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Medical Technology Patenting in India: Intersection with Public Health Facilities-a Doctrinal Study

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Abstract

Medical technologies have become increasingly important in society because of their impact on the health sector along economy. The Medical Device and Equipment Industry amounts around US$ 5 billion according to recent figures and is expanding at an equally high rate. This pandemic period has triggered globally a massive demand for healthcare technologies to combat COVID-19 which includes ventilator, diagnostics, medicines and other devices such as personal protective equipment's (PPE). This led to pressure upon public procurement system, and led to shortage of supply of the medical equipment and PPE.

Keywords: Equipment industry; Globally; Huge investment; Health facilities

Introduction

Innovation in medical technologies involves a complex mix of private- and public-sector inputs. At the same time, a current huge dependence of the present industry on imports, has allowed several foreign manufacturers to exploit the current market and in the process to obtain IP protection in India. It takes a long-term research, be more than 5 years to apply and complete all the essential trials to prove the safety and effectiveness of the new medical technology or pharmaceutical and then to reach the market passing certain other approvals, also it has a huge investment. Therefore, with all these barriers, hard work, without proper IP protection the fruition of years of hard work and huge investment would go in vain if any other company would easily copy the research and put forth the competitive device. The researcher in the research paper basically focuses on the medical technologies' legal regime in India. The innovation of medical technologies significantly contributes in improvement in health condition and health crisis particularly to HIV/AIDS tuberculosis etc. Health is fundamental and universal right. Access to essential medical technologies and health services is an element of the fulfilment of the right of everyone to the enjoyment of the highest attainable standard of health. Further it also deals in intersection with public health facilities.

Significance of Study

Based on the background of the above, the formulation of the problem taken in this study is: how the process of establishing a village owned enterprise in the village of Ponggok Polanharjo District Klaten Regency.

Objective

This research paper aims to the following objective:

3.1 To study the concept of patentability of medical technologies.

3.2 To examine how the patent on medical technologies affect public health facilities.

3.3 To critically analyse position currently afforded for the protection of medical technologies.

3.4 To study the development through case laws of medical technologies and public health facilities.

Literature Review

Smita sahu & saikat panja, 2017 [1]: The authors in the paper deals in the current status and challenges of medical device innovations. Medical device is an instrument which is applied for diagnosis, treatment or alleviation of diseases on human being or animals. The authors review the need of diagnostic capacity building with robust regulatory regime to mitigate the challenges of accessibility in resources poor setting, import dependency, limited innovation with technologies. The authors emphasis on the Make- in India campaign which open new avenues to a flourishing future of indigenous medical health technologies and innovation for delivering affordable health care facilities.

Maria fontanazza, 2020 [2]: The author in article basically talks about the Q&A with Gerard von Hoffmann, partner at Knobbe Martens. It was about the recent upgrade on the IP litigation landscape in the medical device industry. The answer of the lessons that medical device companies learned about protecting their IP is they value patents for their medical devices and investing even more resources into patent landscape searches and analyses to identify potential infringement risk issues in earlier stages of their growth.

Markan s, verma y, 2017 [3]: The author in this paper studies the patent application filing trends in India for the last decade (2005–2014) so as to analyse and understand the medical device patent filing profile. As India is the key emerging market with huge market potential, this study was also undertaken to identify the top medical device companies filing patents in India, the niche technology domains with maximum filings, key gaps in medical device innovation profile and scope for business opportunities. The author concluded that patent application filings in the medical device sector during the last 5 years (2009–2013) contributed only to 2% of the total patent applications filed, which may be attributed to nascent medical device sector and lack of Intellectual Property (IP) awareness or funding support for IP filings. The analysis indicates increasing trends in medical device patent applications in India, with major share of patent applications being filed from the USA. The Indian applications in this sector contributed only to 17% of the total patent application filings in the last decade. Although foreign players dominate the medical device sector, this study indicates that though at a small scale, Indian applicants are actively filing patents in all

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key domains of the medical device sector.

R Basant, S Srinivasan, 2016 [4]: The author undertakes a review of available studies to provide a perspective on the role of intellectual property (IP) protection in developing health care innovations in India. According to author relevant literature in the context of India follows two stands: 1) some studies focus on the implications of the new IP regime on access to health care, 2) others explore the implications of IP on innovation in general and medical innovation in particular. The author tries to clarify the relationship by discussing innovations undertaken by the Indian pharmaceutical industry and in health policy to balance the twin goals of invention and affordable health care.

