



Significance and Factors Hampering Patents Commercialization in India

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Received: 2nd July 2021; accepted: 7th April 2022

As per the Patents Act, 1970 one of the patentability criteria is ‘*the invention should have industrial application*’. The patents’ rights conferred to the patentee are merely not to enjoy the monopoly over the invention, but the patentee has to ensure the use of technology for the societal and economic benefit of the country. Once the patent is granted, the patentee has to ensure the working of the patent in India on a commercial scale. In return, the patentee gets his due amount for his hard work and efforts rendered for the intellectual creativity. Current paper focuses on the working/non-working profile of the patents granted to Indian Higher Education Institutes (HEIs) and National Research Labs (NRLs) in the country from January 2010 to December 2017. The data has been procured from the prescribed ‘Form-27’ by the Indian Patent Office, which the patentee is required to file every year before the end of financial year, post grant of the patent. The research depicts in how many patentees submitted requisite ‘Form-27’, and in how many cases patents granted, worked or didn’t work. Moreover, various reasons cited for the non-working of the patents have also been identified. The issues being encountered with by the patentees have been identified and measures thereof required to be taken, at the individual level, institutional level and government level, have also been suggested.

Keywords: Form-27, Working/Non-Working Patents, Licensing, Compulsory Licensing

The patents’ rights conferred to a ‘Patentee’ are given in the exchange of disclosing the details of the invention in the public domain. As per the Patent Act, 1970 of India, the patent rights are not just to enjoy the monopoly on the invention but the patentee is also mandated to exploit the invention commercially for the benefit of the society. Commercial exploitation of the patent is one of the patentability criteria. The word ‘Commercialization’ can be defined as the act which involves something in commerce. Both innovators and industry acquirers (company/industry/government) will retain partial ownership of the product/idea. Commercialization of patents acts as a bridge between innovation and entrepreneurship. To study the patents commercialization ecosystem of academic and research institutions of India, this study was conducted taking into account the working/non-working statements filed by the patentee, in a requisite form namely ‘Form-27’. The research underlines the significance of patents’ commercialization and suggests ways for commercial exploitation of an invention in the context of Indian academic and research institutions. The study was conducted in two phases. The first phase includes the study on research publications and patents granted to these 904 institutions (HEIs-351, NRLs-553). The

main objective of the study was to identify potential institutes which were publishing a good number of research papers but lagging in patents’ generation.¹ In the second phase, the study has been extended further to assess the commercialization ecosystem of patents in Indian academic and research institutions.^{2,3}

The Centre has compiled data on working and non-working status of patents granted to the aforementioned institutions in a period of 8 years (January 2010 – December 2017). During this period, a total number of 1961 patents were granted to the 904 institutions considered for the study. Year-wise statements for the working/non-working status for these patents were scrutinized from the ‘Form-27’. All the reasons mentioned by the applicants were extracted and studied in detail. During the study, it was found that majority of the patentees/applicants are non-serious towards filing the working and non-working statements in the ‘Form-27’ and those who had submitted the details, did not have satisfactory reasons for non-working of patents.

Form-27

As per the Section 146 (2) of The Patents Act, 1970⁴ after the grant of a patent, the applicant must file the working statement of the patent by 31st March of every financial year. The information provided in these submissions is the basis of which, the Controller

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General of Patents, Designs & Trade Marks decides on granting a compulsory license to the interested party. In a case against a particular patent, the patentee has failed to furnish working information under Form-27, or in case the patentee submits the form, and after examining it the Controller feels the requirements of Section 146 of the Patent Act / Rule 131 are not met, he may pass an order to grant a compulsory license under Section 84. Under Section 122, the punitive measures for non-compliance with Section-146 are punishable with fine which may extend to ten lacs rupees and 6 months imprisonment. Furnishing wrong information will be punishable with imprisonment with fine, or with both.

