis, therapy, or alleviation of diseases in human beings or animals. Indian medical device sector is emerging with innovative and indigenous solutions. However, the sector seeks support from key stakeholder to contribute to public health. This paper reviews the need of diagnostic capacity building with robust regulatory regime to mitigate the challenges of accessibility in resource poor settings, import dependency, limited innovations with technological & funding constraints and skill set of experts. Further, emphasizes upon promising initiative of government like Make-in-India, which opens new avenues to a flourishing future of indigenous medical health technologies and innovations for delivering affordable healthcare to India's billion-plus population.

Keywords: Medical Devices Rules, 2017, Indian Patents Act, 1970, Central Drug Standard Control Organization, WHO, medical device, innovation, regulatory capacity building

According to the Central Drugs Standard Control Organization (CDSCO), medical device is such an item which is used to diagnose, treat, alleviate or resist diseases or abnormality in human beings or animals.¹ However, the Food and Drug association, USA (FDA) has defined medical device as an item which is used for medical purpose, but does not rely on chemical actions.² A medical device can be any instrument, apparatus, appliance, implant or other article, whether used alone or in combination, or with any software for human beings or animals for one or more specific purposes. It also includes a device which is a reagent, calibrator, control material, kit, equipment, system, whether used alone or in combination, intended to be used for examination and providing information for medical or diagnostic purposes, as defined in the Consolidated FDI Policy 2015 issued by the DIPP.³ A medical device can be based on electronic components (for example, blood cell counter) or mechanical parts (for example, surgical screws, plates used for broken legs or hands), it can be as simple as sphygmomanometer or blood pressure machine, or can be as complicated as Imaging diagnostics and others to tackle physiological complications. Generally, global healthcare companies, including Indian firms have R&D departments which are continuously investing and working to upgrade the technologies.

Status of Indian Medical Device Market

Currently, India's disease burden is undergoing transitions from communicable to non-communicable diseases. World Health Organization reported, non-communicable diseases such as cardiovascular, chronic respiratory, diabetes, cancers accounts for 60% deaths in India (Fig. 1).⁴

This mortality statistics, projects a need to prioritize research in cardiovascular, anti-diabetic, gastro-intestinal, neural CNS, and respiratory area, thus a prominence has been witnessed in recent years in our medical device market (Fig. 2).⁵ On the basis of end consumer prices, the Indian medical technology sector was estimated to US\$ 6.3 billion in 2013 and is expected to outreach an approximate growth of 10%-12% per year.⁶

A report by Deloitte (2010) documents the distribution of Indian medical technology market which is majorly occupied by medical instruments and appliances (25%) followed by orthopedic/prosthetic goods (20.0%), syringes/needles/catheters (12.4%), electro-medical (12.4%), x-ray apparatus (9.5%), and bandages (7.6%).⁷ According to another collaborative work, clinical chemistry showed highest research opportunities (35.8%) followed by immune chemistry, haematology, microbiology culture, histology and cytology, infectious immunology and genetic testing (Fig. 3).⁸ Altogether, the Indian IVD market was estimated to US\$ 900.2 million in 2016 (with CAGR 18.1% over last 7 years study period).⁸ Frequent

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occurrence of chronic abnormalities and the advancement of the treatment places such corporate hospitals, are the main reasons for the expansion.

The multi-national companies (MNCs) have been leveraging the Indian medical device market by tailoring their product portfolio as per Indian market needs such as, Transasia Biomedicals which developed an external fixator; Johnson & Johnson developed a knee implant as a reusable stapler for use in surgeries at price points, which are amenable to the Indian market; Roche Diagnostics developed a screening device for cardiovascular diseases suitable for rural settings. The innovation capacity building has also been supported by the success of some