Chao TE, Mody GN, 2015 [5]: Technology innovation has the potential to expand equitable healthcare to underserved populations in global health. While, the device patents and their legislation stand as a barrier to innovation for developing countries. The author in the article reviews the current landscape of international intellectual property regulation and reasons why inventors of healthcare devices for the developing world have varying interest in pursuing patent protection of their devices. Further, it highlights certain opportunities for frugal approaches to intellectual property protection as well as propose more imaginative legislation in developing countries.

Research Methodology

The research paper is an attempt to analyse the "Medical technology patenting in India: intersection with public health facilities". The research is conducted on the basis of secondary data such legal data and online journals. Hence, the scheme of study used is doctrinal research.

Research Questions

6.1 Whether the Medical technology patenting protection is adequate?

6.2 Whether Medical technology patenting in India and public health facilities interrelated?

Research Hypothesis

Following are the hypothesis of this research paper:

7.1 Innovation of Medical technology take a long-term research and huge investment. It could be easily taken by the company creating a competitive device. And the recent development of law provides enough protection.

7.2 Health is fundamental and universal right. The innovation of medical technologies significantly contributes in improvement in health.

Limitation of Study/ Scope of the Study

The author has limited access to online journal worldwide which makes it hard to find relevant research material and when found through the ones provided by the National Library. Not every secondary data resource offers the latest reports and statics. Even when the data is accurate, it may not be updated enough to accommodate recent timelines. Secondary research derives its conclusion from collective primary data. The success of this research paper will depend, to a greater extent, on the quality of research already conducted by primary research.

Innovation of Medical Technologies

Innovation of Medical technologies Medical Device Innovations and Technical Hardships Emerging dual disease burden demands quantitative and qualitative expansion of medical device technologies. Medical devices are either designed to target a specific health condition or improved with slight variations to be more effective (more efficacious and not mere rearrangement) or replicated for mass accessibility. Therefore, only those medical devices which have novelty, inventiveness and utility classify for patent filing. Medical devices also favour design registration for their unique, innovative designs and copyright registration if have a software associated with the device Section 3 of Indian Patents Act, 1970 decides the fate of a patent application for medical devices such as Section 3(b): For example, a bandage is invented which is non-biodegradable and can cause serious hazards to environment as a biomedical waste. It can't pass the patentability criteria even it prevents blood flow from deep cut within 60 seconds. Section 3(c): Mere discovery of living or non-living substance is not invention [6]. In 2009, Senesco Technologies Inc.'s invention, named "Nucleic Acids, Polypeptides, and methods for modulating apoptosis" was related to an isolated nucleic acid rat apoptosis-specific eIF-5A polypeptide and method of modulating apoptosis utilizing apoptosis-specific eIF-5A. From the examiner's point of view, the isolated nucleic acid usually exists in living body- therefore, it is considered as a non-invention. To prove its inventive step, the invention needs to represent any mutation or modification carried out to the claimed nucleic acid sequence [7]. Likewise, Faraday's Law of Electromagnetic Induction which was discovered long back- but, using this principle an electronic blood flow meter (to measure the blood flow within vessel without cannulation) is being developed after ages. Section 3(d): GE Healthcare's invention on (2714/DELNP/2006), a particle for using in x-ray imaging essentially has a core made up of tungsten content (20 to 100% of the total weight of the tungsten) and another metallic element (selected from rhenium, niobium, tantalum or molybdenum) [8]. The core is coated with charged layer (acidic groups such as, carboxylic acid groups, sulphonic acid groups, etc.) in order to protect the reactive surface of the core from corrosion.

First examination report mentioned that the invention does not show any new feature or new application of known substances-therefore, the invention was objected under Section 3 (d) although it was granted after modifications of the specifications [9]. Section 3(f): A low pass filter (frequently used in electrocardiogram) is an electronic filer which passes the signals lower than the cut-frequency and attenuates the signals higher than cut off frequency. The basic components of this type of filter are capacitor and resistor where input signal is applied to the series combinations of capacitor and resistor and an output signal is taken across the capacitor. High pass filter exactly shows opposite performance where the arrangement of capacitor and resistor is exactly reverse. High pass filter can't be applied for patent protection because capacitor and resistor are re-arranged and they are working independently in a known way. Section 3(i): The Encyclopaedia Britannica has stated diagnosis as a process of finding the nature or cause of diseases and differentiates from other possible conditions [10]. It includes method(s) of evaluating (without any help of device) the physical or mental condition or a procedure of investigating whether the patient has the abnormality by examining the test result or imaging and are not considered as invention [11]. For example, X-ray is a diagnostic tool which is usually applied to determine the location of broken part of the bone. Any advancement on X-ray machine and its different components such as collimator, grids, anode, cathode tube etc. are not excluded from patentable subject matter, but any technical or economic advancement on the process undergone by the X-ray technician, is excluded patentable. Claim 26 and 27 of document (Application no: 1537/KOLNP/2006), named- "SGKL As a Diagnostic and Therapeutic Target" clearly stated a method of diagnosis of disease associated