The working of the patents and its significance are specifically mentioned in the Paris Convention and Trade-Related Aspects of Intellectual Property Rights (TRIPS). Though, it is not being taken seriously in some of the countries. Working of the patent now is the part of the national patent system in India. Working of the patent as per the Patents Act, 1970 is defined as the patent granted should be workable on a commercial scale to the fullest scale.⁴ The patents are granted to encourage the inventions and innovators. Once the patent is granted the patentee has to ensure its working and same has to be notified in the prescribed form to the patent office⁵ every financial year. Working of the patent can be ensured by putting the patented product in the market to exploit it commercially. The Intellectual Property (IP) commercialization can be ensured through any means such as licensing (exclusive, non-Exclusive, time-bound), start-up, spin-offs, franchise or assignment of IP, joint venture, in-house, etc. Licensing is done by way of a contract of intellectual property to the interested party in return of royalty within the limits set under the contract signed. Licensing plays a vital role in the commercialization strategies in the companies especially SMEs. Moreover, IP licensing is a win-win situation for the patentee and the licensee (company). By using the intellectual capacity of the inventor, the licensee can prosper his business and maintain the monopoly in the business society, on the other hand, the inventor can encash his intellect in the form of royalty. Moreover, the licensor can retain the ownership of IP and can utilize the established market of the licensee. On the other hand, the licensee can reduce the research and development (R&D) cost and gets a well-tested product to facilitate its clients.⁶

After three years of the grant of the patent, if the patent is still not working in India that patent qualifies

for the 'Compulsory Licensing (CL)'. The highlights of the grounds for the grant of CL are as follows (Section 84 and Section 85 of the Patents Act):⁴

- (i) The reasonable requirements of the public with respect to the patented invention have not been satisfied.
- (ii) The patented invention is not available to the public at a reasonably affordable price.
- (iii) The patented invention is not worked in the territory of India.

The first-ever compulsory license was granted on 9 March 2012, to the Hyderabad based company NATCO Pharma Ltd. (applicant for the CL) for the generic drug production of Bayer Corporation namely NEXAVAR[®] (patentee, got patent in the United States and India under the name of Sorafenib), a lifesaving medicine used for treating liver and kidney cancer. Bayer was selling the one-month dosage of the drug for rupees 2.85 lacs, whereas, NATCO offered the same dosage for approximately Indian rupees 8900. NATCO referred to all the grounds mentioned in Section 84 of the Patent Act for the grant of compulsory licensing. As all the conditions of the CL were fulfilled therefore, the decision was taken in the favour of NATCO. It was also settled that 6% of the net sales of the drug would be paid to Bayer Corporation by the NATCO as royalty. Another case of the CL was recorded on 4 March 2013. The Controller rejected the CL application of BDR Pharmaceuticals, which was filed to get the CL on Bristol Myers Squibb (BMS) owned anti-cancer drug 'Dasatinib (brand name SPRYCEL[®])' because the company failed to make efforts for voluntary licensing from the owner of the patent (IN202937) on reasonable terms and conditions. Although, these cases created controversies like such verdicts will affect the R&D industries and innovations which ultimately will threaten India's position as a potential market for the launch of new pharmaceutical products⁷.

Licensing and compulsory licensing are the two most important parameters to be considered for enhancing commercialization ecosystem in India. Licensing to be looked upon by the patentee and compulsory licensing is to be considered by the third party for taking it to the market for commercial purpose. During the study, it was noticed that patentees are not keen for submitting the Form-27 and the chunk of patentees who have submitted the form shows that the maximum of the patents are not worked and the reasons mentioned for the not-working status are

almost similar. Once the patent is granted to the patentee/applicant he has to maintain the patent by paying annual charges of the patent specified by the Govt. of India.⁸ The Indian applicants are paying huge amount of annuity keeping the patent in force but fewer efforts to commercialize it. The intervention of all the stakeholders such as the Govt, the academic sector and the industrial sector especially SMEs are needed to look upon the matter of patents licensing.

In continuation of the previous research, this study has been conducted to learn about the patents licensing ecosystem in Indian education and research institutions. The data about patents granted (only in India) to the HEIs and NRLs from January 2010 to December 2017 was extracted during August 2019 – October 2019 from Indian patents search engine, Indian Patents Advanced Search System (InPASS). Total numbers of institutions considered for the current study were 904 (HEIs-351 & NRLs-553); the patents granted to these institutions (only in India) were 1961; and granted patents information was extracted for the period January 2010 to December 2017. The information from the InPASS was extracted under the following categories:

- (i) Status (Ceased/In force/Under Extension Period)
- (ii) Single or multiple institutions involved (as applicants)

The data extraction from the ‘Form-27’ was executed for the period 2010-2018 for the following categories:

- (i) Working/Non-Working status
- (ii) Reasons mentioned for not working by the patentee
- (iii) Patent Licensees

It is pertinent to mention that the present study exclusively relies upon the information provided by the applicants/patentee in the Form-27. The information has been extracted by studying individual patents for every year from 2010 to 2018 (the patents, which were in force or granted in 2017 file the ‘Form-27’ in March 2018).

