Intellectual Property Protection in India and Implications for Health Innovation: Emerging Perspectives

Rakesh Basant
Shuchi Srinivasan

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Intellectual Property Protection in India and Implications for Health Innovation: Emerging Perspectives[1]

Rakesh Basant[2]
Shuchi Srinivasan[3]

Abstract

With the advent of TRIPS, the IP regimes have changed in most WTO member countries. India also came up with its own version of TRIPS compatible IP regime which has been hailed by some as a 'model' regime for developing countries, while others are not convinced that it will provide the right incentives for medical innovation and enhance access to healthcare. This paper undertakes a review of available studies to provide a perspective on the role of IP protection in developing healthcare innovations. Broadly, the relevant literature in the context of India has followed two strands: some studies focus on the implications of the new IP regime on access to healthcare, while others explore the implications of IP on innovation in general and medical innovation, in particular. Interestingly, the two strands do not converge. Moreover, many studies view IP driven innovations as a constraint on access, as these are expected to be monopolized by the IP owner. We argue that there is merit in viewing healthcare access and innovation as complementary processes. This is particularly the case when one defines 'health innovation' more broadly to include:(a) Product innovations in drugs; (b) Process innovations in pharmaceutical industry; (c) New drug delivery mechanisms , bio-enhancers and dosage forms; (d) Product innovations in medical equipment and devices; (e) Innovations in the delivery of health services; and (f) Policy innovations to enhance access to healthcare.

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[2]Professor of Economics, Indian Institute of Management, Ahmedabad, India. (Corresponding author and can be reached at rakesh@iimahd.ernet.in)
[3]Doctoral candidate at the Indian Institute of Management, Ahmedabad, India.

1. Introduction

It is not always possible to attribute all the above changes to the change in the IP regime as firms and governments strategically innovate for a variety of reasons. However, in this review, we focus on three types of 'innovative responses' that may affect healthcare access and innovation, as these may be, at least partly, a response to the changes in the IP regime:

1. Changes in innovation inputs and outputs, reviewing studies that capture implications of IP for changes in R&D, technology licensing (or collaboration), patents and other innovations at the firm level;
2. Other strategies followed by firms to cope with the changes in IP regime including M&A, JVs, etc.; and
3. Institutional/policy innovations associated with the emerging situation in the healthcare sector, including the changes in the IP regime, to provide better access to healthcare.

The following section provides a broad overview of the Indian pharmaceutical industry and healthcare provision in India. Section 3 briefly discusses the changes in IP policy in recent years to help appreciate other policy and health related innovations. The subsequent three sections summarize the insights from the literature and available evidence on the three dimensions described above. The final section concludes.

2. Pharmaceutical Industry and Healthcare Provision in India: An Overview

2.1 Pharmaceutical Industry in India

The Indian pharmaceutical industry remained import dependent till 1972, deeming most of the drugs unaffordable (Mohammad &Kamaiah, 2014). Political and policy developments in the early 1970's such as the new patent acts of 1972 and Drug Price Control Order (DPCO), 1970 laid the foundation for a strong pharmaceutical industryin India. Public sector focus on pharmaceutical industry and policies that curbed control of multinationals added to this conducive policy environment that led to the growth of domestic firms and establishment of India as a dominant supplier of pharmaceutical drugs across the world (Basant, 2007). In the pre-TRIPs regime, the absence of product patents allowed local production of patented drugs at a fraction of the original cost while process patents encouraged generic companies to reduce the production costs of drugs.India's compliance with the TRIPS regime that became complete in 2005 has changed strategic options of Indian pharmaceutical firms.

In the year 2013, the Indian pharmaceutical industry was the "third largest in the world in terms of volume"(Horner, 2014) estimated to be worth $ 10 billion in 2010(Gabble & Kohler, 2014).Of about 10500 units engaged in the production of drugs and pharmaceuticals, only about 23 per cent produce bulk drugs; the remaining are engaged in the manufacturing of formulations. Moreover, most of these units are in the unorganized or small sector with approximately 250-300 units that can be categorized as organized or medium/large (Planning Commission, 2012a). The industry also has a very skewed distribution with the top 10 manufacurers accounting for almost 37% of market share (Planning Commission, 2012b).Generic manufacturers dominate the Indian pharmaceutical industry and remain pivotal in providing essential drugs at affordable prices. Patented drugs, on the other hand, comprise approximately 1% of the pharmaceutical market in the country (Kochhar, 2014).

Indian Pharmaceutical Industry at a Glance
• 3rd largest in terms of Volume; 10% of global volume
• 14th largest in temrs of Value; 1.5% of global value
• Prior to 1970's foreign players controlled 80% of the market
• Domestic market size is approximately USD 5.3 billion
• In 2013 Indian pharmaceutical Imports amounted to USD 2.7billion
• In 2013, Indian Pharmaceutical Exports amounted to USD 8.9 billion
• The ten "big" pharmaceuticals control 36% of the Domestic Market

Source: Horner, 2014, Haley & Haley, 2012, Bedi, Bedi, &Sooch, 2013 and Department of Pharmaceuticals, 2014.

2.2 Healthcare in India

Health policy in India has historically centered around the idea of equity. More recently, it has been broadened to incorporate the subject of universal healthcare. Ironically, despite the focus on equity, accessibility and quality, India shoulders a high morbidity and mortality burden (Balarajan et al., 2011) and requires innovative solutions to reduce them.

