STANFORD biodesign

Tracking an Emerging Industry

Barriers to Commercialization of Medical Technology in India

Ritu Kamal, Christine Kurihara, Anurag Mairal, Paul Yock

For information contact:

Ritu Kamal
Stanford Global Biodesign
Stanford University
James H Clark Center
318 Campus Drive, Rm. 121
Stanford, CA 94305-5428
(650) 736 1159
rituk@stanford.edu

http://biodesign.stanford.edu/bdn/gl

Abstract

This paper will discuss the barriers to commercialization of novel medical technology present in India today and will make recommendations for mitigating these challenges. In order to examine these barriers, we surveyed over 200 professionals affiliated with the medical device sector in India to quantitatively determine which of these barriers are most commonly responsible for commercial stagnation and how they may be mitigated for better commercialization outcomes. We also conducted private interviews with medical technology entrepreneurs and investors looking to enter the Indian market. The key barriers for medtech companies in India are a lack of sufficient early-stage financing, inadequate regulations around manufacture and sale of medical devices and the lack of intellectual property (IP) protection for new technologies. Further, there is an absence of a vibrant ecosystem to support the innovation of medical devices in India, including a lack of a defined pathway for clinical testing of medical products, a paucity of professionals with knowledge and experience of medical technology and the fragmentation of distribution networks. Additional studies are needed to fully characterize the difficulties faced by companies in different stages of the innovation lifecycle.

Contents

INTRODUCTION

India's medical device or medical technology market was worth US$3 billion in 2011 and grew at a roughly 15 percent annually in that year.[1] It is expected to grow at a 16 percent compounded annual clip during the 2010-2015 period,[2] far better than the two percent to three percent growth expected in this sector in the US and Europe. This has put India among the top three emerging markets for direct investment by large medical device multinational companies.[3] Nevertheless, with a population of over 1.2 billion people, this market size translates into an extremely low average expenditure on medical technology: less than $2.50 per capita[4]. This presents both an opportunity and a challenge to device innovators looking to decrease the disease burden in India by increasing access to appropriate medical technologies. The opportunity lies in the underutilization of healthcare in India: millions of patients are currently underserved and could be helped with the right medical device or treatment, opening up large markets for medical device companies. Further, the primary treatment modality has traditionally been confined to pharmaceutical drugs, which are limited in their capacity to address a number of acute and chronic conditions prevalent in India. Conversely, the underutilization itself is a reflection of the challenges of the Indian healthcare sector: poor infrastructure, lack of trained personnel, relatively high cost of services and so on. These challenges delay or deny the delivery of suitable medical technology to the Indian patient, particularly by hindering commercialization of new medical technology products.

This paper seeks to explore these challenges, which affect commercialization of all new medical technologies in India, but are especially significant for novel, indigenously developed medical products. This paper has three main goals: 1) to categorically document the barriers to commercialization of medical technologies in India; 2) to quantitatively determine which of these barriers are most commonly responsible for commercial stagnation; and 3) to determine how these barriers may be mitigated resulting in better commercialization outcomes. Further research continues to engage with these issues as well.

Healthcare Overview

Over the last half century, India's public sector has steadily given up market share to the private sector in providing healthcare to Indians. Less than 10 percent of care is delivered in public facilities. The private sector now accounts for over 90 percent of all hospitals, as much as 85 percent of all doctors, 80 percent of out-patient care, and 60 percent of in-patient care in the country (2001)[5]. Public healthcare facilities are divided into Primary Health Centers, District Level Hospitals and Tertiary Hospitals. Private health systems have basic clinics, multispecialty clinics (also known as nursing homes), hospitals, and hospital chains.

---

[1] "India: Medical Device Market," Espicom Report 2012, http://www.espicom.com/india-medical-device-market (March 5, 2013)

[2] "Taking Advantage of the Med-Tech Market Potential in India," PWC, 2012, p.9 http://www.pwc.com/en_GX/gx/pharma-life-sciences/publications/asia-pharma-newsletter/assets/taking-advantage-of-the-medtech-market-potential-in-india.pdf (February 27, 2013)

[3] "Ibid.

[4] Ibid.

[5] "Private Sector in Healthcare Delivery in India," National Commission on Macroeconomics and Health, 2005, p. 1, http://www.nihfw.org/WBI/docs/PPP_SessionBriefs/PPP%20Course%20sessions/Need%20and%20Scope%20for%20PPP/Private%20Sector%20in%20Health%20Care%20Delivery%20in%20India.pdf (February 22, 2013).

Vast disparities in the quality and availability of care characterize India's healthcare system. State of the art Indian secondary and tertiary care institutions provide world-class care attract domestic patients who can afford their services, in addition to about half a million medical tourists each year.[6] However, a large majority of the population is served by healthcare facilities without adequate supplies, staff, or the capacity to provide affordable care. A significant percentage of the existing infrastructure, both public and private, is non-functioning at any given time (see Figure 1).[7] Public health facilities suffer from rampant doctor absenteeism and crumbling infrastructure in both urban and rural areas. In rural settings, where the penetration of healthcare facilities has been traditionally low, patients often resort to untrained traditional healers for healthcare.[8] These circumstances have traditionally deterred the use of medical devices beyond those that are very basic and low cost.

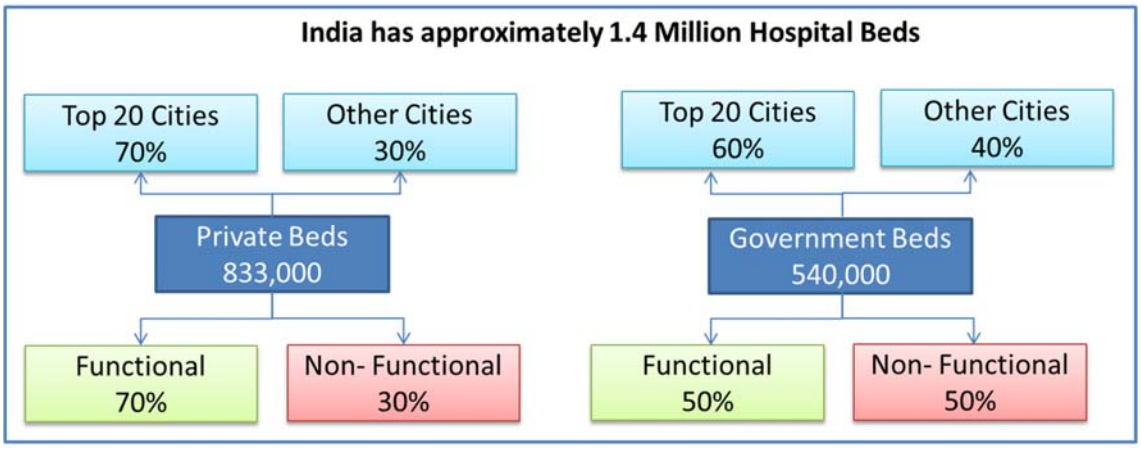

Figure 1: Distribution of Functional Hospital Beds, 2011[9]

Disparities also exist between geographic regions. Southern states, such as Tamil Nadu and Karnataka, have significantly better infrastructure than Uttar Pradesh, Bihar and other northern states (see Figure 2).[10] The good news is that India's economic growth story is propelling improvements in healthcare infrastructure. Corporate hospitals chains, such as Apollo and Fortis, are investing in cities outside major metropolitan areas and driving growth of the hospital sector at 15% per year.[11]

[6] "Medical Tourism in India," Trak.In, May, 23, 2011, http://trak.in/tags/business/2011/05/23/medical-tourism-india/ (February 22, 2013).
[7] "High Level Expert Group Report on Universal Health Coverage in India," Planning Commission of India, November 2011, p. 189, http://uhcforward.org/publications/high-level-expert-group-report-universal-health-coverage-india (February 22, 2013).
[8] Srinath Reddy , K Srinath Reddy, Vikram Patel, Prabhat Jha, Vinod K Paul, A K Shiva Kumar, Lalit Dandona, "Towards Achievement of Universal Healthcare in India by 2020: A Call to Action," *Lancet*, 2011, 377:760-68, http://cghr.org/wordpress/wp-content/uploads/Towards-achievement-of-universal-health-care-in-India-by-2020-a-call-to-action-2011.pdf (February 22, 2013).
[9] "High Level Expert Group Report on Universal Health Coverage in India". Planning Commission of India, Nov 2011
[10] Ibid.
[11] Ibid.

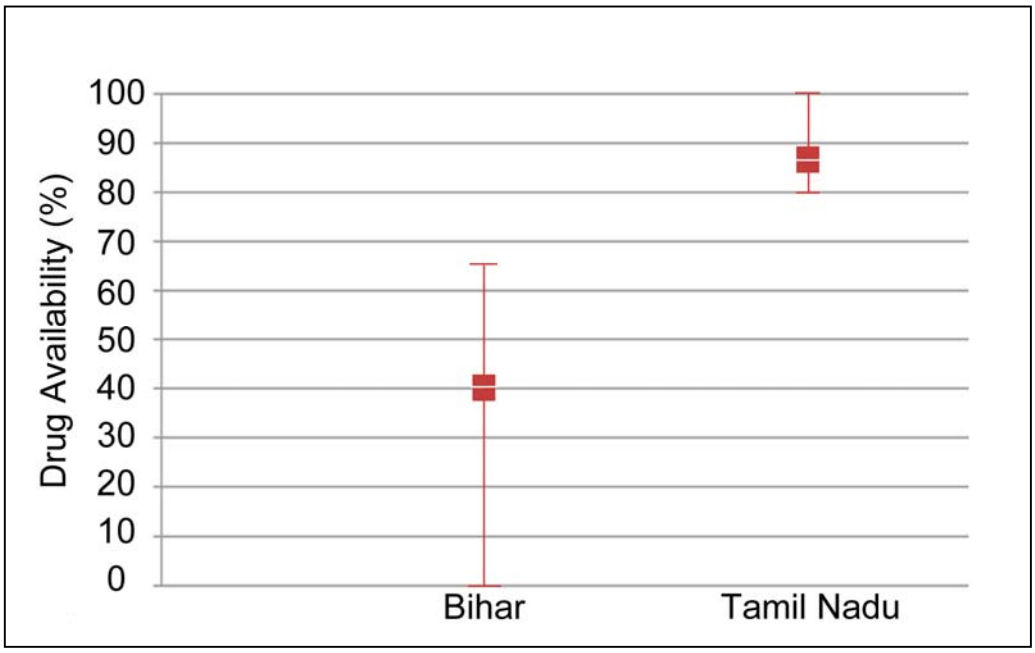

Figure 2: Comparative Analysis of Availability of Drugs between Selected Indian States[12]