Results

The Patents (1961) were granted to only 186 institutions (NRLs-79, HEIs-66 and others-41). Others comprising of industries, Public Sector Undertakings (PSU), trusts, boards, corporation, hospitals, etc. In 2010, a total of 473 patents were ‘In Force’. Out of 473 patents, the working/non-working statement in Form-27 was submitted only for 19 patents and of these 19 patents only 7 patents were working. Till 2012, the trend indicates the raise in the number of patents ‘In force’ whereas, the patents for which the ‘Form-27’ was submitted was almost stagnant (Fig. 1). The word ‘In force’ means the patent is active, either the applicant is paying the annuity (renewal fee) for the patent in order to maintain it or the patents which were granted in that particular year.

Before 2012, the ‘Form-27’ was filed for very limited patents, resultant the number of working/non-working patents is also low. Post 2013, the statistics are depicting consistent increase for all the indicators namely ‘patents in force for the respective years (black line), the number of patents for which the ‘Form-27’ was filed (purple line), the patents for which the form-27 was not filed (blue line), patents

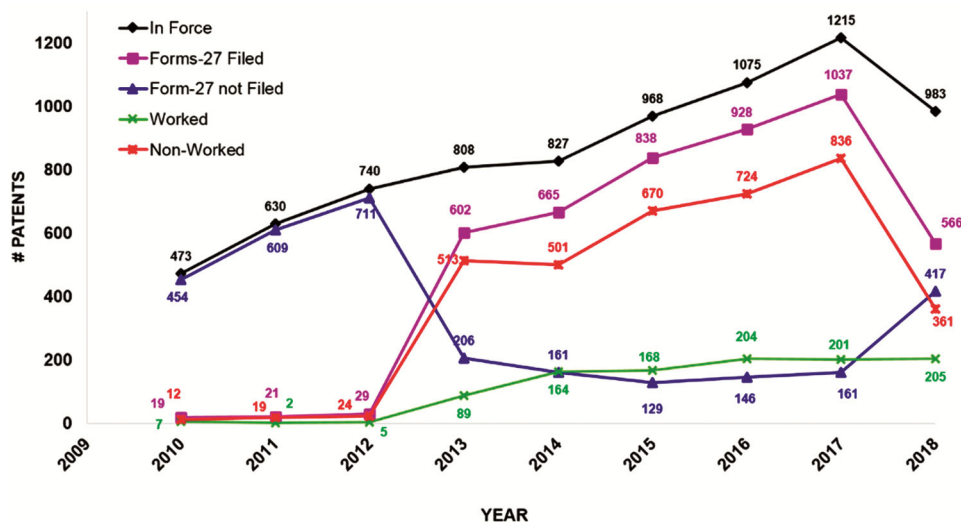


Fig. 1 — Year wise statistics for parameters studied for patents granted

marked as ‘worked’ by the patentee (green line) and the patents marked as non-worked (red line) in the respective years. The dip in the patents for every indicator was observed in 2018. Next section has focussed on the patents marked as non-worked and reasons mentioned for their non-working.

Reasons Mentioned for the Non-Working of Patents

During the data extraction, the reasons for not working of the patent mentioned by the applicants were extracted individually from the Form-27. The mentioned reasons were then standardized because either most of the patentees failed to furnish the information in the form and submitted without mentioning full details regarding the working/non-working status of the patents or the applicants mentioned the similar reasons by tweaking the words of the reason. So it is not practicable to mention all the reasons mentioned by the applicants in the manuscript. Moreover, some applicants such as Defence Research and Development Organisation (DRDO), New Delhi and Indian Institute of Technology (IIT), Bombay had mentioned similar reasons throughout the years for the non-working of the patents. The percentage of the patents for which the common reasons were mentioned (Table 1) has been calculated concerning the number of non-working patent in the respective years (Fig. 1).

The reasons mentioned by the patentee were collected individually for the patents marked as non-working and were standardized afterwards because most of the reasons cited meant the same thing but with different words. During the exercise it was also noticed that most of the patentees were reluctant to mention any reason for non-working in the form. In 2012, for 13% patents, the form was submitted without mentioning any reason which can be attributed to the fact that before 2013 the filing rate of the Form-27 was low (Fig. 1), whereas, in 2013, 26% of patents were filed without any reason which is the maximum in the 7 years span considered for the study. As depicted in Fig. 1 in the year 2013 the patents for which the form