The State in India intervened directly in the healthcare sector by providing health services through a chain of public hospitals and Primary Health Centers (PHCs). But a variety of deficiencies plagued the efficacy of the healthcare system. One of the central drawbacks has been limited expenditure in the sector (Duggal, 2007; Selvaraj & Karan, 2009). The National Health Policy, 2002 directed the state to commit to universal health care through a "realistic"

consideration of capacity (MoHFW, 2002). The policy document identified its limited capacity (infrastructure and resources) as a key challenge towards making healthcare available to all.

Expenditure on health has remained only about 1% of the GDP in 2011-12 (Planning Commission, 2012b: p.4). Over the years, the state's inability to provide for the health needs of the population has resulted in the growth of the private healthcare sector. Currently, India is one of the most privatized systems in the world (Abhiyan, 2012; Duggal, 2007). The state's strategy to withdraw from the public provision of healthcare has been criticized due to the associated increase on the costs of healthcare (Duggal, 2007; Selvaraj & Karan, 2009). Moreover, the recent move by the Federal government to reduce the health budget by 16-17% would imply lower state involvement in the provision of public health (The Economic Times, 2014) and may further increase the cost of healthcare for Indian households unless state governments who are expected to receive more resources from the Federal government use these resources in a more innovative and efficacious manner.

Nonetheless, the 12th five-year plan (2012-17) had outlined universal health coverage as a central goal proposing an innovative strategy of combining insurance (Rashtriya Swasthya Bima Yojana), contracting out services and promotion of generic drugs through prescription drug reforms(Planning Commission, 2013). Such innovative policies are critical for providing affordable healthcare and reduce the out of pocket expenses on the same. A significant fraction (72%) of out of pocket expenses on healthcare is incurred on the purchase of drugs and other medical devices (Kumar et al., 2011). Deregulation of drug prices in recent years had led to an increase in the prices of branded drugs within the country (Bhargava & Kalantri, 2013) and has been brought back partially. Consequently, access to affordable medicines remains a critical issue and any policy or other innovation that can reduce costs would be very useful.

3. Changes in the IP regime and IP Policy Innovations

As mentioned, it is not possible to easily attribute health-related innovations in recent years to the new TRIPS regime as a variety of other confounding factors are at work. Therefore, we do not posit any such linkage. This section provides a brief summary of the new IP regime that highlights the policy innovations that the Indian government has undertaken as a part of

the new regime. Additionally, the section identifies a few IP policy gaps that have surfaced and need correction.

As discussed, the earlier IP regime's protection of process and not product inventions resulted in Indian firms' focus on process innovation and building of capabilities to produce bulk drugs in a very cost-effective manner. There is no consensus on the impact of the new IP regime on the innovation climate in the Indian pharmaceutical industry; while some suggest that the impact has been positive (Bouet, 2014; Godinho & Ferreira, 2012), others argue that the impact has been negative or insignificant (Mani, 2014; Chaudhuri, 2007). Still others argue that while the jury is still out, interesting firm responses in terms of innovation can be seen (Basant, 2011).

A number of firm-level and state-level strategies have helped the industry to adapt to the changes in the IP regime. During the pre-TRIPS period the growth of the domestic public sector and policies relating to science and technology, taxation, and FDI empowered Indian pharmaceutical industry to adapt to the changes in the institutional environment and grow. (Agarwal, Gupta & Dayal, 2007). In recent years, the liberalization policies, TRIPS-compliant patent regime, and other policy support has resulted in a steady flow of inputs to support product and process innovations: post TRIPS regime has seen an increase in the FDI and technology transfers directed towards India (Agarwal et al., 2007; Rai, 2008; Chittoor et al., 2008).

While some critics of the TRIPS compliant IP regime have argued that the new IP regime would lead to a rise in the prices of drugs and expose domestic manufacturers to the vagaries of international market fluctuations, others suggest that provisions to protect domestic consumers and manufacturers are in place (Mani, 2014). These have taken the form of conditions for compulsory licensing[4] (Section 84) and standards of patentability (Clause

[4]Compulsory license provides national governments to allow manufacturers/ companies to replicate products and processes under patent. If the following conditions are met, a compulsory license can be given, three years after the issuance of a patent: (a) The reasonable requirements of the public with respect to the patented invention have not been satisfied; or (b) The patented invention is not available to the public at a reasonable price; or (c) The patented invention is not worked in India.

3d[5]).These provisions attempt to balance the two ideals of ensuring "access to medicines" and fostering innovation.

3.1 Policy Innovation to Avoid Evergreening

In the year 2006, Novartis applied to the Indian patent office seeking a patent for its formulation Glivec. The application was rejected as the IPO viewed the move as an attempt towards "evergreening". Glivec or ImatinibMesylate is a formulation used in the treatment of blood cancer or Chronic Myeloid Leukemia (CML) and costs $ 5,000. The cost of the medication acted as a strong barrier to many Indians who sought treatment. On the other hand, the generic variant of the drug is available in India for a meager $200.

Novartis applied for a patent in the year 1998, and in 2005, was granted exclusive marketing rights and the application was "mailboxed" for consideration (Chaudhuri, 2014). The patent application was rejected under clause 3(d) of the Indian Patent Act on the grounds that the formulation was a "modification" of the existing drug and does not enhance efficay adequately. (Gabble & Kohler, 2014; Chaudhuri, 2014). Post the rejection of the plea in 2006, Novartis challenged the decision in the Supreme Court of India. The court backed the ruling and rejected Novartis' appeal for a patent in 2013. It has been suggested that since the Indian patent legislation does not define the term "efficacy". Hence, the difference in interpretation led to the rejection of the appeal (Gabble & Kohler 2014).

