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Commercialization and Renewal Aspects of Patent Management in Indian Pharmaceutical Industry

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Research on pharmaceuticals has mainly focused on the needs of developed countries while the scenario in developing countries is unclear. This industry is knowledge-intensive and unusually sensitive to intellectual property rights (IPRs).Patents play very important role in their business and this entails good management practices by the firms from various aspects of patent management. Two dimensions *viz.* commercialization of patents and renewal of patents are studied in this paper. There is dearth of in-depth research studies on these dimensions of patent management in India. A random sample of 300 granted pharmaceutical patents for patent renewal and another sample of 300 patents selected through purposive sampling for patent commercialization have been drawn from the population of granted pharmaceutical patents by the Indian Patent Office between 2005-06 and 2013-14. The information on working of patents has been taken from Form-27 submitted by the patent assignees of the selected patents. Some of the main findings are: a weak but positive and significant correlation between patent renewal & commercialization, blocking motive is the top most barrier to commercialization, direct contact with the partners is the chief mode of commercialization, no potential for technology is the main reason for non-renewal of patents, and enhancement of reputation is the main reason for renewal.

Keywords: Register of Patents, patent management, pharmaceutical industry, commercialization, renewal, inventions

Intellectual property rights (IPRs) are often cited as the building blocks of a firm's superior performance.[1,2] However, managers often face the dilemma in creating, using, and exploiting intangible resources that are difficult to codify[3,4] and less amenable to managerial manipulation and measurement. Revisiting the thoughts about these assets as "*Rembrandts in the Attic,*"[5] scholars in strategic management domain have raised serious concern over patents as a part of IP management[5,6,7] since patents help firms to maintain their competitive advantage.[4]This growing concern is reemphasized at the policy level in India where, IPRs, particularly the patents have been recognized as a marketable financial asset and economic tool.

Patent system was established with the objective of developing and protecting technology with a view to incentivizing innovation so as to use the 'knowledge' for social welfare.[8] There has been phenomenal growth in patenting over the past two decades, but this surge would facilitate technology transfer and socio-economic welfare only when the patents are worked locally on a commercial scale.[9]

Patent management (PM) is a multidimensional activity. Majority of the patents have minimal economic or technological importance as many of them are either not been exploited or are not exploitable in the countries[10] when actually the returns in terms of profit from the commercialization of innovation are the ultimate proof of the success of any invention or new product.[11] Patent commercialization has been cited as the most important incentive for monopolistic appropriation, whether innovations have been introduced in the market or not remains vague[10] and mere number of granted patents is not sufficient to evaluate the economic significance of the patents since the figures alone may not indicate the exploitation of the invention. The lack of information on use of patent is due to lack of data on commercialization in most of the patent databases.[12] Patent renewal is another important dimension of PM. It has no such data issue. The two PM dimensions, i.e. patent commercialization and patent renewal have been mostly studied independently[13,14] except in few cases.[10,15]

Managing patents in the pharmaceutical industry is challenging for the firms since this industry is knowledge-intensive and its economics is unusually

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sensitive to IPRs.[16] Moreover, studies have often focused more on the market institutions and regulatory framework of developed countries (US, EU etc.) while the scenario in developing countries is yet unclear. Such a gap needs to be addressed by researching other issues in patent management) so as to provide a wider and microeconomic perspective on the heterogeneity of firms on this aspect. After presenting the literature review and research methodology, this paper attempts an empirical firm-level analysis of granted pharmaceutical patents in India. This is then cross-validated with the survey of pharmaceutical industry. The main findings are: a weak but positive & significant correlation between patent renewal & patent commercialization, blocking motive-the topmost barrier to commercialization, direct contact with partners-the chief mode of commercialization, no potential for technology-the main reason for non-renewal and enhancement of reputation- the main reason for renewal. Findings from Form-27 along with survey responses on these two dimensions are exclusive to the Indian context.