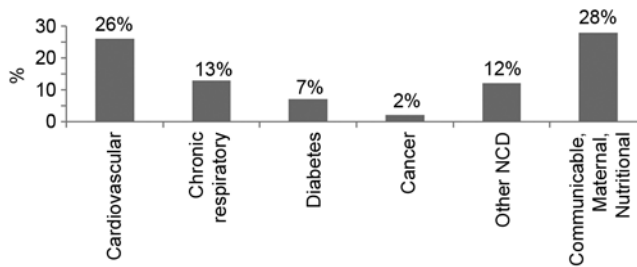


Fig. 1 — Current factors of deaths in India

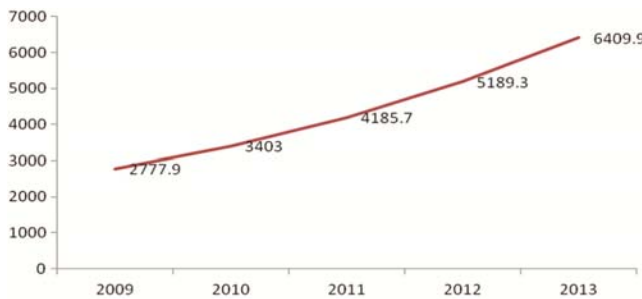


Fig. 2 — Indian medical devices market size (2009-13) in US\$ millions

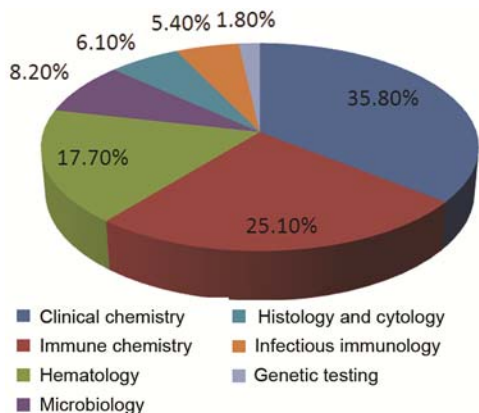


Fig. 3 — Share of IVD market in India by segment

indigenous companies such as Meril, TTK Healthcare, Trivitron Healthcare, Aurolab and Appaswamy Associates by developing innovative, indigenous low-cost medical devices.⁹

Indian medical technology sector is highly relying on import due to a) high quality research in developed countries such as US, Germany etc. compared to India, b) unavailability of several varieties of medical instruments in India, and c) inability of the producers to supply medical instruments according to the demands. There are various fiscal measures taken by Indian Govt. to promote import of medical devices-zero import duty has been implemented for certain devices, but several life-saving equipments are exempted from any excise duty.¹⁰ Surprisingly, there is less custom duty charged to finished imported equipments compared to the rate of excise duty paid to domestically made devices- it results to loss of tax credit.¹⁰ Above information is also reflected by an import-export study conducted by the WHO- the import figure was calculated to US\$ 900 million (in 2005), and showed almost continual escalation; on the other hand, the export figure roamed between US\$ 400 million to US\$ 575 million during the same tenure (Fig. 4).¹¹

Medical Device Innovations and Technical Hardships

Emerging dual disease burden demands quantitative and qualitative expansion of medical device technologies. Medical devices are either designed to target a specific health condition or improved with slight variations to be more effective (more efficacious and not mere rearrangement) or replicated for mass accessibility. Therefore, only those medical devices which have novelty, inventiveness and utility classify for patent filing. Medical devices also favor design registration for their unique, innovative designs and copyright registration if have a software associated with the device.