On March 4, 2015, using Article 3(d) the Indian Patent Office revoked Boehringer Ingelheim Pharma GMBH & Co.'s patent covering the drug 'Spiriva' in a response to a *post-grant opposition* filed by the Indian generic drug-maker, Cipla. Interestingly, a *pre-grant opposition* was also filed by another domestic firm in 2007 but the patent was granted.[6]

3.2 Compulsory Licensing

In 2012, Natco Pharma was granted a compulsory license to manufacture generic variant of the Nexavar drug. Nexavar is the original formulation of Bayer and is used in treating kidney and liver cancer. The drug costs $ 5500 vis-à-vis the generic variant that costs $141 (Kochhar, 2014; Hirschler, 2014). Bayer contested the license in the Indian court and lost (Hirscheler, 2014). The arguments used were that the drug availability did not meet the

[5]Clause 3d states that the discovery of a variant of an existing substance or process that does not enhance efficacy significantly is not patentable. The clause attempts to discourage frivolous inventions.

[6] http://ipindiaservices.gov.in/decision/00558-DELNP-2003-9637/558-delnp-2003%2025(2)%20decision.pdf

reasonable requirements of the public, that it was not reasonably affordable and was not sufficiently worked in India, not being locally manufactured.

3.3 Some Issues Relating to the Validity of the Patent

The Indian IP policy has received wide criticism as it is seen to favour domestic manufacturers (Kochhar, 2014; Gabble & Kohler, 2014). Both the patentability and compulsory licensing criteria have been criticized, apart from cumbersome patenting procedures (OPPI, 2014). However, many argue that the current patent regime increases the vulnerability of small and medium enterprises (SMEs), a segment that dominates the Indian pharmaceutical industry but cannot compete with "big" pharmaceutical companies (Agarwal et al., 2007). These enterprises do not possess deep pockets to engage in technology transfers, marketing, new drug discovery, and acquisitions.

While some provisions reported above are expected to enhance access and ensure that genuine inventions get patented, some others may increase the vulnerability of SMEs and may be detrimental to the promotion of inventive activity and innovation. For example, Section 13(4)[7] under the patent act asserts that granting of a patent to the inventor does not automatically ensure validity of the patent. The ambiguity in the law can prove detrimental to several small Indian firms investing heavily in R&D.

The process of granting of a patent requires the application to go through a number of filters to validate the patentability of the invention. Once conditions of novelty, non-obviousness and industrial application are satisfied, the patent is granted. Like in many other countries the Indian patent act has provisions for *pre- grant and post-grant opposition*, which some find quite onerous (OPPI, 2014) but enhance the efficacy of scrutiny and, as discussed above, have helped revoke patents. However, the presence of Section 13 (4) makes copying easy and stalls infringement action. These combined with the delays in the judicial process work against the inventor and undermine the technical and legal checks provided by the pre-and post-grant opposition processes. Indeed, there have been cases that large firms have copied inventions of small pharmaceutical firms in India adding significantly to the costs of protecting IPRs by the inventive SMEs. The case of the 75ml Diclofenac Injection[8] by

[7]Clause 13(4) states that granting of a patent does not necessarily translate into validity of the patent.

[8] In the February, 2005, Troika pharmaceuticals filed for a patent for its invention: the 75ml Diclofenac Injection, an anti-inflammatory drug. In the following years other companies filed for patent applications presenting a formulation similar to that of Diclofenac injection. Additionally, the grant process was delayed due to the procedural hurdles in the form of measures for pre grant and post grant oppositions.

Troikka Pharmaceuticals provides a strong case, suggesting that Section 13 (4) can be dysfunctional. Notably the courts in the US and Europe treat the patent valid and thereby curb frivolous challenges and facilitate quick infringement action.

4. Innovations in the Indian Pharmaceutical Industry

This section discusses technology innovations and strategic responses by pharmaceutical firms including changes in R&D expenditures and organizational innovations. Studies show that organization level changes have backed the institutional change introduced in the form of a changed patent regime. While Kale & Wield (2008) argue that the new regime has provided India with the opportunity to "exploit" its advantage at reverse engineering and "explore" the area of enhanced R&D in medical innovation, Haley & Haley (2012) suggest that the Indian pharmaceutical industry has been adversely affected by the policy change.

4.1 Manufacturing Capability and ANDA Approvals

The dominant perspective, however, is that given the focus on process innovation during the pre-TRIPS period , India acquired a competitive advantage in the production of quality bulk drugs (Chittoor et al., 2008). This initial strength in "imitative" capabilities provided a fertile ground to develop "innovative" capacities with changes in technology and policy (Kale & Little, 2007). Consequently, the number of FDA approvals obtained by Indian pharmaceuticals has greatly increased. Exploiting this opportunity with better production processes, India is currently one of the leading generic drugs manufacturers. In fact, India manufactures eight out of the ten "blockbuster drugs" (Agarwal et al., 2007). The process innovation driven building of manufacturing capabilities, fostered by the pre-TRIPS regime, has helped Indian pharmaceutical firms capture a significant share of ANDA approvals in the US. In recent years, India's share has been more than 40 per cent (Fig. 2) despite the increasing cost of compliance.