Patent Management at the Confluence of Economics and Management

Economists perceive patents along two criteria: (a) embodiment of new knowledge in innovative product or process and (b) conferring limited monopoly rights to the inventor[17] However, the scholarly discourse on patent management has undergone a major paradigm shift from this role of patents to a tool "serving a gamut of purpose for the owners. "The cost and benefit of patents can be evaluated from various aspects: discovery, disclosure and commercialization.[18] The theory of development and commercialization[19] assesses one of these roles-commercialization. Patents are crucial in negotiating costs of innovation during technology transfer and licensing process.[8] Consequently, the demand for information would be enhanced if it has the peculiar property (inherent in the patent) which acts as incentive for the buyers. The term patent commercialization has been used (as an aspect of patent management) either in specific term[20] or under the broad term patent exploitation.[21,22] It is also discussed in context to evaluation of cost and benefit of patents.

Patent Renewal

The terms maintenance or renewal of patents has been used interchangeably in literature as well as in Patent Manual of Indian Patent office (IPO).[23] The same is followed in this paper to mean enforcement of patents through payment of maintenance fees. Patents once granted can be kept in force till 20 years through payment of renewal fees. The fee increases over time and varies (in US, fees is paid at the end of 4^{th}, 8^{th} and 12^{th}year) across countries, though annuities is quite common (India, China, Europe).The first renewal fee at IPO is effective from the third year of the filing date, before the expiry of second year. In case of patent grant being two years after the filing, payment of first renewal fee can be made three months from the date of record in the Register of Patents. Thus, renewal of patents assures its being kept in force and this does not refer to extension of the term of the patent.[24] Patents of addition (meant for modifications to an existing invention) are exempted from payment of renewal fee except in cases when the original patent is revoked and the status of patent of addition changes to an independent patent.

Patent renewal studies exist in literature mostly from the perspective of renewal as value indicators.[25-27] For example, for more than two decades, using econometric tools with renewal data, several studies have estimated the private value of patents on the assumption that more valuable patents survive longer and owners will only renew their patents if they derive economic benefits from them.[28] There is a widespread concurrence on this finding and that patent renewal influences patenting decision.[29,27] Only few patents have a significant high value and are kept for the maximum period, most patents reflect a low value as observed from renewal data and these show a fast depreciation.[13,27] In practice most of the patents expire before 10 years[30,26] indicating a high expiry rate. In US, 55- 67% percent of issued patents expire due to failure to pay these fees before the end of their term.[27] Literature, thus suggests that renewal of patents is an implicit exercise for the owners and the managers and practitioners in planning their IP strategy.[13]

Patent Commercialization

Commercialization of innovation is very much dependent on the knowledge/technology transfer to the firm which effectively develops it further as per the market needs.[30] There are two main options: either to use it in-house or look for external partners. Commercialization path is to license out the invention to enhance firm's competitiveness and this is the most common external path.[31]

Information on the quality and commercial potential of an invention does not indicate whether and how the invention is commercially exploited, and what its value is. The evaluation of the whole innovation is thus incomplete.[32] In reality, there is quite restricted use of patents (5 to 7 % of all inventions from granted patents hardly reach the commercialization phase). By one estimate, over half of all patented inventions are never commercialized.[33] Different studies report different rates depending on the sector, the geographical area and the nature of invention. British Technology Group (1998) reports approximately 40% of commercialization: 38% of European Patents; 47% of American patents and 55 % of 'US and Japanese' patents did not get commercialized. In a study based on a sample of 1082 patents granted to small and medium firms and individual inventors, 61% are commercialized *vis-à-vis* the rate in above-mentioned studies.[34] Research studies from US and Japan have cited strategic holding of patents as the main reason for non-commercialization of patents.[12] Higher survival rates of commercialized patents *vis-à-vis* the non-commercialized patents are reported in the case of new and original firms.[35] Among the modes of commercialization, in-house is more preferred mode in cases of technological uncertainty and complementary assets while it is licensing in cases of R&D collaboration with firms in a horizontal relationship[10,15] Delinking of patenting process from commercialization has been proposed on the grounds that commercialization is independent of whether inventions are patented or not.[36]

Linkage between Commercialization and Renewal of Patents

Proponents of "patent paradox" debate the innovation-fostering role of patents. They opine that in view of uncertainty in the commercialization of invention, innovation process is hindered[37] which is quite alarming especially in the pharmaceutical industry. Whether, the commercialized patents stand more chance of renewal or vice versa has been explored by few scholars who report that commercialization and defensive strategies increase the probability of patent renewal and patent quality influences commercialization and renewal decisions.[10,15,27] Other studies report commercialization variables to be statistically related to traditional variables measuring patent quality (patent renewal, forward citations, patent family size),[38,39] thus linking the two dimensions directly or indirectly.