to the disturbed activity of tissue factor hence it was rejected by the patent examiner [12]. Application no: 3044/CHENP/2006 disclosed a method for treatment of skin and mucosal membrane disease caused by human papilloma viruses- it was rejected by the patent examiner as method of treatment are not patentable in India. Similarly, an invention on lithotripters and its components (for breaking the urinary stones) is patentable, but advancement on lithotripsy process where nephrologists, or urologists or other technical persons are involved to undergo on human body, is excluded from patentable subject matter in India. An invention (Application no.: 4038/CHENP/2006) on tweezers used for cosmetic purpose was granted by the Indian Patent Office because the independent claim relates to the tweezers (instrument) and its mechanical structure 16 and not the surgical process as an invention related to curative method is not patentable in India. Section 3(k): Software can be a part of a medical device. Modern versions of X-ray, CT, scan, MRI, PET, SPECT etc. machine etc. include software which process the image and make those images suitable for identifying the abnormality- even, the novelty of the software can't make it patentable. An invention (Application no: 4170/DELNP/2005) disclosed a process to measure oxygen consumption and CO_2 production in an anaesthesia machine where gas production is calculated through mathematical equation- the same invention is opposed under Section 3(k) provision [13].

Protection of Medical Technologies

"What lessons have medical device companies learned about protecting their IP? What challenges have they experienced in this area?". Medical device companies continue to value patents as the strongest form of intellectual property for their mechanical devices, such as catheters, heart valves, spinal implants, neurovascular coils and many others. The portion of the total market that involves electronically enabled medical devices continues to expand. More and more involve collecting data that is processed via algorithms "in the cloud". These latter technologies often rely more heavily on trade secret protection, due to recent evolution in the law that reduces the availability of patent protection for algorithm-based innovations (considered further below). While branding may also be important, especially with larger, established companies, trademark protection is generally less critical because it may protect the name, but does not prevent competitors from copying the function or form of a medical device.

Medical device companies just [recently] won a significant lobbying battle by convincing the Congress to definitively repeal the medical device tax that had been weighing down this sector. The 2.3% tax was significant because it applied to gross sales revenue, not profit, thus pushing profitability potentially significantly off into the future. The repeal bill currently awaits signature by President Trump.

Recently, smaller Med Tech companies may be investing even more resources into patent landscape searches and analyses to identify potential infringement risk issues in earlier stages of their growth. This includes efforts to design around competitors and proactive exploration of licensing opportunities (payments to patent holders). It can also involve pre-emptive early attacks on competitors' patents through clearing-the-path Inter Partes Reviews (IPR's). This early IP diligence responds in part to higher expectations from acquiring companies and venture capital firms that this diligence has been done prior to investment or acquisition. If it has not, investing or acquiring firms often require measures to mitigate litigation risk, which may include larger amounts of escrowed funds or other types of insurance backing up representations and warranties.

In addition, acquisition remains a more likely exit than a public offering for early-stage medical device companies. The strategic (buyers) are continuing to seek later stage transactions, to enable the start-up to further de-risk the deal (by achieving higher maturity on matters like market adoption, reimbursement, IP risk and portfolio development). This means start-ups are more likely to stay independent through early commercialization, converting the risk of patent infringement from theoretical to real. That challenges management to develop an appropriate balance in the budget against all of the other spending categories, to optimize their IP position and confidence.