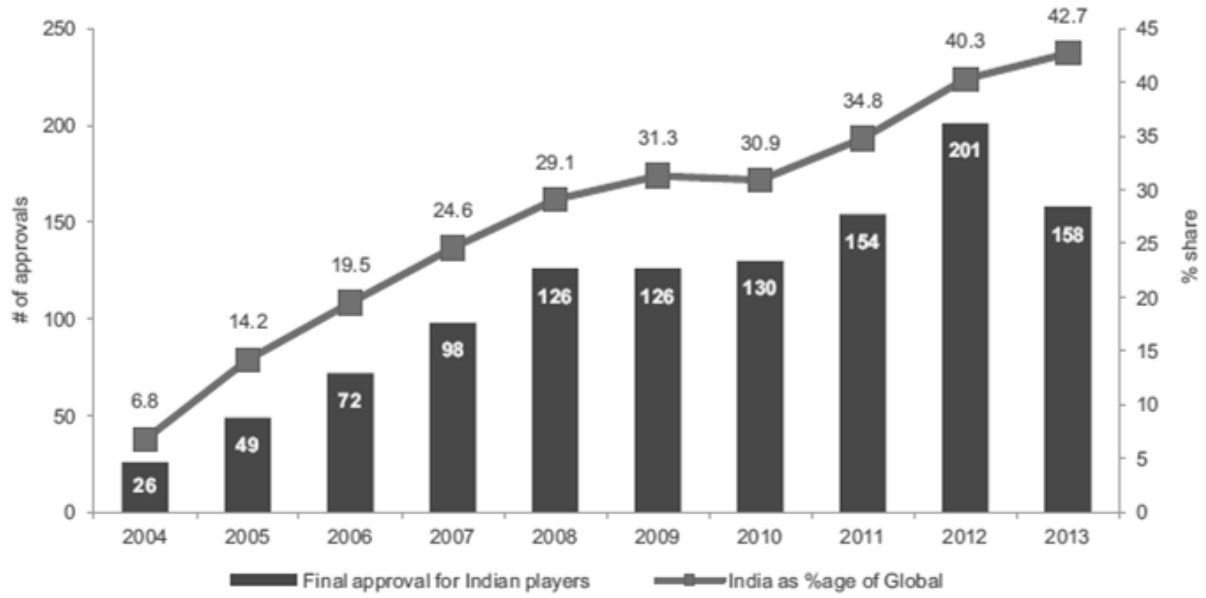

Fig 1: Trends in ANDA Approvals in the US for Indian Companies

Source: CRISIL (2014), Figure 7, p. 7. (http://www.crisil.com/Ratings/Brochureware/News/V5-Pharma%20Article%20EdV3.pdf)

4.2 Trends in Patenting Activity

The post-TRIPS regime has witnessed greater investment in R&D (Jagdeesh and Sasidharan, 2014). A detailed econometric exercise has shown a shift to a stronger IP regime has resulted in greater thrust in the R&D activity in the sector (see some estimates below) and domestic firms have also increased patenting in India and abroad (Goldar et al, 2010). Within pharmaceutical R&D, there has been a significant increase in the focus on novel drug discovery (Agarwal et al., 2007), although new dosage forms remain dominant among product patents. The data on PCT applications (Figure 1) suggests that in anticipation of the change in the IP regime in India in 2005, the top Indian pharmaceutical firms showed an increase in inventive activity. In the subsequent period there has been a trend decline in PCT applications by these pharmaceutical firms. Although, the reasons for this decline are not very clear, studies had observed a global downtrend in the patent applications during the crisis period in the late 2000s and beyond.

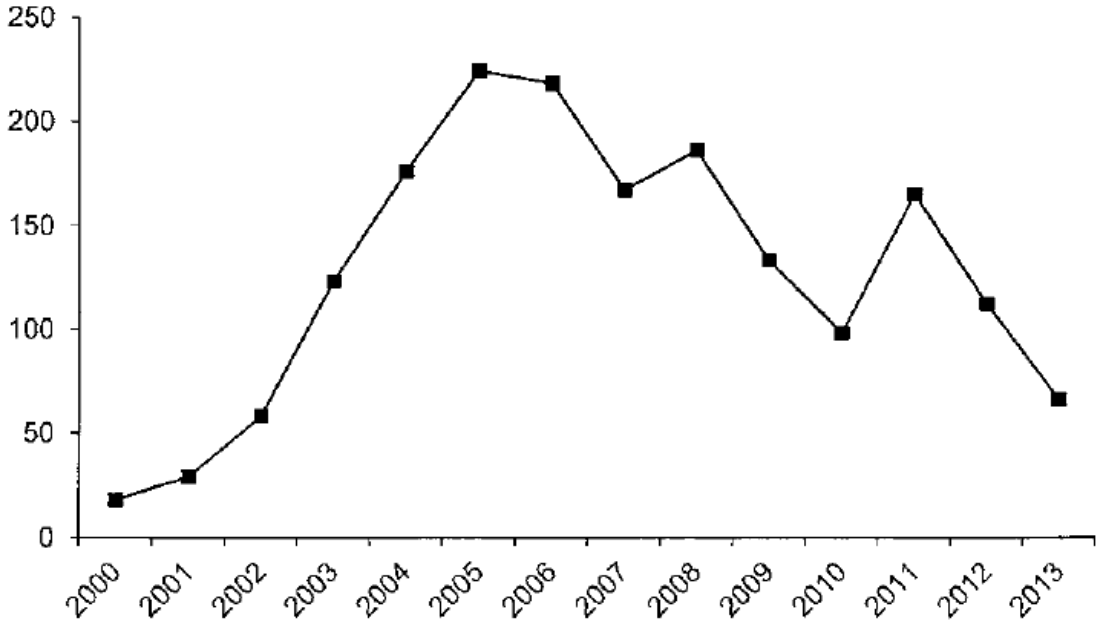

Figure 1: Total PCT Applications filed by top 10 Indian pharmaceutical companies

Source: Tyagi et al (2014), Fig 4.