Patents in Pharmaceutical Industry

Patents are embodiment of invention, containing information on the various aspects of invention: assignee, inventors, IPC class, claims, date of filing/grant etc. They are indicators of technical change[40] and unlike other resources they confer competitive advantage. They vary greatly in their nature across industries (in electronics and computer industry often sharing is required due to multiple patents while in pharmaceutical sector, one patent equals one product, so there is no sharing).[41] The pharmaceutical patent is used as a tool to recoup the investment made in the different stages of drug discovery, before the patent /product enters the market. This industry in India is among the top two in filing of patents. The record of filed and granted pharmaceutical patents between 2005-15 at IPO[42,43] in Table 1 shows, in the first two years of post-product patent regime, there has been a successive increase in the filing and grant of pharmaceutical patents, after which the number has fluctuated till date. The trend in granted patents, however has to be interpreted in terms of filed patents keeping in view other factors(the procedural aspects and technical content in the patent), as well affecting the grant.

Data and Methodology

The study is based on the analysis of secondary data (granted patents) and primary data through survey (elaborated later in the paper). Granted patents reduce the uncertainty about the precise scope of patent rights[44] and in post-grant stage, there are more chances of getting information

Table 1 — Patents filed and granted in the pharmaceuticals sector at IPO

Year	Filed	Granted
2005-06	2211	457
2006-07	3239	798
2007-08	4267	905
2008-09	3672	1207
2009-10	3070	530
2010-11	3526	596
2011-12	2762	282
2012-13	2954	344
2013-14	2507	256
2014-15	2640	389

on commercialization of invention as compared to the application stage. For studies on patent renewal, grant of a patent is must. In literature, there are more studies with filed applications and the fate of granted patents is often neglected except for few studies on the analysis of renewal pattern of patents.[27]

The data is compiled from 2 lists (2005-10 and 2011-13) on pharmaceutical patents at the IPO and later updated till the year 2015. This was done manually with the help of Search Engine of the website of IPO (ipindia.nic.in). To maintain the homogeneity in terms of assignees and for analysis the non-firm entities (universities, individuals and research institutes) were excluded from the sample. Moreover, more than 70% of the total granted patents were assigned to the firms. Finally, a population of 4010 firms was considered for this study.

The details on renewal of patents (whether ceased or in force; the term of fee payment) is recorded from e-register. The commercialization status of patents is recorded through the working of patents (Form-27) which is used as a proxy for commercialization. These forms filed by the firms have information on development/commercialization and working status of the invention. A random sample of 300 patents has been drawn from 4010, following the guidelines suggested for a confidence interval of 95% and p=.05according to which a sample of 364 is adequate for a population of 4000.[45] This is close to the size of population (4010) of patents used in this study.

The data is subjected to descriptive and statistical analysis employing uni-variate to bi-variate techniques-Mean, Pearson's Correlation, Independent Sample T-Test, Pearson's Chi-Square Test with the help of tools Excel and SPSS (Version 20).For the year of analysis (2015), the author could see Form-27 filed for either 2012or 2013 or for both the years, thus restricting the scope of analysis to these years only.