India's healthcare system is plagued by low spending levels. Healthcare expenditure per capita was only US$56 in India in 2010 compared to US$208 in China and US$964 in Brazil that same year.[13] India's private and public sector combined spent only about four percent of GDP on healthcare in 2010. The government is planning to increase its share from 1.4 percent to 2.5 percent of GDP over the next five years.[14] Total healthcare spending is projected to increase from about 2 percent to 6 percent of GDP over the next decade.[15] This woefully inadequate level of spending is the lowest among all BRICS nations (Brazil, Russia, India, China, and South Africa).[16] In contrast, the United States spends 17.6 percent, Germany 11.6 percent, and Mexico 6.2 percent of GDP on healthcare. [17] Although the Indian government plans to increase its spending on healthcare going forward, it only accounts for some 25 percent of total healthcare spending in India.[18] Individuals and institutions contribute the remainder, making India's healthcare system one of the world's most privatized (See Figure 3).[19]

---

[12] Ibid.
[13] "Taking Advantage of the Med-Tech Market Potential in India," op. cit., p. 9.
[14] "Healthcare Spending to Rise to 2.5 Percent," *Indian Express* March 1, 2012, http://www.indianexpress.com/news/healthcare-spend-to-rise-to-2.5--of-gdp/918380 (February 22, 2013).
[15] "The Outlook for Medical Devices in Brazil, Russia, India and China," Espicom Market Reports 2011, http://www.espicom.com/medical-devices-outlook-bric (February 22, 2013).
[16] Ram Prasad, "Medical Device Industry," *The Hindu,* April 15, 2012, http://www.thehindubusinessline.com/industry-and-economy/article3317902.ece?homepage=true&ref=wl_home (February 22, 2013).
[17] "India Healthcare Expenditure," OECD report, 2012, http://www.oecd.org/health/healthpoliciesanddata/oecdhealthdata2012-frequentlyrequesteddata.htm (February 22, 2013).
[18] Parvathi K. Iyer and Dinesh Abrol, "Science and Technology Financing," *India Science and Technology,* 2008, http://www.nistads.res.in/indiasnt2008/t2finance/t2fin2.htm (February 22, 2013).
[19] Nishant Jain, "Analysis of Public Expenditure on Health Using State Level Data," IIM Ahmedabad, June 2004, p.4, http://www.iimahd.ernet.in/publications/data/2004-06-08rbhat.pdf (February 22, 2013).

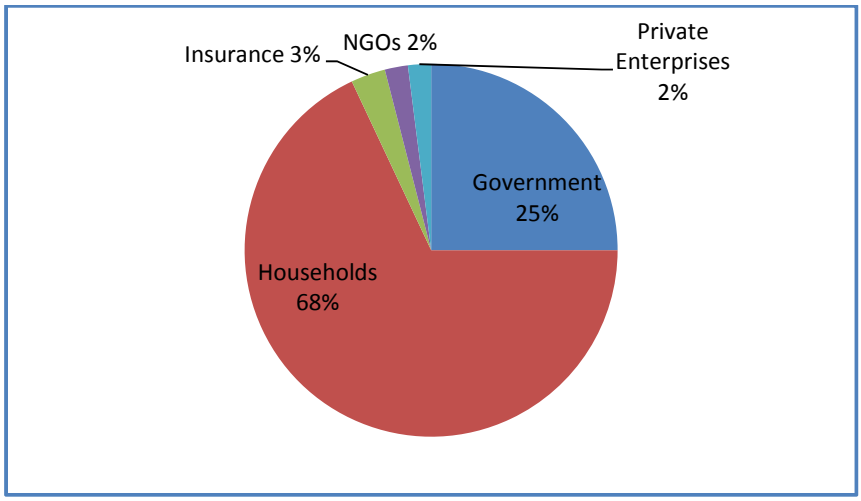

Figure 3: Share in Expenditure on Healthcare in India[20]

Health insurance is rare but growing in India. Only 55 million people had health insurance in 2003. By 2010, 300 million people, mostly below the poverty line, gained access to some partial form of health insurance. Still, only three percent to five percent of patients have full or substantial coverage.[21]

Both government and private insurers are working to increase access to insurance and projections estimate that about half the population will enjoy some level of health insurance coverage by 2020.[22] This increase will be derived partly from the National Rural Health Mission(NHRM), which the Indian government rolled out in 2005. It is an ambitious and wide-ranging public health program that seeks to improve healthcare delivery in rural India.[23] The *Rashtriya Swasthya Bima Yojna* (National Health Insurance Program or RBSY) is also responsible for increasing health insurance access to poor families across the country that make less than US$100 per year[24]. Domestic insurance providers, such as Cholamandalam, L&T General, and HDFC, as well as foreign providers in joint ventures, such as Bajaj Allianz, Tata AIG, and ICICI Lombard, are starting to become more active in the private healthcare insurance sector. Private insurance players served just one percent of the Indian market, but accounted for more than two percent of total healthcare expenditures in the country.[25]

---

[20] Iyer et al. Science and Technology Financing. http://www.nistads.res.in/indiasnt2008/t2finance/t2fin2.htm
[21] "Government Sponsored Health Insurance in India: Are you covered?" World Bank, October 11, 2012, http://www.worldbank.org/en/news/2012/10/11/government-sponsored-health-insurance-in-india-are-you-covered (February 22, 2013).
[22] "Indian Pharma 2020: Propelling Access and Acceptance, Realizing Potential," McKinsey and Company, 2010, p. 18, http://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/Pharma%20and%20Medical%20Products/PMP%20NEW/PDFs/778886_India_Pharma_2020_Propelling_Access_and_Acceptance_Realising_True_Potential.ashx (February 22, 2013).
[23] Ajay S. Mahal, Bibek Debroy, Laveesh Bhandari, India *Health Report 2010*, Business Standard Books, (ISBN:978-8074-000), p. 138.
[24] Jackie Range, "India's poor get health card to fund medical treatment," *Wall Street Journal*, August 26, 2008, http://online.wsj.com/article/SB121971773721671817.html (Mar 3, 2013)
[25] "Taking Advantage of the Med-Tech Market Potential in India," op. cit., p.4

Medical Devices Overview

The $3 billion medical device market in India is dominated by imports, which account for approximately 75% of the devices sold in the country[26]. Of the 25% of devices indigenously manufactured, almost 60% come from small and medium enterprises[27]. This leads to an extremely diverse but fragmented medical device industry in the country. Domestic companies excel at selling medical supplies and consumables, such as sutures and catheters, a particularly price sensitive segment of the market, due to the low labor and manufacturing costs.[28] Indian manufacturers suffer from a perceived lack of quality and have traditionally found it difficult to enter technology-intensive and high-cost device markets. GE Healthcare, Siemens, J&J, and other multinational corporations, lead this market segment with their extensive sales and service networks.

Of the products sold in India, the largest segment of medical devices sold by revenue is the diagnostic imaging devices (see Figure 4). The bulk of these sales are made to the private healthcare sector, which has the sophisticated infrastructure required to generate revenue to compensate for a large capital expense. Although most high tech products are imported, some foreign companies have set up wholly owned subsidiaries in India to develop and manufacture medical instruments. For example, GE developed a handheld ultrasound device intended for resource-constrained markets at its Bangalore campus. This device, called V-Scan, launched globally in 2010.[29] Other companies, such as Siemens, Philips, Stryker and J&J, have also invested in large product development labs in India.

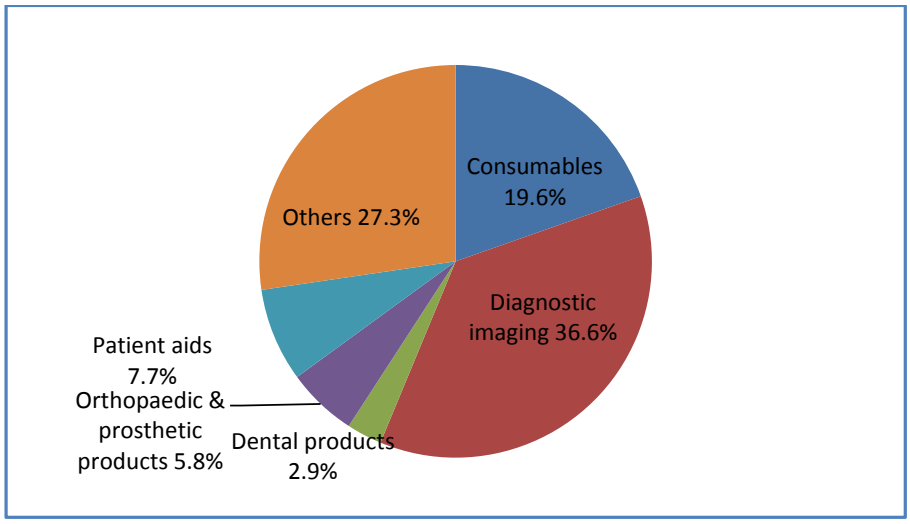

Figure 4: Indian Medical Device Market by Category, 2011[30]

[26] Ibid., p.4
[27] E. Saneesh, "The Emerging role of Small and Medium Enterprises in the Indian Medical Devices Market," *Frost and Sullivan*, September 17, 2012.
[28] Espicom 2012, loc.cit.
[29] GE Healthcare, "VScan," https://vscan.gehealthcare.com/gallery/a-quick-look-at-vscan (February 22, 2013)
[30] Espicom 2012, loc.cit.