One challenge is occurring at the U.S. Patent and Trademark Office, which has recently found more patent applications "ineligible," merely because they include software elements. This is at a time when newer products are more and more often incorporating smart (often software-based) technology. However, the current Director of the Office favours streamlining the patent process and is working to impose regulations making it easier to get patents on these technologies. The Federal courts recently strengthened his hand, ruling in the Arthrex case that administrative patent judges (who some had referred to as patent death squads) could be fired by the director without cause. This changed a provision of the America Invents Act, and the decision is currently being reviewed by the full Court of Appeals for the Federal Circuit. In the interim, companies need to evaluate to what extent they should put resources at risk filing patent applications which may or may not have future value depending upon how this issue is finally resolved.

What impact has IP litigation in 2019 had on the medtech industry?

The Federal Circuit affirmed a $70M patent infringement verdict against Hospira in the Amgen v. Hospira case. Hospira had argued that it made the accused products to assist with the FDA approval process so its actions fell under a statutory safe harbour (35 U.S.C. § 271€(1)). This case limits this widely utilized exemption from infringement liability for pre-FDA approval activities, so pre-market approval IP diligence gained greater importance for medical device companies, as well as for their acquirers and investors.

The Supreme Court's 2017 ruling in Impression *vs.* Lexmark continued to affect medical device companies, which often attempt to prevent the competition from selling replacement disposable components into their installed customer base (e.g., the razor blade model). The case relied on "patent exhaustion" and copyright "first sale doctrine" concepts, making it easier for competitors to recondition disposables and compete with follow on sales that would otherwise have been made by the supplier of the underlying device or capital equipment.

The trend continued of IPR's being increasingly used as appendages to patent litigation. For medical device companies, this has made diverse patent claim scope even more important, especially now that the Patent Trial and Appeal Board in the US Patent and Trademark Office often invalidates the broadest claims but upholds the validity of a few narrower claims. Medical device companies should pay careful attention to meaningful dependent claim strategies and also strategically pursue narrow alternative independent claims, not simply strive to get the broadest claims possible.

In 2019 there was an increase in litigation against foreign (Chinese) alleged knockoff artists and outright trade secret thieves. This may be due, in part, to the Trump administration's more aggressive posture toward Chinese competition and willingness to invoke tariffs and criticize intellectual property theft. This appears to be more impactful in areas other than the medical device industry, possibly due in part

to the regulatory (FDA) requirements to sell medical devices into the U.S. market.

Are there any changes on the horizon for 2020? If not, what actions should MedTech companies take to further protect their IP?. Various proposals were considered by lawmakers in 2019 to change the law on patent eligibility. These may be revived in 2020, especially if the courts continue to strike down valuable intellectual property on this basis. Medical device lobbying groups may turn more attention to this issue after having succeeded on medical device tax repeal.

Medical device companies should continue to focus their IP budgets on patent applications and the competitive environment, but overall budgets also may be impacted by changes in the regulatory expense. The FDA has continued to take steps this year to implement its "Safety and Performance Based Pathway" for medical devices. The FDA has cited a desire to improve the 510(k) programs to keep pace with important innovations in device development.

Overall, nothing in the fundamentals of a well-developed IP strategy has changed. For each new product under development, there are strong economic incentives to explore the same basic three questions that have long been a part of the IP process: Do you own it; can you build a barrier around it to exclude competition; and are you free to sell it. Less than a strong score in any of these categories can result in any of a variety of bad news, including unconstrained competition, an order to pay monetary damages, and a shutdown order taking your product off the market. A degree of care (spend level on the three big IP issues) commensurate with the capital at risk and expectations of the stakeholders is probably more advisable than ever.

Intersection of Medical Technology Patenting with Public Health Facilities

Currently India is aggressively adopting 'Smart life' where everything is driven by smart technology like artificial intelligence and IoT, but a grave reality still haunts most of the population is lack of basic healthcare facilities. In recent years, many projects and initiatives have been undertaken to improve the quality of life of common people, however, more concrete steps are still required to achieve the dream of 'Healthy India'.

In a developing country like India, cheaper drugs & affordable healthcare infrastructure models can work wonders because the more it is affordable the more it is accessible. To make things affordable, we need innovation in drugs, developing therapeutic domain and building healthcare facilities. In last couple of decades India has developed a strategy of delivering highest quality drugs at lowest cost to patients within the country and other developing ones.