Patent Data Analysis

Patent Renewal

Overall Trend and Pattern

The observation of proportion of patents renewed at various ages and their relative renewal fee schedules reveals estimated distributions of the value of holding patents in the case of studies from US.[46,13] This methodology was also applied to European patents[14,47,48,13] and more recently to US patents.[46,49]

The same methodology is applied to the sample of 300 patents, to study the survival rate of patents, patents renewed at different age and a comparison of the active and ceased patents. In the given sample, only 272 patents with the required data could be accessed since data on renewal were missing for 16 patents and the record of 12 patents were missing. All these 28 patents were excluded from the study. The data on renewal fee of the patents has been used in the survival analysis of patents. In other words, this is an estimate of the average life of a patent or even the average duration for which the patents are maintained by the patentee. The insights from Table 2 are developed, based on assumptions that these patents may have expired or still may have been renewed beyond 2015, the year of analysis. In the given sample, patents, 69.12% of patents have completed half of their legal term, while 13.97% of patents have completed ¾ of their term. Only 2 patents have completed their full term. This is 0.74% i.e. not even 1 % of the total patents in the sample. The maximum number of patents fall in the 6th renewal fee category meaning thereby that majority of the patents have been renewed till 6th year, irrespective of their fate ahead.

In the next step, the sample was split in two sub-samples: the active patents (146) and the ceased patents (126) to compare their fee payment pattern from the perspective of payment in clusters as per the latest provision in Indian Patent Act, 1970 in 2015, where by the patentee can pay the 3 instalments in a

Table 2 — Details of renewal of pharmaceutical patents between 2005-06 and 2013-14

Yrs of renewal	20	19	18	17	16	15	14	13	12	11	10	9	8	7	6
Cumulative no. of patents renewed	2	6	10	16	26	38	56	80	128	158	188	216	246	262	270
% of total patents (N=272)	0.74	0.74	3.68	5.88	9.56	13.97	20.59	29.41	47.06	58.09	69.12	79.41	88.97	96.32	99.26

single cluster as an alternative to annual instalments.There are four clusters with uniform fee for each year of the cluster but with different amounts for small entity (small and medium) and other than small entities (the large firms) respectively. The cluster starts from second to sixth payment (Rs. 2000 and Rs. 4000 respectively), seventh to tenth payment (Rs. 6000 and Rs 12000 respectively), eleventh to fifteenth payment (Rs. 12,000 and Rs. 24,000 respectively) and sixteenth to twentieth payment (Rs. 20,000 and Rs. 40,000 respectively).

In the case of ceased patents (Fig. 1a), a miniscule proportion of patents (4) had ceased after paying in 3rd to 6thcluster. The maximum concentration (84) of ceased patents occurs between 7th to 10th instalments which is indicative of their probable enforcement till nearly half of their statutory life. A good proportion of patents (50) expired after the third cluster (11th to 15th) showing the survival trend beyond half of the legal life of the patent. Again, a miniscule proportion of patents (4) show survival beyond 16th instalment. The reasons for the expiry of these patents could not be gauged from the patent data, one of its limitations so these were explored through survey to develop a more holistic view on renewal behavior of the firms. These survey findings are discussed in the section ahead.

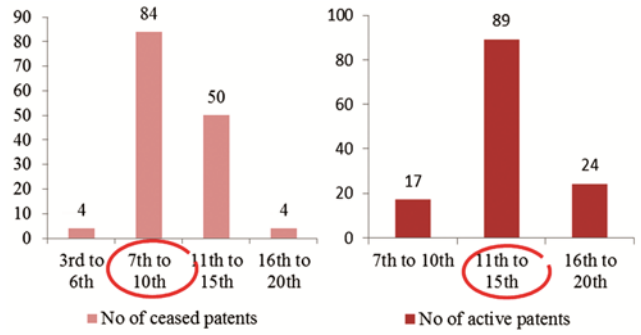

Fig. 1a — Renewal of ceased patents; 1b — Renewal of active patents

In the analysis of active patents (Fig. 1b), out of 130 maximum number (89) of patents lie in the cluster of 11th to 15th instalment and 24 patents lie in the cluster of 16th to 20th instalment. The remaining17 patents belong to the cluster of 7th to 10th instalment. The survival period till which the patents are active can also be calculated but keeping in mind that these patents may be still active or maybe expired or abandoned, after the date of data collection.

Patent Renewal Behavior of Firms

Patent renewal behavior was studied at the firm level, by comparing different categories of pharmaceutical firms in the sample of 300 patents. Literature has reported differences in inter-firm behavior in patent renewal process where firm types based on origin[50] have played a significant role in taking decisions on patent renewal. The number of patents possessed by the firms has also been found to be instrumental in the maintenance duration of patents.