A majority of medical devices sold in India fall on the lower end of product complexity, such as syringes, needles, and so on. Table 1 shows the volume of sales in each of the major categories of medical devices sold in India. Apart from medical imaging, which has traditionally been a strong sector in India, the market is focused on low tech products like disposables.

	US$ Millions	As Percent of Total Market
Consumables	519.1	19.6
Diagnostic imaging	968.1	36.6
Dental products	75.9	2.9
Orthopedic & prosthetic products	152.3	5.8
Patient aids	204.6	7.7
Others	722.6	27.3
Total	2,642.7	100.0

Table 1: Indian Medical Device Sales by Category, 2011[31]

Although traditionally the medical device sector in India has been dominated by goods developed and manufactured abroad, there is a burgeoning industry for indigenous production of medical technology. Many of these companies manufacture existing products such as ECG scanners and ventilators to be sold at costs that are appropriate for the non-premium Indian market segments. In the last 5-7 years, there has been increased activity in the entrepreneurial medical technology sector in India, with several promising startup companies developing novel technologies for the Indian market. For instance, several companies have been started by alumni of the Stanford India Biodesign program (SIB). Established in 2008, the Stanford-India Biodesign program trains young innovators in India to become leaders in biomedical technology innovation. Over the years, the program has created an ecosystem for alumni fellows and other entrepreneurs in medtech by connecting them to relevant resources and by providing a blueprint for medtech startup success in India. Several SIB fellows were interviewed for this paper.

COMMERCIALIZATION AND ITS CHALLENGES

The diversity of the Indian healthcare system presents a particularly thorny challenge to the distribution and sale of medical products. Enormous differences exist between various healthcare settings: urban versus rural, public versus private centers and non-profit versus for-profit healthcare companies, among others. Further, regional differences in economic potential, quality of infrastructure, density of population, and education add to the difficulty of scaling sales beyond a specific segment of the market.

As in other industries in India, distribution networks for medical products are fragmented, divvied up by region, medical specialty, class of device and product branding. In order to cover that elusive last mile in the healthcare chain, there are several layers of wholesalers, distributors and salesmen involved. Due to the preponderance of low tech devices in the sales pipelines, salesmen may lack the education and training needed to sell more sophisticated products.

[31] Ibid.

Under the current model, manufacturers or multinationals in India typically appoint different distributors for different territories. As in the US, Indian distributors operate on either exclusive or open contracts. Exclusive contracts give sole authorization to the partnering distributor. In contrast, in an open contract, more than one distributor can be authorized to distribute goods. Interviews indicated that medical device fairs currently play a major role in linking distributors with OEMs. Relationships are formed based on a distributor's market focus and portfolio of products. Indian distributors maintain proprietary networks and employees for product distribution. Most also provide after-sale-services to customers and maintain medical equipment under warranty. These value-added functions make OEMs attractive, in particular to small young companies who may not have the resources to provide them on their own and whose products may lack the credibility to be successful commercially without such guarantees. [32]

It is important to note that large distributors, such as those maintained or employed by MNCs, generally do not distribute products to small towns and rural areas. The effort required to reach these territories does not justify the resources required to serve them. As a result, indigenous manufacturers/entrepreneurs focusing on low cost devices that are primarily targeted at the rural market are faced with the daunting task of creating their own channels to distribute in these areas. Figure 5 shows the complexity of the distribution networks of the pharmaceutical sector, an industry with many parallels to the medical device industry as they are both in the multifarious healthcare sales space.

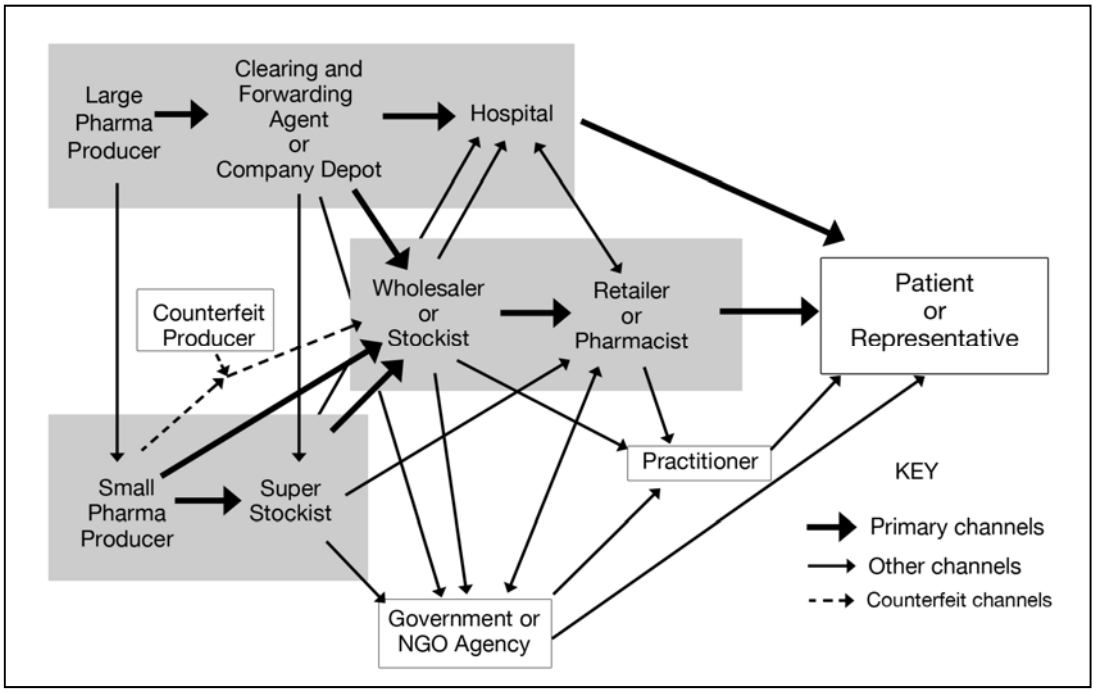

Figure 5: Patterns of Distribution of Pharmaceuticals in India[33]

[32] Private interviews, 2011

[33] Roger Jeffery, "Pharmaceuticals Distribution Systems in India", *Center for International Public Health* Policy, Working Paper 1a, 2007, http://www.csas.ed.ac.uk/__data/assets/pdf_file/0003/38829/PharmaDistributionIndia.pdf (March 6, 2013)

In India, even established companies with deep reserves of capital use a multipronged approach to sales and distribution rather than investing in an end-to-end in-house sales team. Commonly cited examples include the chocolate maker Cadbury, with 60% of market share in India, and toothpaste maker Colgate, with 50% share[34]. These companies have been successful by using multiple distribution channels in order to reach customers in all geographies and social classes. For example, Colgate uses a mixture of stockists, wholesalers and a proprietary sales force to reach 2.8 million retail outlets[35]. However, this strategy can pose challenges for even the largest companies to execute: during a recent analysts call, Apple's Tim Cook[36] cited India's multi-layered distribution as the main reason for his company's small share of the market. The challenge for a smaller, startup can be even more daunting.

Selling medical technology products in India, especially for smaller, younger companies, requires a commitment to business model innovation that is just as important as the technical innovation of their products. Failure to do so can result in limited success or even outright failure. Startup medical device companies in India have experimented with different types of business models to sell their products, as shown in Table 2.

Type of Model	**Name of Company**
Partnership with multinational	Embrace[37]
Partnership with Indian company	Brilliance (D-Rev)[38]
Partnership with foundations/NGOs	Jaipur Knee[39]
Direct sales	Perfint[40]
Third party service provider	Cura Healthcare[41]
Indirect sales	XCyton Diagnostics[42]

Table 2: Types of Business Models in Indian Medtech[43]

[34] Prathap Oburai and Michael J Baker, "A Grounded Exploration of Sales and Distribution Channel Structures in 13 Industries in India," IIM Ahmedabad 2004, http://www.iimahd.ernet.in/publications/data/2004-09-05oburai.pdf (March 6, 2013)
[35] Ibid.
[36] http://blogs.barrons.com/techtraderdaily/2012/07/24/apple-conference-call-mountain-lion-out-tomorrow/
[37] "GE Healthcare partners with Embrace to help address infant mortality in rural India through affordable infant warmer," GE Press Release December 16, 2010, http://www.genewscenter.com/Press-Releases/GE-Healthcare-Partners-with-Embrace-to-Help-Address-Infant-Mortality-in-Rural-India-Through-Affordable-Infant-Warmer-2d80.aspx (March 6, 2013)
[38] "Brilliance licensed to Phoenix Medical Systems," D-REV Press Release, December 22, 2010, http://blog.d-rev.org/2010/12/22/brilliance-is-licensed-to-phoenix-medical/ (March 6, 2013)
[39] "Stanford-Jaipur Knee," Jaipur Foot, 2009, http://www.jaipurfoot.org/what_we_do/prosthesis/stanford_jaipur_knee.html#.UTeigaXFV8E (March 6, 2013)
[40] Prem Kumar, "Devising Medical Innovation," *The Smart CEO*, March 15, 2010, http://www.thesmartceo.in/Industries/healthcare-and-pharma/devising-medical-innovation.html (March 6, 2013)
[41] Cura, "Organisation," http://www.cura.in/organisation.php (March 6, 2013)
[42] Xyton, "Company Profile," http://www.xcyton.com/company_profile.html (March 6, 2013)
[43] Private Interviews

Literature Review

There are many reasons for the low penetration of medical technology in India. Some of these have been highlighted before: poor healthcare infrastructure, high cost of devices, and lack of trained personnel. Many others exist, such as difficulty of servicing medical instruments or sourcing spare parts, poor quality of affordable medtech products, inappropriate design for a developing world setting[44] and even patient preferences for pharmaceutical solutions[45]. A WHO study, the "Priority Medical Devices Project" documented catalysts and barriers to medical device innovation in developing countries. The various reports generated as part of this project detail the barriers to innovation in medical devices (see Figure 6). Though meant to be generally applicable across the developing world, all these challenges are found in the Indian context as well.