The patent filing activity in the Indian Patent Office has increased dramatically in recent years (Table 1). Overall, the top pharmaceutical firms seem to have engaged significantly more in inventive activity in the post-TRIPS period. A comparison of the patenting activity of the top eleven large pharmaceutical companies during the period 1999-2009 has brought out some interesting patterns (Bedi, Bedi and Sooch, 2013). During 1999-2004, when product patents in pharmaceuticals were not permitted, a much larger share of applications related to inventions in the field of new/improved processes to make products than for the products themselves (Figure 2). There has been an increase in the product patent applications filed by large Indian pharmaceuticals companies after 2005 (Figure 3). The product related applications include intermediates and formulations with maximum contribution from modified release dosage forms. Besides, most top companies are increasingly using the PCT route for filing patent applications. (Bedi, Bedi and Sooch, 2013). Patenting by SMEs in the sector is, however, small although as we shall see below patenting is widely prevalent among start-ups in this sector.

Table 1: Status of Patents Filed at the Indian Patent Office				
Patent	2002-03	2005-06	2009-10	2012-13
Filed	11466	24505	34287	43674
Granted	1379	4320	6168	4126

Source: Compiled fromController General of Patents, Designs, Trademarks, Annual Reports 2005-06, 2009-10 & 2012-13.

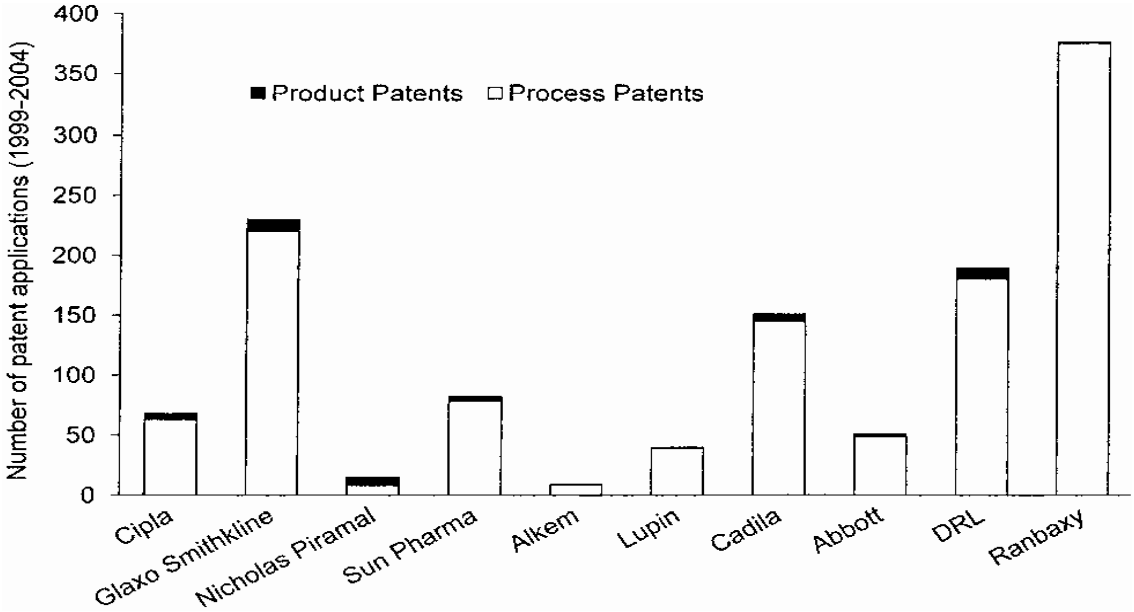

Figure 2: Patent Applications Filed in India (1999-2004)

Source: Bedi, Bedi and Sooch (2013), Figure 1, p. 106

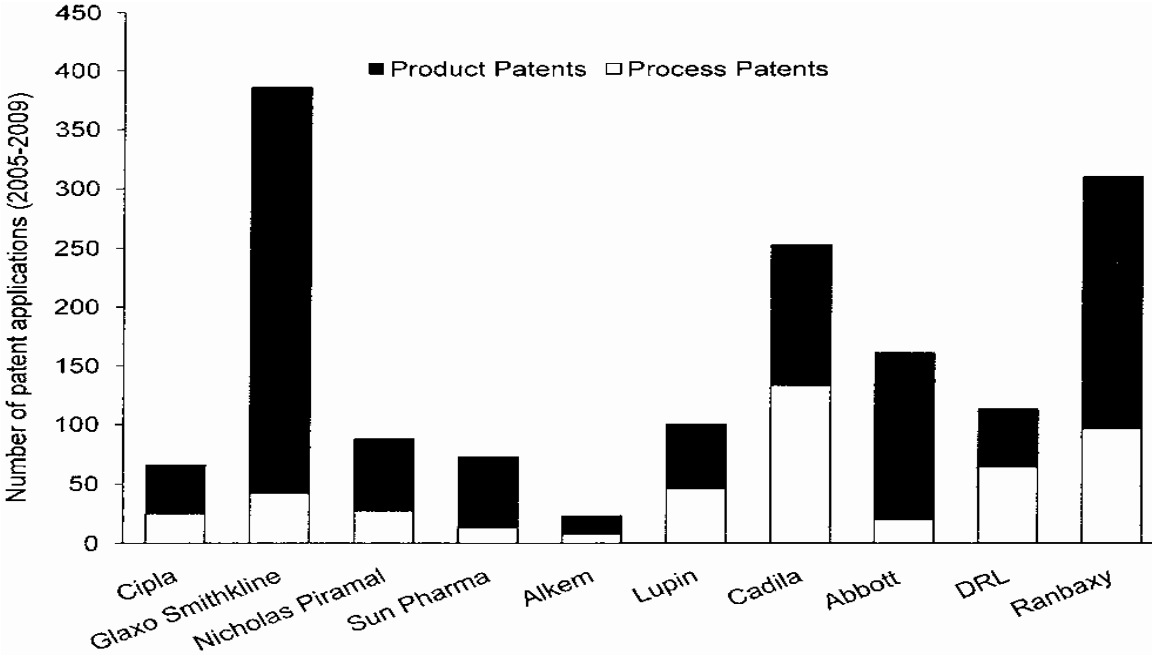

Figure 3: Patent Applications Filed in India (2005-2009)