Accordingly, firm size is defined by categorizing the firms, firstly on the basis of their number of granted patents in the given period of study 2005-2014 and secondly based on the nature of the ownership of patent. On the basis of number of granted patents, firms are categorized as small firms denoted by A (possessing 1 patent) and large firms denoted by B where (possessing >1patent). In the second case, based on the ownership of the patents, firms are categorized as non-residents or residents, depending on based out of or in India respectively.

Patent Maintenance Duration based on Firm Size

The continuous nature of outcome variable "maintenance duration" enabled the use of independent sample t-test to measure the difference between the maintenance duration of patents of the two categories of firms (A and B). It is was observed (Table 3a) that firms in category A have maintained their patents for lesser duration (Mean=10.84;

Table 3a — Descriptive statistics for patents groups based on number of granted patents

	Firm's category based on patents	N=Patents (Firms)	Mean	SE	SD
Maintenance duration of the patent	A= 1 patent	102(102)	10.84	2.246	.222
	B> 1 patent	198(60)	11.70	3.394	.259

Table 3b — Mean-difference between the maintenance duration of patents in different groups of firms

	t	df	Sig.	Mean diff.
Maintenance duration of the patent	-2.3	272	0.02	-.855
	-2.5	0.27	0.01	-.855

SD=.222) than the firms in category B (Mean=11.70,SD=.259). The t-statistics=2.265 and p-value=0.000 indicate a difference in variance between the two groups of firms. With p= 0.024,there existed a significant difference in the maintenance duration of patents of these groups (Table 3b). The mean value of patent maintenance duration in each category of firms is close to 10 years or slightly more. This echoes the findings that "about half of all patents are renewed through age 10", indicating a significant usefulness of most of these patents.[27]

Patent Renewal Status and Firm Size

Further, the correlation between the firm's types and the patent renewal status was studied. Pearson's chi-square, anon-parametric test was performed using the sample of 300 patents from which only 296 complete cases were used in the analysis due to missing value of 1.3% which is within the acceptable limit of 5%.[51] The results were used to compare the patent renewal behavior of firms.43.8% of the patents owned by category A firms, are renewed while 56.2% of their patents are not renewed (expired). On the contrary, 40.2% of patents owned by firms in category B are renewed while their 59.8 % of patents are not renewed (Table 4a).

Table 4a — Relationship between firm size and patent renewal behavior

Firm type based on no. of patents	Working status of the patent		
	Patent is renewed (Y)	Patent is not renewed (N)	Total
Firms with 1 patent (A Type)	43.8%	56.2%	100.0%
Firms with >1 patent (B Type)	40.2%	59.8%	100.0%
(N=296) 2×2 table	42.6%	57.4%	100.0%

Table 4b — Measures of significance between the groups

	Value	df	Asymptomatic Sig. (2-sided)
Yate's Continuity Correction	0.225	1	.635
Phi^ (strength of correlation)	0.035		0.000

p-value is significant at 5% (2-tailed)
^ indicates the strength of correlation

The renewal status of the firm's patents (whether the patents were active or ceased) was examined further to find out whether the existing differences were significant or not. From the observed statistics on Chi-square, χ^2 (2, N=296), (Asymptomatic sig.=0.635, p=0.000), a significant correlation between the patent renewal behavior and the firm types was found. However, the relationship was moderate[52] from the given value of Phi (φ), a measure for the strength of correlation (Table 4b).

Patent Commercialization

The commercialization aspect of patent management is studied through the analysis of Form-27, the findings of which are cross-validated with the survey responses. 'Working of the patents has been used as the proxy for patent commercialization, as disclosed in Form-27. Under the Indian Patents Act, 1970, Section 146, it is mandatory for the patentee to disclose the working/non-working of the patent with other details of reasons for not working of if working, the mode of working, the geographical area of working, the amount of product/sales/ revenue and whether or not the public requirement is met.[53] However, in practicality, due to high confidentiality and secrecy element in pharmaceutical sector based on fear of losing the competitive edge, most of the assignees either do not disclose the details or disclose vaguely restricting the scope for a comprehensive analysis from the research perspective.