- **Supplier Driven**
- **Lack of coordination between facility staff and/or manufacturer**
- **Procurement issues with mediating ministries**
- **Lack of direct link between producer and end-user**
- **Weak management culture**
- **Linguistic Barriers, i.e. literature not translated into regional languages**
- **Maintenance contracts are missing**
- **Insufficient trained staff**
- **Lack of technical expertise**
- **Poor maintenance and repair facilities**
- **Lack of "training culture", i.e. poor use of instructions**
- **Limited access to technical information**
- **No spare parts**
- **Unrecognized standards for quality control and maintenance**
- **Lack of quality assurance**
- **Cost**

Figure 6: Barriers to Innovation in Medical Devices[46]

In his paper on barriers to innovation[47], Prof. Krishnan uses four categories to elucidate the types of challenges present in India that hinder the growth of technological prowess. This classification of barriers—behavioral (social), organizational, systemic, and governmental –can easily be applied to medical technology innovation as well. Barriers to commercialization of technology cited in the literature can be grouped as shown in Table 3.

[44] Hrsitina Petkova. "Barriers to innovation in the field of medical devices," *WHO* Background Paper 6, Aug 2010, p. 14, http://whqlibdoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.6_eng.pdf (March 6, 2013)
[45] G Tomson et al, "Drug utilization at primary health care level in southern India". EUROPEAN JOURNAL OF CLINICAL PHARMACOLOGY Volume 43, Number 4:413-415. 1992
[46] Petkova, loc.cit.
[47] Rishikesh Krishnan, "Barriers to Innovation and the Creation of a Knowledge Economy in India," Working Paper 243, IIM Bangalore, Feb 2006

Social	Organizational	Systemic	Governmental
Culture of basic research deters monetization	Absence of support organizations for entrepreneurs	Poor healthcare infrastructure	Regulatory approvals
Risk averse capital	Lack of effective lobbying	Quality of education	Tax and tariff structures
Fear of failure	-	Lack of success stories beyond IT	Lack of meaningful incentives for innovation

Table 3: Types of Barriers to Innovation[48,49]

Another way to look at the *barriers* to commercialization of medtech listed above is to think of them as *constraints*. There are many examples of successful healthcare innovations in India, ranging from Aravind Eyecare to Jaipur foot. Each of these medical products and services understand the constraints inherent in the Indian healthcare system — low paying potential, poor infrastructure, shortage of trained medics, etc. — and innovate around them. These success stories (see Table 4) have been lionized as examples of frugal innovation and demonstrate the viability of innovative solutions to clinical needs.

Constraint	Example	Description
Cost	GE ultrasound (V-Scan)	Low cost ultrasound that retails for 80% of cost of traditional machines
	Jaipur Foot	$30 foot prosthetic that has been fitted on over 4 million amputees
	Tata Swach	Nanotechnology based water purifier that costs less that 50% of nearest competitor
Infrastructure	Kerala Neighborhood Network in Palliative Care	Community based primary care network serving 70% of the state's population with 36 doctors and over 4000 volunteers
	Narayana Hrudralaya	Multispecialty hospital providing low cost or free care at high quality
	Aravind Eyecare	Eye care hospital providing screenings and surgeries at high volume and high quality

Table 4: Examples of Innovation under Constraints[50]

[48] Ibid.
[49] Sharma, "India's National and Regional Innovation Systems: Challenges, Opportunities and Recommendations for Policy Makers". Industry & Innovation Volume 19, Issue 6, 201, 2012
[50] Kristin Bound and Ian Thornton, "Frugal Innovation in India", *Nesta*, July 2012

Primary Research

In order to quantify the extent of the barriers faced in the commercialization of medical devices in India, an extensive survey of doctors, innovators and other key stakeholders was conducted during the Annual Indian Medtech Summit in 2011. Using an online survey, about 200 affiliates of the Indian medical technology sector were asked about perceived barriers to commercialization in the industry. The full survey has been attached as Appendix 1. The profile pattern of respondents is indicated in Figure 7. Results were compared to a similarly conducted in the prior year, and changes in responses have been noted.

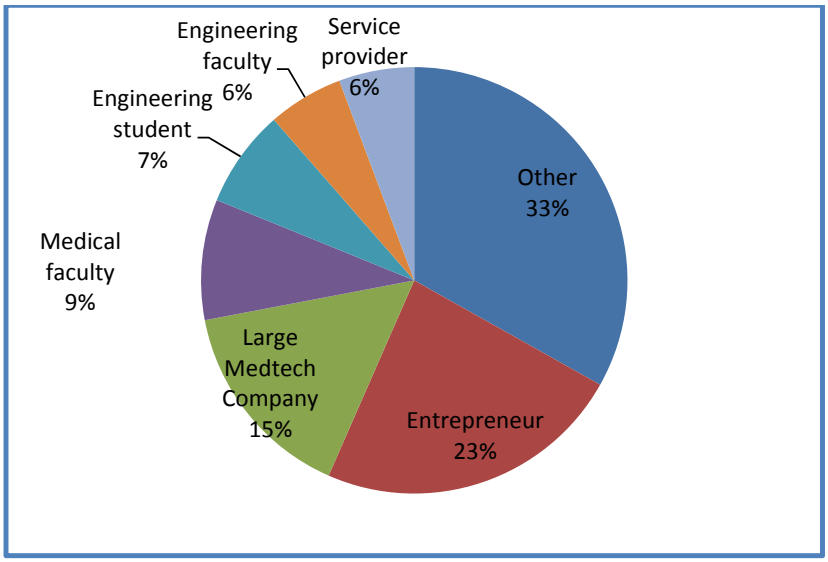

Figure 7: Types of Respondents in the Medtech Summit Survey, 2011[51]

The largest representation in the survey pool was from entrepreneurs and large companies, with faculty members, students, and service providers also contributing. Taken as a whole, the survey results reveal that the ecosystem required for robust commercialization of medical technologies in India is in a nascent stage. Interviewees considered almost all of the factors deemed necessary for commercialization to be a significant hindrance, unsurprising for a young ecosystem. For instance, survey results indicated that the "overall difficulty of commercialization" in India had an average rating of 2.6 out of a possible 5.0, corresponding to the option "commercialization of medical technologies is possible with *some* difficulty" (see Figure 8). Further, respondents felt that commercialization had become somewhat easier in the last five years, corresponding to an average of rating of about 2.6 on a scale of 5.0 (see Figure 9).

[51] Results from Indian Medtech Summit Survey 2011

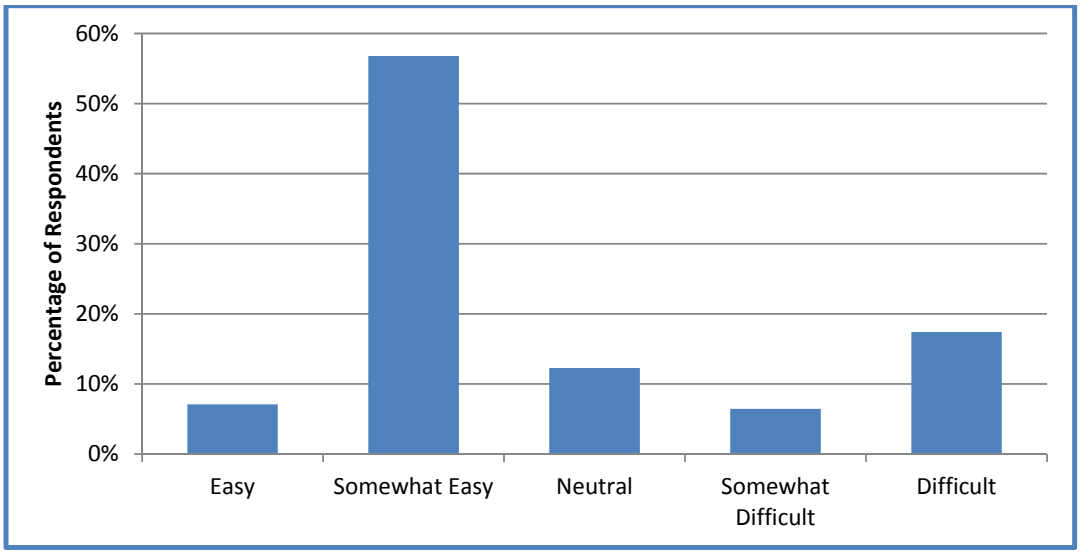

Figure 8: Ratings for Difficulty of Commercialization in India

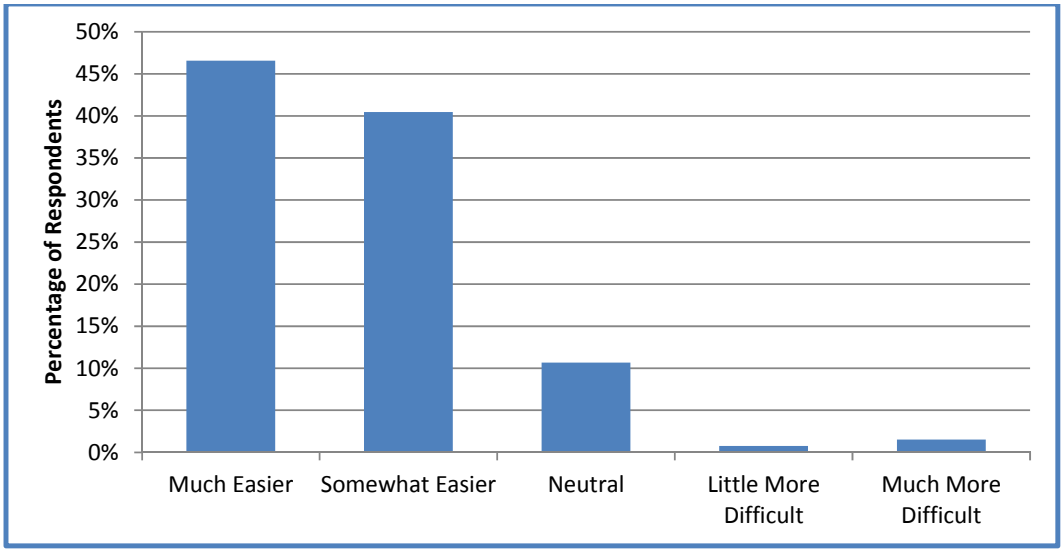

Figure 9: Ratings for Change in Commercialization Outcomes in the last 5 years

Most factors deemed necessary for commercialization were rated between 2 and 3, as indicated in Figure 10Figure 10. The top three barriers cited by survey respondents: financing, regulatory and intellectual property (IP) considerations.