Source: Bedi, Bedi and Sooch (2013), Figure 2, p. 106

Apart from New Drug Discovery a number of firms are also participating in Novel Drug Delivery Systems (NDDS). Firms like Ranbaxy, Alembic and Dabur have been able to produce NDDS formulations with great success and have as a result also entered into licensing agreements with foreign players (Joseph, 2012). In an earlier study, it was shown that while few pharmaceutical and biotech firms in India patent in the US, a significant proportion (ranging from 48-59% depending on the estimates used) of these firms have product claims. However, most (about 55%) of these applications are for incremental inventions including those relating to bio-enhancers, new dosage forms, new use and NDDS (Basant, 2011).

In vaccine development, Rotavac Vaccine presents a salient example of indigenous innovation. Rotavirus diarrhea is a major cause of death amongst several children from poor socio-economic backgrounds. Estimates suggest that rotavirus accounts for 37% of diarrhea related deaths globally and 22% of diarrhea related deaths amongst the under-five age group in India (Bhaumik, 2013;N. Mehta, 2015). Pioneered by Indian pharmaceutical company, Bharat Biotech, the three dosage vaccine displayed 56% higher efficiacy and is available at a fraction of the current cost. This provides an example of tropical and other deseases where the magnitude presents a profitable opportunity to innovate and achieve economies of scale and low cost solutions.

Despite the evidence of higher inventive activity, studies in the domain of biotechnology provide divergent perspectives; while some argue that the changed patent regime has benefitted in the take-off of the knowledge intensive sector (Agarwal et al., 2007), others suggest that it may not have contributed at all (Ramani & Maria, 2005). But all the studies reviewed make a case for the immense potential the sector holds in delivering for the medical needs of the future. The writings recommend focus on off-patent products such as bio-generics, vaccines and diagnostics arguing that reengineering is the true edge required for establishing Indian biotech competence on an international stage (Ramani& Maria, 2005). Besides, given the decentralization of drug development process, Indian firms are finding niches to become part of the international R&D networks. (Basant, 2011)

4.3 Entrepreneurial Innovation

High penetration of mobile phones and the Internet in India has fostered a variety of innovative medical devices and healthcare solutions. Many of these have been introduced through start-ups as these increasingly provide profitable business opportunities and also have a social impact by enhancing healthcare access. Many of these innovations currently lie outside the ambit of TRIPS and once scalable, the products hold great potential to address a variety of public health concerns.

While there is a fair bit of entrepreneurial activity in the healthcare provision, many IP based biomedical start-ups have also been set-up in recent years. Unfortunately, there is no systematic database of such start-ups. A recent survey of 50 such companies has brought out two very interesting features[9]:

a. There is a fair bit of diversity among these IP based biomedical startups. Firms provide diagnostics products, biologics & services, medical devices, small molecule drug discovery, chemistry based or other drug discovery services and software based services; and
b. Almost all (44 out of 50) either have some sort of IP or plan to have it in future. More than 50% (27) of these firms have either filed for patents or have patents issued in their name and an additional 20% (10) plan to file for patents. Interestingly, apart from protecting their technologies from imitation,

[9]These observations are based on a personal communication from Dr Gayatri Saberwal who has undertaken this survey.

patenting is used by them to attract venture capital, enhance reputation and improve their bargaining power in inter-firm deals.

Innovation possibilities in medical devices seem quite high. Available estimates suggest that the market size of this sector is about USD 2400 Million (Planning Commission, 2012a) and is growing at the rate of 16% annually (Pulakkat, 2014). About 75% of the medical devices available in India are imported (Jaroslawski & Saberwal, 2013). Entrepreneurship in this arena has targeted low-cost innovative solutions but in the absence of the required resources (infrastructure, capital, and technical know-how), innovations in non-drug based products remains gravely underinvested.

Broadly, innovative entrepreneurial solutions in healthcare have taken three forms; replacing, supplementing and enabling the public sector or established private sector endeavours in this space. Replacement aims to occupy the space inadequately covered by the public/private sector; Aravind Eye Care that aims to target eye illnesses and blindness in cost effective manner, is an example. Similarly, emerging telemedicine based solutions like eVaiday can replace several health care initiatives. (https://www.evaidya.com/home.html#!/home)

Several new devices can supplement the services that are currently being provided by existing healthcare systems or be enablers to make them more efficacious by supporting the paramedics, frontline health workers and PHCs with technology. The innovation of *Swasthya Slate*[10] (Health Tablet) is a prime example that facilitates decentralized diagnosis. Similarly, a diagnostic equipment, *3Nethra* developed by a start-up, Forus is revolutionising remote decentralized screening of a variety of eye ailments (http://forushealth.com/forus/). In the same vein, innovations such as *Biosense* (http://www.biosense.com/) and *Achira* (http://www.achiralabs.com/) are easy to maneuver diagnostic devices that aim to take testing and diagnostic services to each household. While one innovation assists in non-invasive hemoglobin level testing, the other is dependent upon micro fluids to diagnose the ailment. Innovations such as a *Windmill* (http://windmillhealth.weebly.com/neobreathe.html) and *Embrace* (http://www.embraceinnovations.com/) address the issue of infant mortality. Other

[10]For details see, For details see, http://venturebeat.com/2014/11/18/this-indian-startup-could-disrupt-health-care-with-an-affordable-diagnostic-machine//

innovations include low-cost sanitary napkins[11], devices to monitor cardiac health[12], low cost health products (insulin)[13]etc.