was filed had also increased drastically (602) which were only 29 in 2012. It was also observed that the maximum patentees had cited the common reason i.e. *“Efforts made for commercialization, but unsuccessful”* for the non-working status. In the year 2018, for 55% patents, the efforts were being made to license them by the patentees. Either the patentees were in the process of negotiation with the interested party or despite efforts any queries were not being received for licensing it. Although, according to the statistics, some patentees are attempting to disseminate the technology via advertising in newspapers or on their individual official websites. Some of the patentees had cited the reason like *‘A customised version is being used of this technology or better technology available in the market’*, *‘Lack of marketing support’*, *‘Large scale production in progress’*, *‘No availability of facilities’*, *‘Awaiting approval-transgenic material is being cleared by Genetic Engineering Appraisal Committee (GEAC)’*, *‘Strategic importance, Department of Atomic Energy (DAE) contacted’*, etc.

Such reasons need to be looked upon and appropriate steps should be taken by the Govt. or concerning organizations to resolve them. Moreover, the industries can access easily ‘Form-27’ on the official website of the Indian Patent Office. Any interested party for the licensing can access all the patents from the same so it is high time that every patentee should take this seriously and should mention the genuine and precise reason for non-working status of the patent so that the relevant licensor/company can approach them and act upon accordingly. Although, there were some patents for which the exceptional and curious reasons were mentioned by the applicants. These cases are discussed in the further section of the paper.

Exceptional Reasons Mentioned by Some Patentees

- (i) Due to non-availability of the marketing chain in rural areas, the patent was not licensed. The patent is currently being considered to be taken up for the

Table 1— Percentage (%) of patents for which common reasons were mentioned

Reasons mentioned/ (%) of patents	2010-12	2013	2014	2015	2016	2017	2018
Efforts made for commercialization, but unsuccessful	29	32	21	35	33	36	55
Looking for potential buyers/clients	4	9	11	9	10	9	16
Advertised in newspaper/disseminating	13	7	6	5	2	5	12
Lab scale work/Further R&D required	46	16	17	16	12	12	7
Discussion in progress for commercialization	4	7	10	8	7	6	4
May work in future projects	nil	2	7	7	6	4	3
No reason mentioned in Form-27	13	26	24	17	22	19	2

development of production prototype under the District Industries Centre (DIC) programme at the department.

- (ii) To make this invention, it is essential to be able to prepare thin films of these materials in suitable substrates, compatible with electronic devices. This is a very demanding and specialized task, requiring sophisticated approaches, particularly for such multi-component systems. We have made limited attempts to prepare such thin films on various substrates in collaboration with different groups, since we do not have any expertise in that specific area and shown the feasibility of device construction. However, it is now for the device companies to feel the need for such high K materials and come forward.
- (iii) Combined Heat and Power (CHP) sponsored the project, more research was to be carried out but as the project was time-limited, could not continue due to lack of funds.
- (iv) For the development of the automatic machine, automation was retrofitted on an old machine purchased from m/s Vikram India Ltd. Kolkata. Few mechanical modifications were done on the old machine. At present many new technologies are found in the market. Under such circumstances, this technology which was developed 12 years back is not relevant in today's scenario.
- (v) Genetically Modified (GM) crops related - Govt. not taken any decision on the release of GM crops.
- (vi) Hepatitis C Virus (HCV) animal model is not available in India, which is the major hindrance for testing in an animal before commercialization. We have now managed funds from the Department of Biotechnology (DBT) for testing the antiviral efficacy of the above antiviral agent in HCV mice model in Japan (PXB-Bio). Accordingly, we have signed Memorandum of Understandings (MOU) (through our IP cell) with the company and are in progress of sending the material to them for testing in their assay system. Results will increase the chance for commercialization.
- (vii) Kala-Azar (leishmaniasis) IS A POOR MAN'S DISEASE and affects the population in Bihar and other economically deprived areas of the country. Companies are hesitant to license the patent due to this reason.
- (viii) The patent is not under any commercial utilisation because of some internal company policy.
- (ix) Presently the food industry is mostly dependent on synthetic colours to reduce the cost of production. In future due to the health benefits of natural colours, the patent may attract the processors. Articles already published, which may lead to patent exploitation.
- (x) The process is linked to the plasma reactor; clients are yet to be identified.
- (xi) The selectivity of Polymeric membranes developed for sulphur sorption from gasoline stream is not substantial for commercialization.
- (xii) Steps were taken in conjunction with Integrated Skill Development Scheme (ISDS) of Ministry of Textiles, Govt of India, to create Common Facility Centre for benefit of trade-in PPP.
- (xiii) The Claims of the Patent relate to loaded mode 2&3 wheeler for use vehicle testing. Present regulations in India do not address enforcement of methodology as claimed in the Patent. As The Internal Combustion (IC) engine technology matures in India, it is expected that the methodology as claimed will be implemented.
- (xiv) The patent was filed along with Reliance, however, now they are not interested for the commercialization.