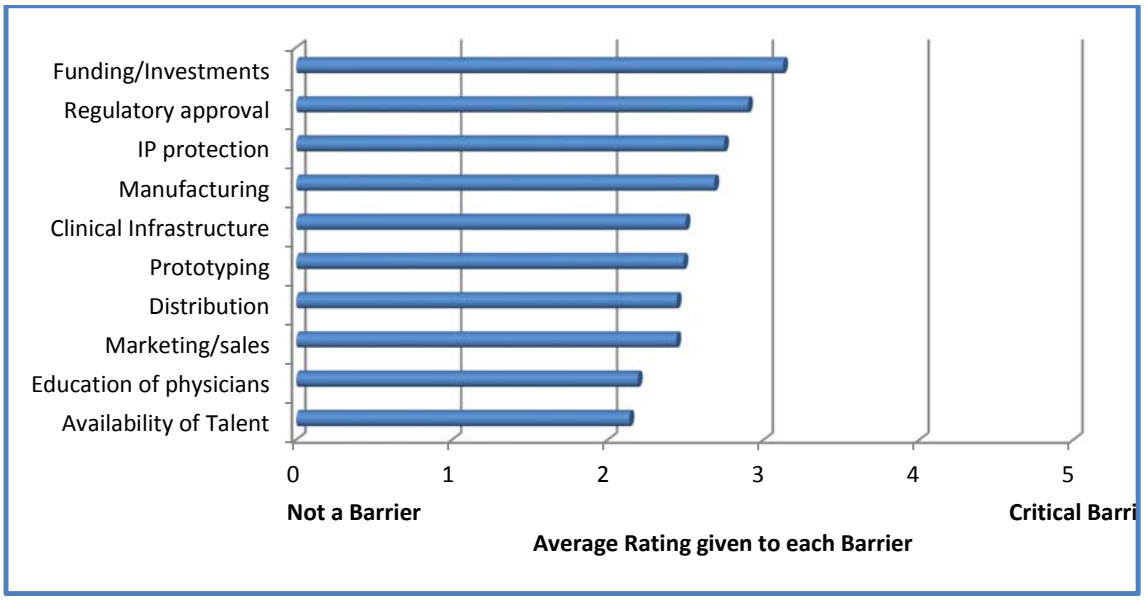

Figure 10: Average Ratings for listed Barriers to Commercialization

Figure 11Figure 11 shows these top cited barriers grouped by the background of the respondent (numbers do not add up to 100%). The three factors—financing, regulatory and IP—were consistently cited as the main barriers to commercialization by different types of respondents. However, some differences were present. For example, neither engineering students nor faculty considered intellectual property (IP) threats to be a significant barrier.

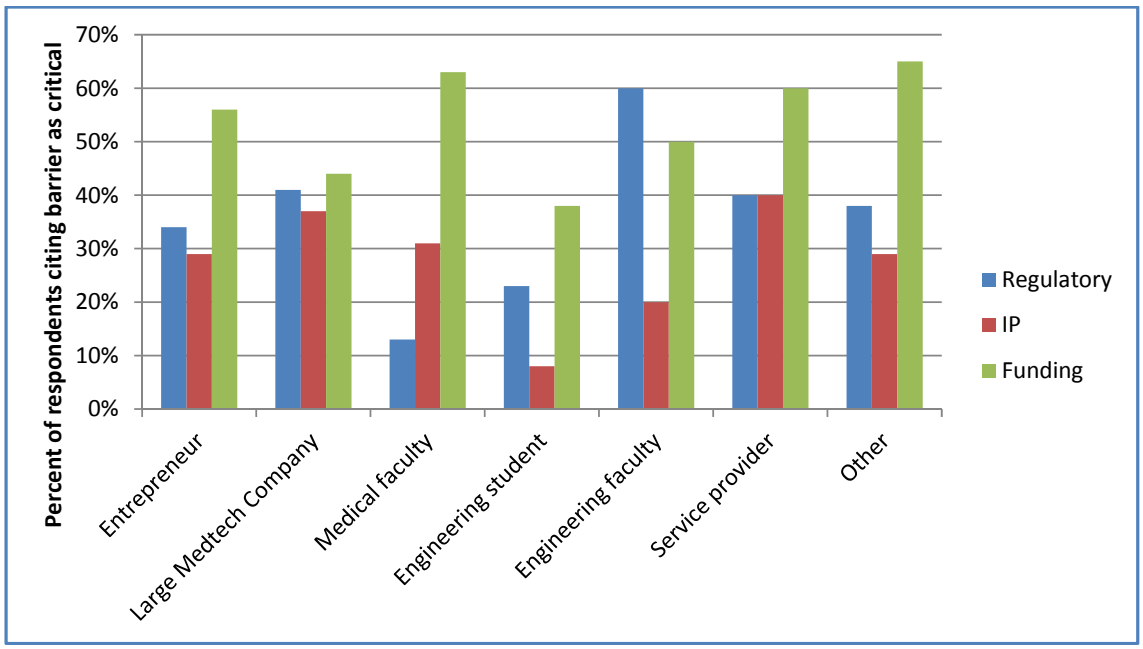

Figure 11: Top Cited Barriers by Respondent Type

Beyond the main challenges that were highlighted, several other factors were also listed as barriers to commercialization: clinical infrastructure, availability of experienced people, facilities for prototyping and manufacturing, and education of physicians. Interestingly, these barriers had been listed as the main hurdles facing entrepreneurs in a previous, similar survey conducted in 2010, also at the Annual Indian Medtech Summit. The 2011 survey showed that while it is not perceived to be

impossible to commercialize in India, it has not gotten significantly easier in the last few years. Further, it is not considered significantly easier to commercialize a Class 1 device (Class A in India) compared to a Class 3 device (Class D in India), pointing to a high barrier to entry in this sector of the market.

To further explore the nature of the barriers to commercialization listed above, several entrepreneurs and medtech company executives were interviewed. They were able to provide context and in some cases, a contrary viewpoint to the general survey results. Each listed barrier is detailed below.

BARRIERS TO COMMERCIALIZATION

Financing

Financing is a key necessity for early-stage medical device companies, and access to capital was an oft-cited barrier to commercialization in the survey. It indicated that while there are attempts on the part of government and the industry to boost entrepreneurship, they are not sufficient and the sector struggles to gather early stage funding.

Public Funding

The Government of India has been steadily increasing its engagement with the nascent medtech sector in the country. The current decade (2010-20) has been declared the "Decade of Innovation" [52] and a new science, technology and innovation policy will be released in 2013. As part of this push to encourage innovation, government funding of scientific research has been increased from 0.9%[53] to 2% of GDP[54]. There are several government agencies under the aegis of the Department of Science and Technology (DST) that offer research grants, fellowships, and soft loans or equity to technology entrepreneurs. For instance, Department of Biotechnology (DBT) has a Biotechnology Industry Partnership Programme (BIPP) for public-private partnerships and SBIRI (Small Business Innovation Research Initiative) which encourage innovators and companies through various means such as soft loans, grants-in-aid and partnerships and make funds up to Rs 50 Crores ($1M) available. In order to bridge the gap between invention and commercialization, DBT has recently made a new fund available under its Biotechnology Industry Research Assistance Council (BIRAC) scheme. Named Biotechnology Ignition Grant (BIG), this will be used to fund grants up to Rs 50 Lakhs ($100,000) for 18 months[55]. Table 5 shows the funding allotted to different funding agencies to promote scientific innovation in India.

---

[52] Indian Ministry of Science and Technology, "Decade of Innovation," Department of Science and Technology Press Release, 10 March, 2010, http://www.dst.gov.in/whats_new/press-release10/pib_10-3-2010.htm (March 6, 2013)

[53] "Annual Global Funding Forecast 2012," *Battelle*, December 16, 2011, http://www.battelle.org/media/news/2011/12/16/battelle-r-d-magazine-annual-global-funding-forecast-predicts-r-d-spending-growth-will-continue-while-globalization-accelerates (March 6, 2013)

[54] R Koul, "Public Funding in the Lifescience Zooms," *Biospectrum,* Oct 8, 2012

[55] BIRAC, "Programmes," http://www.birac.nic.in/programmes.php?prg=big (March 6, 2013)

Agency	Funding 2011-12 (Rs Crore)	Funding 2011-12 ($M)	Funding 2012-13 (Rs Crore)	Funding 2012-13 ($M)
DBT	1400	280	1485	297
DST	2349	470	2477	295.4
ICMR	622	124.4	700	140
ICAR	2800	560	3000	600
DSIR	1930	386	2013	402.6
Total	*9101*	*1820.4*	*9675*	*1735*

Table 5: Funding Available through different Government Agencies[56]

DBT funded projects in particular, such as the Stanford India Biodesign program (SIB) are managed by the Biotech Consortium India Limited (BCIL). The consortium funds innovators after sanction orders have been given by DBT.

Private Funding

Venture capital (VC) and private equity (PE) firms have significantly increased their activity in India over the last decade[57]. Starting with a focus on investing in IT companies, VC/PE funds in India have expanded their scope to include clean energy, services and healthcare sectors. Figure 12 shows the volume of PE and VC funding allocated to the healthcare sector in 2012, totaling about $268M to date.