Given the healthcare needs of the nation, such innovations have thus far targeted affordability and ease of use. A critical challenge to popularizing the technologies is the cumbersome and expensive process of accessing administrative approvals (Jaroslawski & Saberwal, 2013).

4.4 Strategic Responses and Innovations

Kale (2010) suggested that the new patent regime has led to organizational learning to provide strategic response to the changed situation. The learning has been both internal, focused towards developing stronger processes and external, whereby firms collaborate with foreign partners. Indian firms have employed alternative strategies that focus on greater internationalization which has taken two forms: facilitating greater inflow of FDI and entering into joint ventures and acquisitions abroad. Kale and Weild (2008) divide Indian pharmaceutical firms into three categories: alpha, beta and gamma. Alpha firms invest in foreign subsidiaries; beta firms enter into joint ventures with foreign partners to leverage the existing capacities in biotechnology capabilities and gamma firms acquire foreign firms. Between, 1999-2004, the number of joint ventures rose from 7 to 20, and wholly owned subsidiaries grew from 4 to 52 (Agarwal et al., 2007). International JVs and acquisitions have focused on accessing marketing, manufacturing and R&D capabilities. Besides, the trend towards joint ventures and acquisitions indicates a higher risk appetite. Arguably, two institutional changes had a noteworthy impact on the number of mergers and acquisition undertaken by Indian pharmaceutical and drug industry; the liberalization policies undertaken since 1991 and the changes in the IP regime post TRIPS. (Mishra and Chandra, 2010) There has also been significant consolidation within the Indian pharmaceutical industry with a lot of M&A activity suggesting the need of large size to compete effectively in the new business environment. (Table 2)

[11]Aakar Innovation (http://www.aakarinnovations.com/) provides access to menstrual hygiene to women in a low cost and environmentally friendly manner.

[12]GEH's Cardiology Diagnostics' Indian (http://www3.gehealthcare.in/en) division called In India for Indiawith the central objective of catering to the specific needs of medical practitioners in low-resource scenarios(Jarosławski & Saberwal, 2012).

[13]Bigtec Holdings is currently developing low cost insulin for sale in the Indian market (Jarosławski & Saberwal, 2012).

Table 2: Mergers and Acquisitions in Indian Pharmaceutical Industry		
Year	M&A-Completed Deals	Announced Total Value (US mil. $)
2005	15	39.6
2006	7	24.8
2007	9	605.8
2008	9	2336.8
2009	5	197.6
2010	12	3809.2
2011	7	241.9
2012	11	199.8
2013	9	1859.7
2014	7	406.1

Source: Compiled from Prowess Database

Overall, the trend seems to be that Indian firms, at least the larger ones, are adopting strategies to remain competitive in this knowledge intensive sector with a sharp focus on building technological capabilities (Basant, 2011). Chittoor et al. (2008) argue that the Indian pharmaceutical industry has adapted to greater indigenous growth and entry of MNCs. Besides, in order to make up for the "late-mover" disadvantage, Indian firms have acquired absorptive capacities and have begun importing technology and other inputs. (Chittoor et al., 2008).Guennif & Ramani(2012) provide a comparative analysis of "catching up" strategies in Brazil and India under a national system of innovation framework. The authors conclude that the system of catching up has adopted a three stepped process, by enhancing capabilities towards 'production', *'re*-engineering*'* and finally *'*new drug discovery*'*.

R&D expenditures in the pharmaceutical industry have increased significantly while expenditure on technology purchase has not increased. In fact, the share of technology purchase expenditure as a proportion of sales has reduced and is less than 1% while that of R&D is more than 5%, a remarkable rise. (Table 3) This trend indicates that an increasing

number of pharmaceutical firms are engaging in various aspects of research relating to drug development and manufacturing. And probably foreign technology is now coming in through FDI rather than arms-length technology licensing arrangements. This is now feasible given the liberal FDI regime in the industry.

Table 3: Trends in R&D and Technology Purchase in the Indian Pharmaceuticals

Year	Expenditure on Royalty/Technical Knowhow (US Mil $) As per exchange rates as of April 14, 2015	Expenditure on R&D (US Mil $) As per exchange rates as of April 14, 2015	Expenditure on the purchase of technical knowhow as a percentage of sales	R&D Expenditure as a percentage of sales
1998-99	3.8	2.7	0.13	0.91
1999-00	4.5	4	0.13	1.18
2000-01	5.1	5.3	0.15	1.55
2001-02	2	7.4	0.05	1.96
2002-03	2.8	10.2	0.06	2.21
2003-04	2.5	16.3	0.05	3.04
2004-05	2.2	22.8	0.04	3.99
2005-06	3	30.3	0.05	4.59
2006-07	3.2	38.6	0.04	4.66
2007-08	6.4	41.2	0.07	4.31
2008-09	8	49.7	0.07	4.41
2009-10	9.8	58.2	0.08	4.51
2010-11	8.6	68.7	0.06	4.67
2011-12	6.3	75.5	0.04	4.63
2012-13	6.4	87.2	0.04	5.13
2013-14	9.8	107.3	0.05	5.85

Source: Computed from Prowess Database.

5. Public Policy Innovations

Healthcare access and innovations in healthcare provisioning are often not seen as complementary. We already discussed how entrepreneurial innovations along with product/process innovations can potentially be complementary. Given the possibility of increases in healthcare costs with the new IP regime, policy innovations become necessary to ensure affordable access to health care services. In this section, we discuss some of these health policy related innovations as issues relating to IP policies have already been highlighted in an earlier section.