Conclusion

To study the PAN India ecosystem of patents commercialization, the institutions considered for the study are state universities, central universities, deemed to be universities, private universities, autonomous institutes and national research institutes/labs. The research reveals that the patentees are reluctant for furnishing the information regarding working and non-working of the patents in spite of being a punishable offence. The patentees are hesitant to reveal the details in the public domain that's why some of the patentees are submitting the form without filling the important details. For the enhancement of patents commercialization ecosystem in India, stakeholders need to work in tandem. The academic sector is rich in knowledge but acquiring limited funds whereas, the industrial sector doesn't have financial constraints but lack in knowledge, expertise and time for conducting R&D.

The Govt. plays a crucial role by introducing, implementing and monitoring the policies to enhance commercialization ecosystem. There is a need for synchronization between these three entities as they are working in silos. Moreover, Govt can incentivise

institutions for researching in collaborative mode.⁹ The second measure, which is needed to be taken, is to have a serious look upon the reasons mentioned by the patentee. The reasons should be reviewed in detail and action should be taken to resolve them. The pendency will affect the process of licensing too. The task can be assigned to the existing Govt. agencies such as Cell for IPR Promotion and Management (CIPAM), National Research Development Corporation (NRDC), Technology Information, Forecasting and Assessment Council (TIFAC), etc. A collaborative networking mechanism can also be created by incorporating already existing IP organizations to deal with such issues. A special body may be established to look after the issues related to Form-27 and resolving for the issues related to non-working of patents. It is also recommended that a dedicated mediator can play a crucial role to bridge the gap between the knowledge creator (academia) and knowledge exploiter (industry). That mediator should have knowledge, experience and exposure of work culture, environment and processing of industries as well as a research/academic institutions.

The IP rights are granted in return of the sharing the details in public domain and the rights holder has to assure the commercial exploitation of patented IP. The HEIs and NRLs are major chunks of patents and technologies generation. A researcher devotes a lot of efforts and time to reach until the grant of the patent since the inception of the idea conceived. The process is time-consuming and an expensive affair so the researcher should receive his rewards for his hard work and dedication. Hence, the patents and technologies generated at HEIs and NRLs should be disseminated by putting the details on the respective institution's websites, flyers, conferences, seminars, technology fairs, etc.¹⁰ The measures need to be taken for popularizing the licensing through organizing patents and technology fairs, conducting workshops in HEIs in collaborations with the industries. Collaborative research, contract /sponsored research can play a crucial role in the enhancement of patents licensing. Universities can establish dedicated cells to take care of activities related to sponsored research, commercialization, consultancy, IP generation and awareness. The involvement of the cell should start from the inception of the project, submission, management, budget, negotiation with funding organization, recruitment, etc.

Most suitable example of such kind of initiatives can be witnessed in first generation IITs such as, Kharagpur,

Madras, Delhi, Roorkee, Bombay, etc. These institutions can act as role models for the other HEIs in India as these institutes are leading in patents generation and commercialization. Recently IIT, Bombay has received 'National Intellectual Property Award', many times under the category of 'Top Academic Institution for Patents and Commercialisation' given by Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry, Govt. of India¹¹. These institutions also have established close linkages with the industries for knowledge creation and technology development, to identify new and emerging areas, to address real-time problems, for impactful quality of research and to design the curriculum as per the industry perspective.

Govt. of India also has floated some good schemes, which can be availed on the individual or institutional level by the researchers, scientists or faculty members. The most outstanding example of the scheme on the involvement of industries in research activities is 'Patent Acquisition and Collaborative Research & Technology Development' (PACE) by DSIR. This scheme started to support 'Make in India' products on an exclusive and non-exclusive basis. The scheme facilitates the early-stage acquisition of technologies from academic institutions, research institutions, industries from any part of India and abroad.