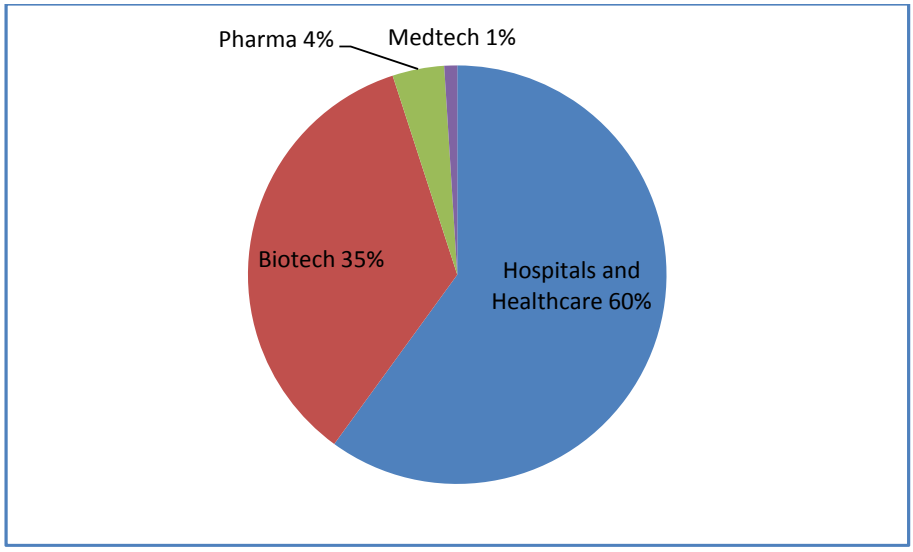

Figure 12: Private Equity and Venture Funding in Healthcare, 2011[58]

[56] Koul, loc. cit.
[57] R Jai Krishna, "India Private Equity Investments up 24% in 2011," *WSJ Deal Journal India*, January 12, 2012, http://blogs.wsj.com/dealjournalindia/2012/01/12/india-private-equity-investments-up-24-in-2011/ (March 6, 2013)
[58] Koul, "PE Investments in Biosciences," *Biospectrum* Oct 8, 2012

As it is clear from these numbers, medical technology is an extremely small piece of the funding pie in India. Still, the funding for medical devices is on the rise, as detailed by medtech deals completed in 2012, shown in Table 6 [59].

Deal	Amount ($M)	Investor
Insightra	8	Aarin Capital
Perfint Healthcare	NA	Norwest, IDG Ventures India, Accel India
Shilpa Medicare	1.6	Tano Capital
Sutures India	40	CX Partners
Consure Medical	.8	India Innovation Fund, India Angel Network, India Venture Partners
Vyome Biosciences	3.6	IndoUS Ventures, Navam Capital, Aarin Capital

Table 6: Indian Medical Device VC Deals in 2012[60]

Barriers

Despite the large numbers of funding avenues that the government has made available, there are very few that really cater to the funding needs of an early stage medtech startup, such as the new BIG fund. In interviews with SIB fellows who are in the process of developing new medtech products, it became clear that government grants were either too small to make a significant dent in their funding needs or so large that only more established companies could benefit from them.

Investment in the medical device industry in India competes for funds with established sectors in the Indian market such as Information Technology (IT). The IT sector is considered more lucrative in India, with the e-commerce industry booming and the considerable depth of experience present in India. Investors can expect 5-6X returns in just 2-3 years, which presents a lower-risk proposition than many medtech devices[61].

Discussions with several angels and venture capitalists including Jasmin Patel, an angel investor who has invested in a medical device company that has cross-border operations in India and US, indicated that funds for medical devices in the pre-commercialization stage are almost non-existent in India. The primary reason stated was that Indian investors are risk averse, and early-stage devices commercialization presents significant risk. Predominantly Indian investors have finance backgrounds, and as such do not feel comfortable investing in the medical device space. This is in contrast to the Silicon Valley/US investment community, where a number of investors have academic and professional backgrounds well suited to investment in pharmaceuticals and medical devices. The main challenges have to do with the immaturity of the medical device sector, limited domain-specific knowledge in the investment community for evaluating opportunities, and the unwillingness to sit on investments for 8-10 years, which is the average time required for a medical device company to become cash flow positive.

[59] Ibid.
[60] Ibid.
[61] "Venture capital beats private equity as Indian start-ups attract millions of dollars in funding". Economic Times, Feb 2012. http://articles.economictimes.indiatimes.com/2012-02-08/news/31037698_1_venture-capital-start-ups-private-equity

In conclusion, while limited funds exist for investments in the medical devices or related technology space, investments are held back due to a lack of familiarity with evaluating opportunities in medical technology as well as the availability of a booming alternate industry with shorter lifecycles and more predictable returns.

Regulation

Regulatory barriers were one of the three most cited barriers to commercialization in the survey. Medical devices are part of a heavily regulated industry worldwide and regulations touch every stage of the lifecycle of a medical device: research and development, clinical trials, premarket approvals, manufacturing, labeling and ultimately marketing. As a result, regulations represent both a barrier as well as a key opportunity in India's medical device industry.

Medical device regulation is relatively new in India, although pharmaceuticals have been regulated by the Central Drug Standard Control Organization (CDSCO) since 1940, under the Ministry of Health and Family Welfare. The Indian government proposed regulatory guidelines for medical devices in 2008, through amendments to the 1940 Drug and Cosmetics Act (DCA). New guidelines on applying drug rules to medical devices were introduced in 2012, and an updated bill will be presented to India's Parliament in 2013. The new bill is expected to bring all medical devices sold in India under the purview of the government agency charged with regulating medical devices, the Central Licensing Approval Authority (CLAA) which is under the CDSCO.

Whereas the DCA was originally meant primarily for drugs and pharmaceutical products, the new regulations attempt to regulate medical devices as a sector separate from drugs.[62] Based on advice from the World Health Organization, the U.S. Food and Drug Administration (FDA), the Global Harmonization Task Force and industry experts, medical devices are classified into four groups according to their risk level (see Table 7). In general, higher-risk devices are subject to stricter regulations and a more stringent pre-market conformity assessment process.

Europe	U.S.	India	Device Profiles
Class I	Class I	Class A	Non sterile items or sterile items with a low potential risk: surgical instruments, urine bags, stethoscope, examination gloves
Class IIA	Class II	Class B	Sterile items, surgical gloves, urinary catheters, stomach tubes, needles, tracheal tubes, IV giving sets
Class IIB	Class II	Class C	Blood bags, condoms, non-absorbable sutures, and anesthesia machines
Class III	Class III	Class D	All active implantable devices, cardiovascular catheters, absorbable sutures, heart valves, collagen implants

[62] Central Drug Standards Control Organisation, "Medical Devices," http://cdsco.nic.in/Medical_div/medical_device_division.htm (February 22, 2013).

Table 7: Classification of Devices[63]

For the moment, however, the CLAA only requires certain categories of devices that have been the subject of notifications in the Official Gazette of India (21 device categories in total) to register with CDSCO. These include cardiac stents, bone cements, intra-ocular lenses, orthopedic implants, and heart valves. Since CLAA currently requires pre-market reviews of only certain devices, all other devices do not require registration prior to sale in India.

Under current rules, CLAA oversees conformity assessment and awards the Indian Conformity Assessment Certificate (ICAC) mark, which allows a company to sell its medical device in India. Imported medical devices on the Notified Devices list that have already obtained approval in the United States (by the FDA) or the European Union (by CE Marking) are allowed on the Indian market without undergoing separate conformity assessment procedures. Conformity assessments can take from six months to one year to complete. The CDSCO website maintains a list of licensed indigenous medical device manufacturers of Medical Devices.[64]

Barriers

Although progress has been made, implementation of the new system has yet to become the norm. This in itself may not be a deterrent for entrepreneurs, as a relatively ineffective regulation may also translate into fewer bottlenecks. The lack of regulation increases the ease with which these devices get licensed when compared to a sophisticated regulatory regime with more stringent criteria for obtaining licensing. However, this environment also creates a lack of credibility for products on the market in the eyes of clinicians, their patients and the investors who may be interested in funding these products and companies. Until the standards are properly implemented across the board, it is difficult for doctors and others making procurement decisions to determine which products are truly worth purchasing. Also, healthcare is considered a state matter in India, subject to state laws and regulations. This can sometimes mean added bureaucracy and complications in the device registration process. [65]

Regulatory body	Approval	Timeline
Drug Controller General of India (DCGI)	For conduct of clinical trials (all phases	First response or approval within 45 working days
	For conduct of bioequivalence study for export	28 working days
IEC/IRB	IEC approval by various study sites	4-6 weeks (in parallel)
DCGI	Test license to import supplies	2 weeks
Total (parallel processing)	Not applicable	14 weeks
Bodies/sent for expert	Radiopharmaceuticals, stem cells, etc.	Additional 12 to 14 weeks

[63] Ibid.
[64] "ICAC Mark," http://www.icac.in/ (February 25, 2013).
[65] Private interviews

Table 8: Regulatory timelines in India[66]

Regulations affect not only product marketing but also areas such as import and export of devices. As mentioned earlier, over 75 percent of medical devices sold in India are imported, making import tariff structures very important to this sector as well. The Association of Indian Medical Device Industry (AIMED) has been petitioning the government to change the import duty structure so as to not favor imports of medical device parts as compared to finished medical goods[67]. AIMED argues that this structure dis-incentivizes the domestic medical device manufacturing industry. They are also lobbying for changes to the taxation structure of medical devices with an eye to making it uniform across different states[68]. These issues of tax law can act as barriers to innovation.

Although regulatory issues figured highly in the survey results, private interviews with early stage entrepreneurs downplayed regulatory barriers. In particular, interviews with SIB fellows indicated that they expected only to have to register their product in India before sales, without any significant clinical trials. Conversely, they mentioned that hospital procurement systems sometimes preferred to see clinical data in order to make a purchasing decision, and for this reason a CE Mark could be valuable as it signifies safety of the product[69].