A high percentage of the out of pocket expenditure incurred on healthcare can be attributed to the purchase of drugs. The high price of patented drugs poses a barrier to universal access to healthcare. Horner (2014) argues that TRIPS-compatible IP regime would not bring any additional benefit to the population in the developing world as increasing number of pharmaceutical firms would be oriented towards lucrative Western markets with nations like India becoming the "pharmacy of the developed world".

Other factors that contribute to rising prices are: marketing practices adopted by pharmaceuticals that lead to increased cost of treatment and weakening of the drug price control order. The "unholy nexus" between doctors and pharmaceuticals may also reduce access to healthcare. Marketing practices employed by several pharmaceutical companies aim to influence doctors to prescribe drugs by certain companies (Mehta, 2015; Kalaskar & Sagar, 2012). The high cost of prescribed drugs and diagnostic services escalates the costs associated with treatment and might even deter several households from seeking treatment for ailments.

DPCO that came into force in 1970 was instrumental in controlling the price of essential drugs. The DPCO has the authority to monitor the prices of the drugs listed under the National List of Essential Medicines. The price regulation is carried out by the National Pharma Pricing Authority (NPPA). The DPCO monitored the prices of 75 drugs in 1995 and by 2002 only 30 drugs remained under price control. The argument supporting the trend maintains that due to rising competition in the Indian drug market, the drugs were already priced very low and hence were affordable (Chittoor et al., 2008). While others argue that more drugs should be included under price control and in the essential drug list that have

reference prices based on the lowest price alternative (Selvaraj et al., 2012). In a policy reversal in 2013, DPCO brought 348 essential drugs within its purview (Department of Pharmaceuticals, 2014). The intervention is aimed towards controlling the expenditure incurred upon medical bills and demolish cost barrier to access healthcare.

Recognising the importance of keeping the drug prices affordable in the current context of the liberalized economy and the new IP regime, a few policy changes seem noteworthy:

a) The recent legislation- Uniform Code of Pharmaceutical Marketing Practices (UCPMP) - aims to control for the unethical and unwanted prescriptions and to ensure access to health for all. The legislation is currently voluntary in nature and mandates doctors to prescribe generic brand names. The current legislation is not a new development but is another effort to control the unethical practices and alliance between Pharmaceutical companies and doctors.

b) Introduced in the year 2008, *Jan Aushadi* scheme aims at making low-cost and quality generic drugs available for sale to the general populations. The ambitious project took off from the state of Punjab in Amritsar and at present 40 such stores have come up. The *Jan Aushadi* scheme aims to address concerns associated with access, availability, and affordability (Jayaraman, 2010; Kotwani, 2010).

c) Other state-based initiatives (Tamil Nadu Medical Services Corporation model, Nirmalaya) have attempted to enhance access to healthcare through the strengthening of supply side procedures for procuring and providing high quality and low cost generic drugs (Lalitha, 2008;Nautiyal, 2015). Additional state based inititatve such as mobile medical units (http://healthmarketinnovations.org/program/deen-dayal-chalit-aspatal-mobile-units; http://healthmarketinnovations.org/program/arogya-rath-mobile-medical-units-mmu-bihar) in Bihar and Madhya Pradesh offer the communites located in difficult and remote topographies greater access to healthcare.

6. Some Concluding Observations

As in many other developing nations, introduction of TRIPS compatible IP regime has generated a lot of debate in India. In general, the debate has focused more on pharmaceutical and food sectors as these affect access to food and healthcare, two of the most critical human

needs. The case of India is different from many other countries given its capabilities in the pharmaceutical industry. The data on health related innovations is fragmented and sketchy and therefore it is not easy to unequivocally answer the question if the new IP regime has fostered inventive and innovative activity in the Indian healthcare sector. The Indian pharmaceutical firms have shown a higher propensity to invent and patent although their R&D focus may have shifted somewhat in favour of Western markets. While there is also a shift in favour of product inventions, not many of these are new chemical entities but new dosage forms and drug delivery mechanisms. There is a lot of activity in the medical devices domain although it is not clear to what extent it has been impacted by the new IP regime. Strategic forays into foreign nations to acquire technology and consolidation in the domestic market seems to be a pre-requisite for Indian firms to deal with the increasing technology based competition. And Indian firms have been quite active on that front. Recent decline in PCT applications is puzzling and needs to be explored. The emergence of IP based start-ups and social ventures in the healthcare space are noteworthy. Given the penetration of the Internet and mobile technologies, supporting such initiatives is critical for healthcare access in the near future. Apart from policy innovations to enhance access and affordability of healthcare services, public policy will need to be flexible to nurture and encourage such experiments. Such flexibility is critical as the success of these ventures is intricately linked to the ability of the start-ups to get integrated with the public healthcare delivery system. Therein lies the essential complementarity between entrepreneurial efforts and public policy innovations. Encouragement of entrepreneurship in the sector requires a combination of powerful financial incentives, capacity for quality research, supportive regulatory system, and an active investment community (FICCI, 2011).

As India gains more experience with the new patent regime, it will have to be cognizant of the dysfunctionalities that the new regime might have created. While the MNCs have complained about the criteria of patentability (Article 3 (d)) and compulsory licensing (Article 84), some small firms seem to have suffered with respect to the confusion regarding the validity of the patents granted (Section13 (4)). A critical review of these seems desirable. The complaints regarding cumbersome patenting procedures seem to be common across different types of firms. Admittedly, it is a learning phase for the country and the State should be flexible enough to change policy to balance the twin objectives of creating incentives for invention and providing affordable healthcare.

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