India revised the patent regime in pharmaceutical sector to comply with the WTO agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 2005, which excluded certain types of chemical entities such as polymorphs and salts combination of drug patentability so as to prevent patent 'ever greening' by large pharmaceutical companies, which can make drugs unaffordable to the general population. Below are the changes that Indian Pharmaceutical Industry has gone through during the pre-compliance (till 2005) and post compliance (after 2005) phases:

Pre-compliance phase:

- Indian pharmaceutical sector flourished and became fastest growing generics industry.
- Encouraged domestic players to manufacture drugs.
- The Act granted patents, based on the process of manufacturing, as against the global practice of granting patents, based on the new drug alone.
- Wider distribution of generic medicines at reasonable prices.
- Less interest from global pharmaceutical companies to introduce their drugs in Indian Market.

Post -compliance phase:

- Duplicating of post- 1995 patented drugs illegal.
- Global pharmaceutical companies gradually started showing interest in Indian market.

Needless to say, a strong IP policy is expected to increase the foreign investments in R&D in healthcare sector within India. A favourable patent regime, and a smooth patent granting system will increase investment in innovation. In fact, the recent "Make in India" initiative has also brought about further changes to the Indian patent laws encouraging patent protection for innovation. As a result of the changes to the Patent laws, in recent years, Indian pharmaceutical industry has started moving up the value chain. Indian companies are investing more and more in money in R&D to develop new drugs, rather than copying the existing ones.

A look at the patent office annual report shows that Pharmaceutical industry is major contributor of patents filed in India. Since 2015 more than 20 thousand patents have been filed by pharma giants in India, and the major players include – Johnson & Johnson, Sanofi, Roche, Pfizer, Bayer, Novartis, BMS etc. Although, 72 percent of granted patents for pharmaceuticals are granted for marginal improvements over previously known drugs, this is evidence in itself that Pharma companies are protecting even smallest of the innovation rigorously. However, some have shown concerns over the patent phenomenon in Pharma sector, anticipating that the patent protection will eventually lead to a rise in price of drugs making them more and more unaffordable –there is nothing further from the truth. Indian government and Indian judiciary have demonstrated in past that the welfare of people is not being compromised by introducing the changes – this was demonstrated not so long ago, in year 2013 in the Novartis' Glivec case. In April 2013, the Supreme Court of India denied a patent to Novartis for its cancer drug Glivec due to lack of improved efficacy under section 3(d) of the Indian Patent Act. It is to be noted that Novartis has been granted patent by many countries across the world for the same drug, which the company tried to protect in India, and was eventually denied. It is quite evident from the case that the amendments made to the Indian patent laws, were carefully crafted and were done keeping in mind the welfare of the people. The enacted laws seem to have enough provisions crafted within them so as to prevent frivolous and non-meritorious patenting activity.

Though, the outcome of this case led to a decision by Novartis to stop their R&D spends in India, and to shift their existing R&D facilities from India to a more favourable destination. We can safely assume that this is but an isolated instance. Despite the case, a quick look at statistics indicates that many of the global pharmaceutical companies have decided to join hands with Indian companies to mark their presence in domestic business, for example, Roche has entered a partnership with India's Emcure Pharms in 2012 in order to increase affordability and access to some of its blockbuster products Herceptin (for breast cancer) and Mab Thera (for rheumatoid arthritis).

All in all, it can safely be said that patents, specifically for Pharma and Healthcare sector, are a very serious business indeed, and the Indian

policy makers seems to have done a good job of correctly balancing the people's welfare on one hand, and securing interests of Pharma companies on the other, by allowing only the genuine innovation to pass through to patents.

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 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 others argue that the impact has been negative or insignificant [14,15]. Still others argue that the jury is still out as interesting firm responses in terms of innovation can be seen [16-18].

While the protection of product patents in the TRIPS-compliant IP regime restricts the reverse engineering options of domestic firms and may potentially increase prices of drugs, some provisions exist to protect domestic consumers and manufacturers. These have taken the form of conditions for compulsory licensing (Section 84) e and standards of patentability (Clause 3[d]). Compulsory license provides national governments to allow manufacturers/ companies to replicate products and processes under patent. The license can be given, three years after the issuance of a patent if "the reasonable requirements of the public with respect to the patented invention have not been satisfied" or "the patented invention is not available to the public at a reasonable price" or "the patented invention is not worked in India". On the other hand, Clause 3(d) states that the discovery of variant of an existing substance or process that does not enhance efficacy significantly is not patentable. The clause attempts to discourage frivolous inventions. These provisions attempt to balance the two ideals of ensuring "access to medicines" and fostering innovations.