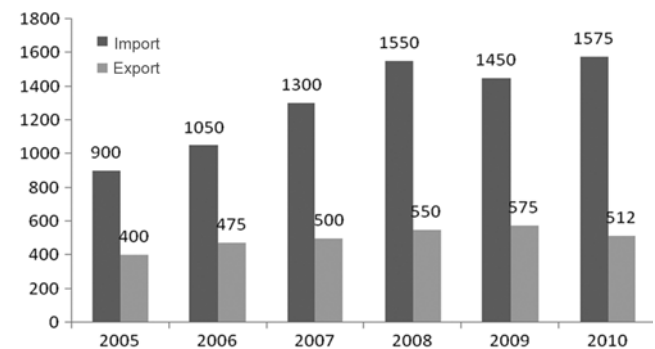


Fig. 4 — Import and export of medical devices in India

Section 3 of Indian Patents Act, 1970 decides the fate of a patent application for medical devices such as Section 3(b): For example, a bandage is invented which is non-biodegradable and can cause serious hazards to environment as a biomedical waste. It can't pass the patentability criteria even it prevents blood flow from deep cut within 60 seconds. Section 3(c): Mere discovery of living or non-living substance is not invention.¹² In 2009, Senesco Technologies Inc.'s invention,¹³ named "Nucleic Acids, Polypeptides, and methods for modulating apoptosis" was related to an isolated nucleic acid rat apoptosis-specific eIF-5A polypeptide and method of modulating apoptosis utilizing apoptosis-specific eIF-5A. From the examiner's point of view, the isolated nucleic acid usually exists in living body- therefore, it is considered as a non-invention. To prove its inventive step, the invention needs to represent any mutation or modification carried out to the claimed nucleic acid sequence.¹³ Likewise, Faraday's Law of Electromagnetic Induction which was discovered long back- but, using this principle an electronic blood flow meter (to measure the blood flow within vessel without cannulation) is being developed after ages. Section 3(d): GE Healthcare's invention on (2714/DELNP/2006),¹⁴ a particle for using in x-ray imaging essentially has a core made up of tungsten content (20 to 100% of the total weight of the tungsten) and another metallic elements (selected from rhenium, niobium, tantalum or molybdenum). The core is coated with charged layer (acidic groups such as, carboxylic acid groups, sulphonic acid groups, etc.) in order to protect the reactive surface of the core from corrosion. First examination report mentioned that the invention does not show any new feature or new application of known substances- therefore, the invention was objected under Section 3 (d) although it was granted after modifications of the specifications.¹⁵ Section 3(f): A low pass filter (frequently used in electrocardiogram) is an electronic filter which passes the signals lower than the cut-frequency and attenuates the signals higher than cutoff frequency. The basic components of this type of filter is capacitor and resistor where input signal is applied to the series combinations of capacitor and resistor and a output signal is taken across the capacitor. High pass filter exactly shows opposite performance where the arrangement of capacitor and resistor is exactly reverse. High pass filter can't be applied for patent protection because capacitor and resistor are re-arranged and they are working

independently in a known way. Section 3(i): The Encyclopaedia Britannica has stated diagnosis as a process of finding the nature or cause of diseases and differentiates from other possible conditions.¹⁶ It includes method(s) of evaluating (without any help of device) the physical or mental condition or a procedure of investigating whether the patient has the abnormality by examining the test result or imaging and are not considered as invention.¹³ For example, X-ray is a diagnostic tool which is usually applied to determine the location of broken part of the bone. Any advancement on X-ray machine and its different components such as collimator, grids, anode, cathode tube etc. are not excluded from patentable subject matter, but any technical or economical advancement on the process undergone by the X-ray technician, is excluded patentable. Claim 26 and 27 of document (Application no: 1537/KOLNP/2006)¹⁵, named- "SGKL As a Diagnostic and Therapeutic Target" clearly stated a method of diagnosis of disease associated to the disturbed activity of tissue factor- hence it was rejected by the patent examiner.¹⁵ Application no: 3044/CHENP/2006 disclosed a method for treatment of skin and mucosal membrane disease caused by human papilloma viruses- it was rejected by the patent examiner as method of treatment are not patentable in India.¹⁶ Similarly, an invention on lithotripters and its components (for breaking the urinary stones) is patentable, but advancement on lithotripsy process where nephrologists, or urologists or other technical persons are involved to undergo on human body, is excluded from patentable subject matter in India. An invention (Application no.: 4038/CHENP/2006) on tweezers used for cosmetic purpose was granted by the Indian Patent Office because the independent claim relates to the tweezers (instrument) and its mechanical structure¹⁶ and not the surgical process as an invention related to curative method is not patentable in India. Section 3(k): Software can be a part of a medical device. Modern versions of X-ray, CT, scan, MRI, PET, SPECT etc. machine etc. include software which process the image and make those images suitable for identifying the abnormality- even, the novelty of the software can't make it patentable. An invention (Application no: 4170/DELNP/2005) disclosed a process to measure oxygen consumption and CO₂ production in an anesthesia machine where gas production is calculated through mathematical equation- the same invention is opposed under Section 3(k) provision.¹⁷