Intellectual Property

In the survey, IP protection was the third most cited barrier to commercialization. IP enforcement traditionally has been weak in India. Before the Indian Parliament passed the Indian Patent Act in 2005 after ratifying the World Trade Organization's TRIPS agreement,[70] India enforced product patents but not process patents. As a result, companies could legally sell reverse engineered products in the Indian market. Although this phenomenon helped fuel the growth of a strong pharmaceutical industry in India, it also contributed to lax IP protection, a problem that persists to this day. Technology companies subsequently had a hard time protecting their IP in the Indian market.

Nevertheless, the post-TRIPS scenario for technology patents in India is encouraging. The Indian law recognizes utility patents, copyrights and trademarks as protected intellectual property, similar to other member countries of the World Trade Organization[71]. India follows a "first to file" rule. If two or more applicants apply for a patent for the same invention separately, the first applicant will be granted the patent right. Patents take between 3-5 years to be granted and the term is 20 years. India is a contracting state to the Patent Cooperation Treaty (PCT) and Indian patent holders can file

[66] B G Jaysheel, "Carrying out Clinical Trials in India," *Raj* Pharma, June 2010, http://www.acunovalife.com/pdf/whitepapers/RAJ_Pharma%20June%202010_Jayasheel%20final.pdf (March 6, 2013)
[67] Association of Indian Medical Device Industry, "About Us," http://www.aimedindia.com/ (March 6, 2013)
[68] Ames Gross, "Indian Medical Device Manufacturers push for Changes in the Industry," *Pacific Bridge Medical*, May 1, 2010, http://www.pacificbridgemedical.com/publications/indian-medical-device-manufacturers-push-for-changes-in-industry/ (March 6, 2013)
[69] Private interviews
[70] "World Trade Organization TRIPS Implementation," International Intellectual Property Alliance, http://www.iipa.com/trips.html (February 22, 2013).
[71] "Intellectual Property Rights," Embassy of India, http://www.indianembassy.org/intellectual-property-rights.php (March 5, 2013)

a PCT application. This allows the "priority date" or date of patent application to be recognized in other countries where the inventor may also wish to file a patent[72].

The number of patents filed each year has grown steadily (see Figure 13), with the telecommunications and pharmaceuticals industries dominating Indian Patent Office (IPO) filings. Judicial courts have tried several high profile cases of IP infringement. In particular, indigenous pharmaceutical companies have been aggressive in both their patent filing and defense strategies,[73] setting a crucial precedent for other high-tech industries in India. The pharmaceutical industry example also underscores IP creation and acquisition as a legitimate source of revenue in the Indian market and could be a viable business model for other companies in the healthcare sector.

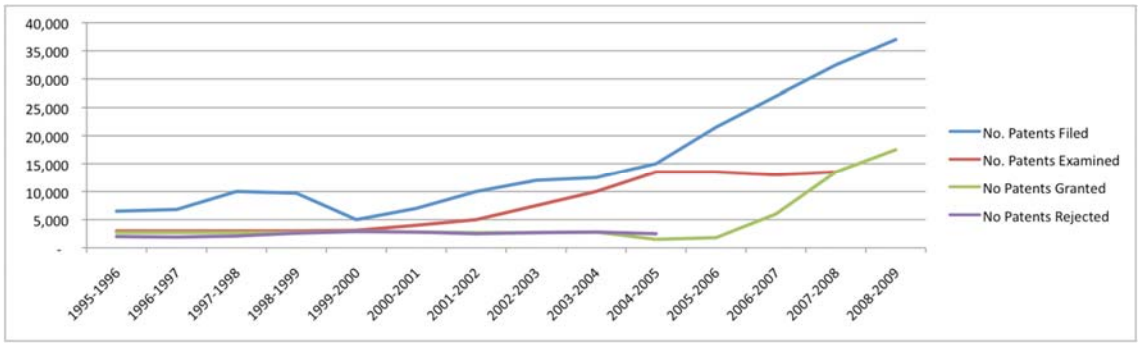

Figure 13: Patent Filing Trends at the Indian Patent Office[74]

Barriers

Fear of patent infringement is a constant concern for young medical technology companies, as indicated by interviews with several entrepreneurs. This makes prototyping difficult, especially for entrepreneurs. (Further details are discussed in the specific section on prototyping.) Entrepreneurs are hesitant to initiate discussions with small enterprises that could be potential partners in manufacturing or distribution, fearing that their IP might be replicated without giving them credit upon commercialization.

For example, Shitij and Mansi, SIB interns[75] who have invented a patient transfer device, were concerned that potential licensing partners might simply reverse engineer their invention and sell it under another name. As a result, they have chosen to seek a partnership with a large medical device company or MNC that has a strong brand, to make it difficult for smaller companies to replicate the product and gain significant market share. However, this route is complicated by many factors, most importantly the paucity of viable partners interested in commercializing third party products. Companies such as Embrace[76] (an infant warming device manufacturer) have an issued patent in the US and pending patent applications in India, but feel that strong partnerships and licensing agreements will be more important for protecting their IP than a portfolio of issued patents. Bharat

[72] "PCT Resources," World Intellectual Property Organization, http://www.wipo.int/pct/en/ (March 5, 2013)
[73] D. Sharma, "Pharma Patent War at Crossroads," *India Today*, March 28, 2012
[74] B Rawat, "Patenting Landscape in India," *IP Frontline*, Oct 21, 2009
[75] Private interviews
[76] Private interviews

Biotech[77], a firm specializing in developing vaccines and biologics that holds a 50 patent portfolio, believes that a better IP protection framework is required to stop companies from infringing IP developed by others. Ultimately, almost all parties expressed concern that the IP enforcement situation in India requires significant reform. Without the ability to enforce patents, young medtech companies are often forced to pursue suboptimal strategies to prevent infringement.

Ecosystem

In addition to the key barriers to commercialization that emerged from the survey, such as funding, IP, and regulatory, interviews with entrepreneurs and multinationals highlighted many other challenges present in the Indian ecosystem (see Table 9). Some of these challenges are discussed in greater detail here.

Interviewee	Description	Main Barriers
Patient Transfer Device	*Grant funded device in development*	Lack of prototyping facilities, IP protection, market research data, mentors for first-time medtech entrepreneurs in India
Intra-Osseous Access Device	*Grant funded startup*	Lack of trained people, manufacturing facilities, relevant partners, clear clinical pathways for acceptance of new medical devices
Limb Immobilization Device	*Product licensed to large public company*	Lack of funding for product licensing structures as opposed to building a company, lack of prototyping facilities, IP protection, market research data
Consure Medical	*Venture funded early-stage startup*	Lack of IP protection, trained people
Perfint Healthcare	*Venture funded growth-stage startup*	Lack of clear clinical pathways for acceptance of new medical devices, time required to educate/evangelize doctors about a new device, low quality of medical school education
Philips Healthcare	*Large multinational company*	Lack of transparency in government procedures such as device registration, difficulties in distribution channels

Table 9: Key Barriers to Commercialization cited in Interviews

Manufacturing

The present ecosystem offers little support for the high-grade manufacturing required by the medical device industry, presenting yet another challenge to commercialization. Despite a high number of small manufacturing outfits present throughout India[78], quality controlled and regulatory approved manufacturing remains the domain of larger companies with deep pockets that can set up proprietary manufacturing centers. Although the government has set up several Special Economic Zones (SEZ) in states like Tamil Nadu, Gujarat and Maharashtra[79], these cater to companies with the capacity for large capital outlays rather than smaller, young enterprises. Further, the current excise

[77] Private interviews
[78] Association of Indian Medical Device Industry, "About Us," http://www.aimedindia.com/ (March 6, 2013)
[79] SEZ India, "Facilities and Incentives," http://www.sezindia.nic.in/about-fi.asp (March 6, 2013)

duty structure favors medtech imports[80], reducing the competitiveness of the indigenous industry and discouraging local entrepreneurs from setting up manufacturing plants.

Prototyping and Testing

Building prototypes is critical to the development of a medical technology product and to demonstrate proof of concept of the invention. As previously mentioned, IP considerations limit an entrepreneur's options for creating prototypes. Further, the small quantities prototypes required at this stage of development cannot benefit from economies of scale, leading to increased development costs[81].

In absence of rigorous government regulation for all but 33 types of medtech products, most entrepreneurs need to rely on definitive clinical evidence in the favor of their invention in order to raise funds or get procurement contracts[82]. This requires a significant amount of clinical validation and testing of the device, which can be difficult to achieve in India, where there isn't a well-established clinical pathway for medical devices. Although India is fast becoming a key destination for global clinical trials, tightening regulations at hospitals and increasing costs are a source of concern for startup medtech companies hoping to test products in India. Getting approvals and conducting clinical trials in India is no easy feat. Approval is challenging due to delays and red tape. The following table summarizes the timeline for the approval of clinical trials in India[83]. The process can take from 6 months to more than a year.

Human Resources

Interviews with entrepreneurs in India pointed to the lack of experienced medical technology professionals as a barrier to developing new medical devices. Besides competing for available funds, the IT industry is a formidable challenge to the medtech industry in the area of talent as well. Anecdotally, service sectors like financial, IT and consulting draw the most interest among university students. While India has a large base of technical manpower with basic qualifications, it lacks trained and experienced professionals to undertake high-end research and development in the field of medical technology[84]. There does appear to be a growing focus on training talent for the medtech industry[85], though most programs are in their early years and will take time to mature. Skilled engineers who have a working knowledge of medical issues are difficult to find or are priced beyond the reach of a young startup company[86]. Further, the problem of attrition is a common one in India[87], and it does not spare the medical technology industry.

---

[80] Ames Gross, "Indian Medical Device Manufacturers Push for Changes in Industry," *Consultants Corner,* June 2010

[81] Private interview

[82] Private interview

[84] Raymond Tham, "Resolving India's Entrepreneurial Paradox: Key To Starting Up The Economy?" *EconomyWatch*, Dec 2012, http://www.economywatch.com/economy-business-and-finance-news/resolving-indias-entrepreneurial-paradox-key-to-starting-up-the-economy.07-12.html (March 6, 2013)

[85] "Texas Instruments and IIT Kharagpur to collaborate on breakthrough technology research," TI Press Release, April 1, 2008, http://www.ti.com/ww/in/news_detail/2008_2005/news_detail_IIT-Kharagpur.html (March 6, 2013)

[86] Private interviews

Another human resource scarcity is that of the "educated physician". Several interviewees referred to the process required to educate and evangelize physicians to order for their product to gain acceptance. This is a common rite of passage for medical devices around the world. However, in India this practice is difficult as physicians are often not open to the idea of trying new devices. The entrepreneur must expend considerable energy finding those one or two key doctors who can be early adopters of the invention.