Policy innovation to avoid ever-greening

In the year 2006, Novartis applied to the Indian Patent Office seeking a patent for its formulation Glivec®. The application was rejected as the Indian Patent Office viewed the move as an attempt toward "evergreening". Ever-greening refers to the practice adopted by inventors of patented products to extend the monopoly benefits offered under a patent [19].The practice is not legally identified but combines a variety of strategies that leverage on legal and technical deficiencies in the patent law [20]. Glivec or imatinib mesylate is a formulation used in the treatment of blood cancer or chronic myeloid leukaemia and costs US$1,800 per month. On the other hand, the generic variant of the drug for the same duration is available in India for approximately US$120.

TRIPS required that countries, not providing product patents in respect of pharmaceuticals and chemical inventions, put a mechanism in place for accepting product patent applications with effect from January 1, 1995. Such applications were to be examined for patent grants, after making suitable amendments in the national patent law. This mechanism of accepting product patent applications is called the "mail box" mechanism. Novartis applied for a patent in the year 1998, and in 2005, was granted exclusive marketing rights and the application was "mail boxed" for consideration [21]. 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 efficacy adequately. 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 "efficacy", the differences in interpretation of this term led to the rejection of the appeal. More recently, Gilead's hepatitis C drug was also denied patents on similar grounds [22].

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 pregrant opposition was also filed by another domestic firm in 2007 but the patent was granted.

Compulsory licensing

In 2012, Natco Pharma was granted a compulsory license to manufacture a generic variant of the drug Nexavar. Nexavar is the original formulation of Bayer and is used in treating kidney and liver cancer. The drug costs US$5,500 per month with regard to the generic variant that costs US$141. Bayer contested the license in the Indian court and lost [23]. The arguments used were that the drug availability did not meet the reasonable requirements of the public, that it was not reasonably affordable, and was not sufficiently worked in India, not being locally manufactured.

Some issues relating to the validity of the patent

The Indian IP policy has received criticism as it is seen to favour domestic manufacturers. Both the patentability and compulsory licensing criteria have been criticized, apart from cumbersome patenting procedures [24]. However, while some provisions reported above are expected to enhance access and ensure that genuine inventions (pharmaceutical products and processes that possess marked novelty with respect to other products in the market) get patented, some others may deter inventive/innovative activity among small and medium enterprises as they do not possess deep pockets to engage in technology transfers, marketing, new drug discovery, and acquisitions [25]. For example, Section 13(4) under the patent act asserts that granting of a patent to the inventor does not automatically ensure its validity. This ambiguity in the law can prove detrimental to small Indian firms investing in R&D.

The process of granting a patent requires the application to go through a number of filters to validate the patentability of the invention. Once the conditions of novelty, no obviousness, and industrial application are satisfied, the patent is granted. Like in many other countries, the Indian Patent Act has provisions for pre- and post-grant opposition, which some find quite onerous. But these enhance the efficacy of scrutiny and, as discussed earlier, have helped revoke patents. However, the presence of Section 13(4) "incentivizes" copying as it 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 in which large firms have copied inventions of small pharmaceutical firms in India adding significantly to the costs of protecting Intellectual Property Rights by the inventive small and medium enterprises. The case of the 75 mg/ mL Diclofenac Injection by Troikaa Pharmaceuticals is a case in point,

suggesting that Section 13(4) can be dysfunctional. In February, 2005, Troikka pharmaceuticals filed for a patent for its invention: the 75 mg/mL 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 pregrant and post grant oppositions. The apparent infringement by Glenmark Pharmaceuticals of the patented process developed by a small firm Symed to make Linezolid provides a similar example. Notably, the courts in the USA and Europe treat the patent valid and thereby curb frivolous challenges and facilitate quick infringement action [26].

Conclusion

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 health care, 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 are 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 health care 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 seem to be a prerequisite for Indian firms to deal with the increasing technology-based competition. Moreover, Indian firms have been quite active on this front. The recent decline in PCT applications is puzzling and needs to be explored. The emergence of IP-based start-ups and social ventures in the health care space is noteworthy. Given the penetration of the Internet and mobile technologies, supporting such initiatives is critical for health care access in the near future.

Apart from policy innovations to enhance the access and affordability of health care 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 health care delivery system. Therein lies the essential complementarity between entrepreneurial 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.

As India gains more experience with the new patent regime, it will have to be cognizant of the dysfunctional ties that the new regime might have created. While the multinational corporations 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 (Section 13) [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 health care.

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