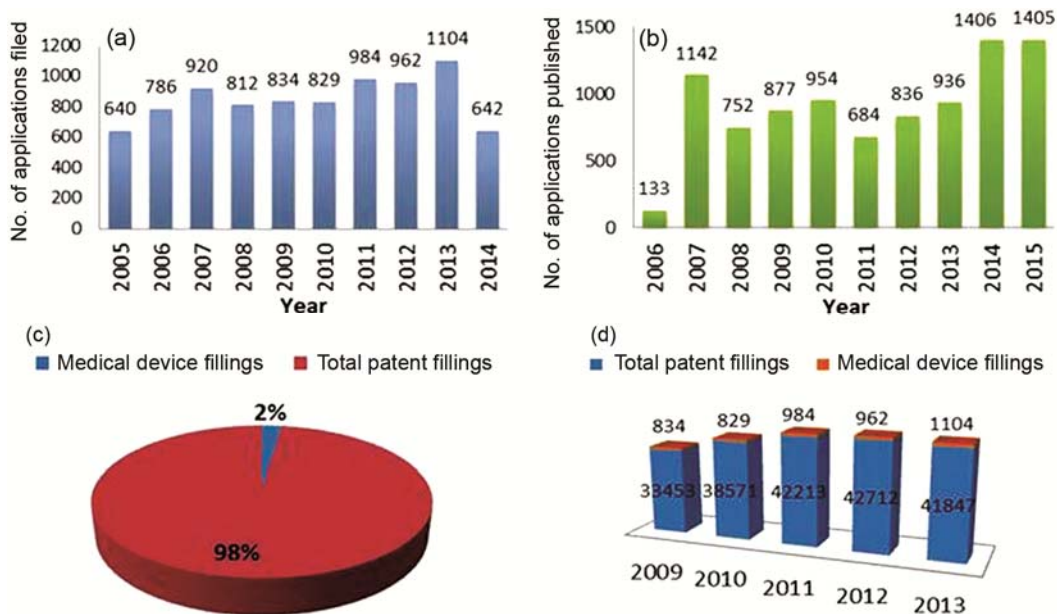


Fig. 5 — Patent filing trend in medical technologies (2005-2014)

During the last 10 years (2005 to 2014), patent filing trend projects an escalation in medical device domain as the patent filing has roughly doubled with 1104 filings in 2013, as compared to 640 filings in 2005 (Fig. 5).¹⁸

Philips, Sanofi Aventis, Becton Dickinson, Siemens, etc. are some of the key medical device companies with active IP in the medical device sector in India for the period of 2005–2013¹⁸ (Fig. 6).

Singh and Abrol (2014) in their study on the current Indian scenario of Indian diagnostic market found that foreign companies filed significantly higher number of diagnostic patents (80% of the total market) compared to the public sector institutions (9.78%), domestic companies (7.60%) and young start-ups (6.52%) between in the year of 1991 to 2013.¹⁹

Other Challenges for Medical Device Invention in India

Import Centric

India mostly depends on imports- 75% of the total diagnostic instruments are generally imported and are treated as drugs under the Drugs and Cosmetics Act.¹⁹ The kits which are designed in other countries, can fail to perform because of India ambience environment. Also, the kits which are manufactured for well-set laboratories- proper maintenance is not done in Indian laboratories.¹⁹ The Regulator (Central Drug Standard Control Organization) is challenged to