Business Models

As discussed in the previous section on commercialization in India (page 8), the diversity of the Indian market and the complexity of the healthcare sector result in convoluted distribution channels and necessitate strong, multifaceted business models. Given the early stages of the medical device industry in India, it can be difficult for an entrepreneur to gather market data for understanding the invention space as it simply may not exist[88]. Further, predicate devices may not exist for the Indian market or if they do, their business models may not be replicable by a startup company. The infancy of the sector can also mean a dearth of mentors and advisors for entrepreneurs to leverage in their own development process. There has been significant growth of tech clusters all over India, with their own incubators and funding vehicles (see Figure 14). However, a lot of this growth has occurred in the IT sector, leaving the medical technology sector still starving for the support of a thriving ecosystem[89].

[87] "Attrition "Big Worry" for India's job market," *The Hindu*, March 23, 2012 http://www.thehindubusinessline.com/industry-and-economy/info-tech/article1564049.ece (January 13, 2013)
[88] Private interviews
[89] Jayant Sinha, "Why India Needs a 100 Incubators to Spark Mass Innovation," *Startup Central*, September 1, 2012, http://startupcentral.in/2012/09/why-india-needs-1000-startup-incubators-to-spark-mass-innovation/ (March 6, 2013)

Figure 14: High Tech Clusters in India[90]

[90] Sharma, op. cit. p. 529

Recommendations

Despite significant barriers to commercialization, the Indian medical technology industry is expanding and increasing patient access to medical devices. The Indian growth story is propelling changes in the healthcare sector: healthcare spending is projected to increase from about 2% to 6% of GDP in the next decade.[91] Up to 45% of the Indian population is slated to be covered by health insurance by 2020, up from about 2% of the population today.[92] Keeping pace with these advances, healthcare infrastructure is improving, with corporate hospitals investing in facilities in cities outside the major metropolises and driving growth of the hospital sector at 15% per year.[93] These inherent strengths of the Indian healthcare sector provide new opportunities for medical device innovation and commercialization. However, significant reforms are needed, both by the industry and the government, to enhance the number and quality of innovations in the medical device sector in India.

Funding: There have been major improvements in the funding landscape in the last two years. Private equity, grants and soft loans from the government, and angel investors have dramatically increased the funding avenues available to a medical device innovator in India. These changes must continue and grow, in order to satisfy the funding needs of entrepreneurs and to attract other innovators to the medical technology field. Studies conducted by the Planning Commission of India have concluded that over $55 billion of early stage financing will be required by Indian start-up companies over the next decade.[94] Significant growth is needed in the equity financing sector in order to meet those targets.

Regulations: While the lax regulatory environment in India can be beneficial for innovators, changes to the regulatory regime are required for several reasons. First, an unregulated market cannot protect the patient from unsafe products and this hinders the growth of the sector as a whole. Secondly, approval of products is a differentiator in the marketplace, allowing better and safer products to be successful. This benefit is lost to the innovator of a novel device in the absence of regulation. Finally, the current tariff and import duty structure dis-incentivizes indigenous medical device manufacturers because of the low duties on finished imported goods, resulting in a large trade deficit in medical technology. The Association of Indian Medical Device Industry (AIMED) has been petitioning the government to change the tax structure on locally made products to incentivize the domestic medical device manufacturing industry. The first step towards a better regulatory regime is the approval of the Medical Devices Regulation Bill[95] which creates a system of control, separate from that of drugs, for quality, safety and efficacy of medical devices in India.

Intellectual Property: The Indian patent office has undergone significant reforms since 2005, when the WTO agreement effects took place and both process and product patents were recognized.

---

[91] Espicom 2012, op.cit.
[92] Palash Mitra and Vikas Bhadoria, "Indian Pharma 2020," McKinsey and Company report, 2012, p. 19
[93] Ibid.
[94] "Creating a Vibrant Entrepreneurial Ecosystem in India," Planning Commission reports, 2012, p. 16
[95] Ames Gross, "India: New Medical Devices Regulation," *Pacific Bridge Medical*, July 5, 2011, http://www.pacificbridgemedical.com/news/india-new-medical-devices-regulation-bill-and-foreign-facility-inspections/ (March 6, 2013)

Adequate IP enforcement, especially in small businesses like prototyping shops and distributors, would greatly increase innovation in technology sectors of the Indian market.

Ecosystem: There are various elements that make up a successful innovation hub like Silicon Valley: proximity of research universities, availability of venture funding, a culture that accepts failure, and plentiful opportunities for like-minded individuals to connect and work together. Encouragingly, all these elements are available in India to a certain degree. For a medical technology innovation ecosystem to flourish in India, these elements must converge in select locations. Our research shows that Indian healthcare entrepreneurs are also starved for appropriate mentorship from experienced mentors and necessary infrastructure for startup companies. It has been suggested that India needs over 1000 incubators in the next decade in order to serve the needs of entrepreneurs.[96] Such measures, if implemented, would accelerate the growth of the Indian medtech industry.

We recommend several policy level changes to incentivize innovators and reduce barriers to commercialization of new medical devices. First, the Medical Devices Regulation Bill[97], drafted and presented to the Parliament first in 2006 and then again in 2012, should be approved to streamline all laws concerning medical devices in India. Second, adequate IP enforcement would improve innovation in all technology sectors of the Indian market. Third, medical technology should be introduced to medical students as part of their coursework at college so that future doctors are open to adopting new technologies as part of their practice of medicine. Fourth, engineering students should be exposed to medical technology in order to create a pool of skilled engineers who can develop new medical devices appropriate for the Indian setting. Last but not the least, different stakeholders of the Indian medical technology industry, such as startup companies, investors, entrepreneurs, multinational companies, management schools, medical and engineering colleges and government organizations, should embrace opportunities to engage with each other and build networks to help commercialize new medical technologies. The Indian growth story, which is slated to add 500 million people into the middle class by 2025, up from 50 million today[98], presents enormous opportunities for healthcare innovation, and the medical technology industry must seize them.

[96] Jayant Sinha, op.cit.
[97] Ibid.
[98] Sumit Gupta, "The Bird of Gold: The Rise of India's Consumer Market," *McKinsey Global Institute,* May 2007, http://www.mckinsey.com/insights/mgi/research/asia/the_bird_of_gold (March 6, 2013)

Acknowledgments

We would like to thank all the entrepreneurs and investors who completed the surveys and gave us their time during the interviews. We would also like to the thank Jaipreet Bindra, Atul Verma, Nikhil Sikri, Sayekiren Ravindran and Professor Anand Nandkumar from the Indian School of Business and Reshma Karipineni and Ankur Gigras from the Stanford Graduate School of Business (GSB) for their help conducting research for this paper. Prof. Stefanos Zenios and Lyn Denend from the Stanford GSB's Program in Healthcare Innovation were also helpful in identifying sources of funding for this research. We would like to thank the Stanford University Freeman Spogli Institute for their financial support.

Appendix I: 2011 Survey

1. Are you currently:
    a. Working for a large medtech company
    b. An entrepreneur or working for a small medtech company
    c. An investor (corporate house, private equity, venture capital, individual, etc)
    d. An engineering faculty
    e. A medical faculty
    f. A Clinican/Physician/Surgeon not affiliated with a teaching hospital
    g. A hospital administrator
    h. An engineering student
    i. A medical student
    j. A service provider (consultant, lawyer, etc.)
    k. A vendor (prototyping, CRO)
    l. A distributor/marketer
    m. A government official/ regulator, policy maker
    n. Other (specify) _____

2. How difficult is it to commercialize medical technologies in India? Please indicate on a scale of 1 (easy) to 5 (difficult):
    a. Commercialization of medical technologies is possible without difficulty
    b. Commercialization of medical technologies is possible with minor issues
    c. Commercialization of medical technologies is possible with some difficulty
    d. Commercialization of medical technologies is possible with significant difficulty
    e. Commercialization of medical technologies is not possible in India
    f. Don't know

3. Over the past 5 years, has it become easier or more difficult to commercialize new medical technologies in India? Please explain:
    a. It has become significantly easier _____
    b. It has become somewhat easier _____
    c. It is neither easier nor more difficult _____
    d. It is somewhat more difficult _____
    e. It is significantly more difficult _____

4. For each class of device, please indicate the difficulty of commercialization on a scale of 1 (easy) to 5 (difficult) or 6 (don't know):

    Class 1 (basic med supplies, i.e. gloves, bandages, hand-held surgical instruments): _____
    Class 2 (such as wheelchairs, infusion pumps, surgical drapes):_____
    Class 3 (such as implantable pacemakers, pulse generators, HIV tests):_____

5. How significantly do the following factors impede the commercialization of medical technologies in India? Please indicate on a scale of 1 (not a challenge) to 5 (presents significant challenges):

    a. Regulatory/ approval
    b. Obtaining funding
    c. Manufacturing
    d. Distribution
    e. Clinical Infrastructure
    f. Other (please describe): _____
    g. Prototyping
    h. Recruiting talent
    i. IP protection
    j. Marketing/Sales
    k. Education of physicians

6. In which areas of medical technology are you seeing the most innovation? Please indicate on a scale of 1 (not much activity) to 5 (lots of activity in this space):
    a. Cardiovascular
    b. Orthopedic
    c. Diabetes
    d. Surgery
    e. Ophthalmology
    f. Diagnostic/Monitoring
    g. Pediatric
    h. Emergency medicine
    i. Other (specify) _____

7. In the space below, please specify 3 things that you would like to see done to help promote a vibrant medtech system to serve India's clinical needs.