Moreover, to facilitate the public-private partnership and bridge the gap between industry and academia, the scheme also aims to develop a database of existing patents and expertise¹². Industries can avail the benefits floated by the DSIR through this scheme on exclusive, non-exclusive mode, co-development mode, or undertaking the technology advancement projects. The project categories and benefits have been classified based upon the mode of technology/patent acquisition by the industry¹³. Biotechnology Industry Research Assistance Council (BIRAC) has also introduced a scheme for academia with a similar name and alike mandates. The scheme mainly has two components i.e. Academic Innovation Research for promoting the development of Proof-of-concept for a process/product by academia with or without the involvement of industry and Contract Research Scheme for the validation of a process/prototype developed by the academia¹⁴. To avail, the benefits under both aforesaid components the institutes vis-a-vis Public or Private Institute, University, NGO, or Research Foundations, should have proper accreditation and registration from a Govt. body.

Mention of Bayh-Dole Act finds always a place when it comes to the debate on the patent generation and commercialization in the education institutes. This Act is being practised in the USA and has a great impact on the universities and encourages them to get involved in patenting the research and licensing afterwards. The patents generation have increased in universities about 500% since 1980 when the Act came into practice in the USA and this Act had an impact on the contract and collaborative research as well¹⁵. It is the fact that every nation has different legislation but such kind of Acts or its equivalents needs to be adapted in India too for encouraging innovators and entrepreneurship ecosystem.

It is also suggested that some crucial initiatives need to be taken on the institutions level such as every institution should have dedicated IPR policy with proper guidelines on revenue sharing in case of patent/technology transfer, guidance for patent/technology management procedures, clarity on ownership criteria, transparency in decision-making process, etc¹⁶. This initiative will encourage the researchers more to get involved in active research and they will get their due amount for their hard work and efforts they have rendered in. Recently, CIPAM has created a draft on 'Model Guidelines on Implementation of IPR Policy for Academic Institutions' with the prominent objectives like protecting IP rights generated by faculty and students of the academic institution, laying down fair and transparent administrative process for ownership control, and sharing of IP generated revenues, promoting collaborations between academia and industry, and establishment of an IP cell for supporting innovation of students, research scholars, and faculty members.¹⁷ Effective networking between institutions and regional/national IPR agencies may be a crucial aspect for the enhancement of IP generation and commercialization. Higher education institutes and universities can team up with the local 'Patent Information Centres' (PICs), which have been established by Technology Information and Forecasting Council (TIFAC)¹⁸ (GoI) in 20 states. IP commercialization can play a crucial role in strengthening the innovative capacity of MSMEs. The weak implementation of IPR legislation also impacts the innovation-driven micro and small scale (MSMEs) industries, whereas, MSMEs are the most crucial pillar of the commercialization aspect of the patent/technologies.

Compulsory Licensing

Compulsory licenses are generally defined as "authorizations permitting a third party to make, use,

or sell a patented invention without the patent owner's consent if it is not commercialized after the 3 years of its grant. Under the Patent Act, 1970 of India the provisions of 'Compulsory License' are specifically given under Chapter XVI, and the conditions which need to be fulfilled are given in Sections 84-92 of the Act⁴. In 2012, India granted first compulsory license to a Hyderabad based drug maker firm NATCO. This was a landmark decision in the history of Indian patent regime. Delhi High Court gave the decision in the favour of NATCO to make and sell a similar version of an advanced kidney cancer drug by Bayer's NEXAVAR[®]. The Judge imposed a condition on the NATCO Company to pay Bayer 6% royalty of net sales. It was observed that, after this case, Indian applicants took the case seriously and came out to furnish the information in the Form-27 as evident from the current study that filing of the Form-27 increased abruptly post year 2012 (Fig. 1). (This can be an important aspect for enhancing the technology commercialization ecosystem in India. There are so many patents which are being maintained by paying huge annuity for the sake of reputation but they are not commercialized. This attitude needs to be taken serious and compulsory licensing should be popularized.

India is a low-income country therefore it has fertile ground for the patents licensing and compulsory licensing. The technological proficiency of India needs to be addressed and India should be characterized more appropriately as a 'technologically proficient developing country' as opposed to a mere developing country. This information can be supported by the fact that, in the year 1992-93, the number of patents applications filed in India by foreign applicants was more as compared to the Indian resident applicants whereas, In the year 2001-2002 the reverse trend was observed. India have more of a technological base to make licensing and compulsory licensing more feasible.¹⁹ The issues related to food, medical, education, etc. can be addressed through the patents licensing and compulsory licensing. The Indian patents and technologies are being acquired by foreign markets and this scenario is not in the favour of the technological and economic development of India. The stakeholder like funding agencies from the state and central governments, education and research intuitions need to work in collaboration moreover students/researchers needs to be encouraged and educated to participate more in research and further to exploit the

research for the societal and economic development of the country.

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