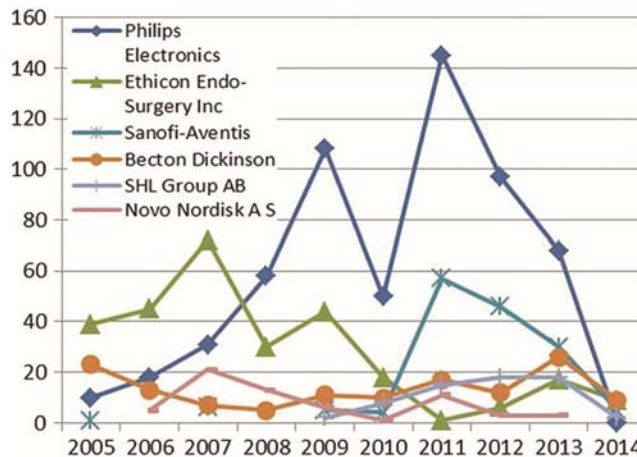


Fig. 6 — Contribution of some of the key medical device companies

tackle both, the flood of substandard imports as well as the production of poor quality medical devices in the country.²⁰ The poor monitoring of the purpose of foreign investment (100%) provides an opportunity to foreign investors to build local subsidiaries and continue imports.²¹

Inadequate Distributions

Now, poor working conditions of medical devices and the insufficient supplies are the great cause of broken Indian healthcare system. The experts from WHO found that 64% of the diagnostic devices were allocated to five Indian cities in 2004 aiming to distribute those devices among 5% of total Indian

population.¹¹ Therefore, feedbacks about the devices are not completely received from all of the corners across India. When a govt. survey is carried out to find out the issues and problems of the healthcare status, the respondents (common people) do not care to answer in correct way- it is one of major roadblock of the inventions.

Limited Funding

Limited funding is another important aspect. Although, the list of funding resources (International donors such as Welcome Trust, Bill and Melinda Gates Foundation, PATH, Foundation for Innovative New Diagnostics etc. and Indian funding sources like DBT, DST, CSIR, ICMR, AICTE, UGC, DRDO, etc.)¹⁹ is quite long, the amount is meager. Singh and Abrol (2014) revealed that diagnostic research received low funding compared to drugs and vaccinations¹⁹ - the diagnostic research sector received less than 2% of the total annual funding for research and development for diseases.¹⁹ For this reason, the current Indian diagnostic market requires very affordable, but high quality diagnostic instruments which is difficult for the researchers to invent such kinds of devices.

Proper Training and Education

Deficiency of training and education is another challenge for medical device inventions. Government and reputed privately owned organizations recruit laboratory technicians with formal educations and experiences- sometimes, they arrange for necessary trainings. But, most private organizations employ technicians with no education and training- therefore, there is a high chance of damage of the kits.

Regulatory Body

Stringent regulatory is very serious concern for the medical device inventions. CDSCO acts as the national regulatory authority for medical device in India. The import of all medical devices are fallen under Import-Export policy although some devices (such as, cardiac stents, catheters, heart valves, orthopedic implants, disposable hypodermic syringes and needles, etc.) need additional attention the regulatory body.² For import, the devices must comply to the quality standard set by the country of manufacture although registration in US, EU, Japan, Australia, or Canada streamlines the registration process.¹⁰ Also, high import duty and complicated custom clearance process make a barrier for the medical devices to enter within Indian soil.

Weak Technology Transfer Process

There is a huge gap between industry and academics. A WIPO document (published in 2007)²² stated that most Indian universities have not encouraging in-house projects (with-in their campus). The report additionally stated that consultancies play a crucial role for collaborations although those consultancies do not prefer large-scale projects. Similar study (2007) also remarked that Indian universities do not have sufficient knowledge of IPRs resulting in low rate of inventions in India.²²

A Way Forward

Medical Technology

Vision 2025 anticipated Indian medical technology sector to witness a market of US\$ 50 billion where local productions and inventions would contribute significantly.⁶ International companies as well as local manufacturers and the Indian researchers are already paving their way. "Jaipur Foot", a significant invention targeted to physically challenged persons, was manufactured by BMVSS (Bhagwan Mahaveer Viklang Sahayata Samiti- World' largest NGO working on devices for amputees). The device is made of rubber (soft and easily available) and offered to the patients without any charge. Additionally, BMVSS partnered with American MIT Mobility lab produced a wheelchair which facilitates the users to travel faster. In 2007, GE Healthcare manufactured an electrocardiogram (MAC 400) targeting a major portion of Indian population.¹¹ The device is portable, simple-to-use and very low cost. Other local inventions are low cost X-ray (manufactured by Mysore based Skanray Tehnologies) and low cost high quality lenses (by Aravind Eye Care). The foreign made lenses which priced around US\$ 200 in 1992, was impossible for a major portion of Indian population to afford. Aravind Eye Care offered such kind of lenses for US\$ 5 and also has been working on other optical devices.¹¹

To improve the university-industry relationship, universities are establishing business incubation unit and intellectual property rights cell to encourage students to work for new ideas apart from conventional studies such as Foundation For Innovation And Technology Transfer (IIT Delhi)²³, SIDBI Innovation & Incubation Centre (SIIC) at IIT Kanpur²⁴, Technology Business Incubator at University of Madras²⁵, Rural Technology & Business Incubator at IIIT Madras²⁶ etc. Government and industry have started various fellowships like Prime

minister Fellowship Scheme²⁷, Sun Pharma Science Scholar Award²⁸ to inculcate innovative temperament among students. Government lays another strong foundation for innovation ecosystem in India through Start-up India²⁹ and flexibilities for entrepreneurs in National IPR Policy 2016.³⁰

Government's landmark initiative of Make-in-India²¹ Policy emphasizes to a) reduce imports and b) promote the Indian products to international markets. To meet the objective the Department of Industrial Policy and Promotion (DIPP) has allowed a 100% FDI in medical device sector through automatic route i.e. without the involvement of Foreign Investment Promotion Board (FIPB).³¹ 100% FDI in medical device sector is envisaged to build strong platform for technology transfer by encouraging local production and innovation. It also initiates global economic integration by supporting host country to promote their products widely in global markets.³²

The release of Medical Devices Rules, 2017, aimed to standardize and regulate medical devices manufacturing industry, on par with international standards. These Rules have been framed in conformity with Global Harmonization Task Force (GHTF) framework and specifies norms for obtaining license, conducting clinical trials, sales of devices, duties of medical officers, labelling of devices, loan parameters, import activities and reduced manufacturer-regulator interface by promoting digital platform.³³

The Union Budget, 2017 has given the flexibility to increase the depreciation rate on the medical devices and equipment from 15 per cent to 30 per cent. Also, the import tariffs/duties which are levied on the health care (drugs, surgical equipment), can be completely removed if manufactured in India.³⁴

Conclusion

Rapid introduction of the innovation has become the need of the hour in order to catch up with the increasing demand and contribute to technological progress in medical device sectoral growth. In order to increase the accessibility of affordable and reliable devices across India, it has become imperative to explore potential industry-academia/research/medical fraternity partnerships to manufacture low cost devices indigenously through sustained Research and Development (R&D) efforts, technology development, strong IPR base and advancement in areas related to diagnostics. Analysis of the current innovation ecosystem pattern in the resource poor

settings of medical devices sector shows dominance of maladapted import being undertaken by the foreign and domestic firms, lack of coordination between the R&D institutions, challenges of positive alignment of the conducive policy regime for industrial development needs a new push and pull mechanism.

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