The samples of only active patents (300) are taken through convenience sampling technique, since Form-27 is applicable to only active patents. This sample is distributed among 50 resident and 100 non-resident firms, each firm represented by 2 patents. From 300 patents, only 266 patents were accessible while 34 had missing record. The break of 266 patents in terms of no record of Form-27 (despite the availability of patent details), non-working and working patents is 40:167:59. Non-resident and resident firms have 25 and 15 missing record on Form-27 respectively. Even for non-worked patents the share of non-resident firms is higher (142) than for resident firms (24) which could be attributed to the unequal sample size. The number of worked patents for the two groups is quite close: 27 for non-residents and 33 for resident firms (Table 3).

A further detailed investigation of the available Form-27 disclosure of 226 patents was done to

study a) the modes of working the patents and b) reasons disclosed for not working the patents in India. There are 25 reasons disclosed by the patentees for non-working of the patents and 5 reasons for modes of working of patents. In few cases (16) where working status is confirmed, the records for Form-27 were not accessible. This could be attributed to lapses on the part of the patentee or even the technical problems in uploading the form by the patent office.

Modes of Working of the Patents

A total of 60 patents (27 non-residents and 33 residents) were found to have been reported as working through 5 different modes (Table 5). Manufacturing of the product in-house has featured as the most prominent mode. Licensing has been observed in very few instances of disclosure, the major reason most likely being due to nascent stage of invention or invention being in different phases of development. The prolonged life-cycle of the product may also prolong licensing process. Even if the invention is ready to be commercialized or licensed, search for potential partners/market seems to have kept the firms back from out-licensing. There are very few cases of licensing (single and multi licensees) implying that firms in the sample had perhaps less of R&D collaboration with firms and external industrial knowledge.[35] There have been few cases of export (6) of products and still fewer for import of products (3). A miniscule proportion of the patents (3) have failed to make disclosure about the mode of working of the patent.

Reasons for Non-working of Patents

The analysis of 166 non-worked patents led to the identification of 25 different reasons for not working the patents (Fig. 2), the most prominent reason being "nothing in particular" which was reported in 19 cases of disclosure. This may be due to non-disclosure policy of the firm or no decision on the working of the patent.

The top 5 reasons which have emerged as the major reasons for not commercializing the patents are "search for commercial partner", "underdevelopment of the technology"/ "improvement in invention", "under pre-clinical development" and "further development of the invention" and "no marketing approval". Of all the disclosed reasons, only search for commercial partners overlaps with the survey findings with respect to rank though many other reasons/barriers are common between the two cases. For example, the economic and technical evaluation has a very low rank in Form-27 disclosure in contrast to their ranking in survey. "Under development of technology" and "potential demand for technology" is also identified as top barriers in survey responses. The information from Form-27 partially cross-validates the findings from the primary data. A total of four barriers is common to both, the Form-27 disclosure list and survey items.

Patent Ownership and Patent Commercialization

The relationship between patent ownership and status of patent commercialization has been analyzed with the use of Chi-square test, due to the categorical nature of both the variables. Table 6a presents the results of analysis of 218 complete cases which showed that 89.60% of non-resident patents are worked while 10.4% patents are not worked while in the case of patents owned by the residents 52.70% of patents are not worked while 47.3% patents are worked. In the overall sample, 80.3% of patents are worked while 19.7% of patents are not worked. From the significance value (p=0.000) of Yates continuity correction (meant to reduce the overestimation of result in case of unequal samples), the two groups of assignees differ significantly in the working of their patents, a measure for patent commercialization (Table 6b).

Table 5 — Modes of working of patents from Form-27 analysis

S. No.	Modes of working		Worked patents	
		Total patents	Resident firms	Non-resident firms
1	In-house manufacturing	28	18	10
2	License granted	20	10	10
3	Product exported	6	2	4
4	Product imported	3	2	1
5	No information	3	2	1

Source: Details extracted manually from Form-27

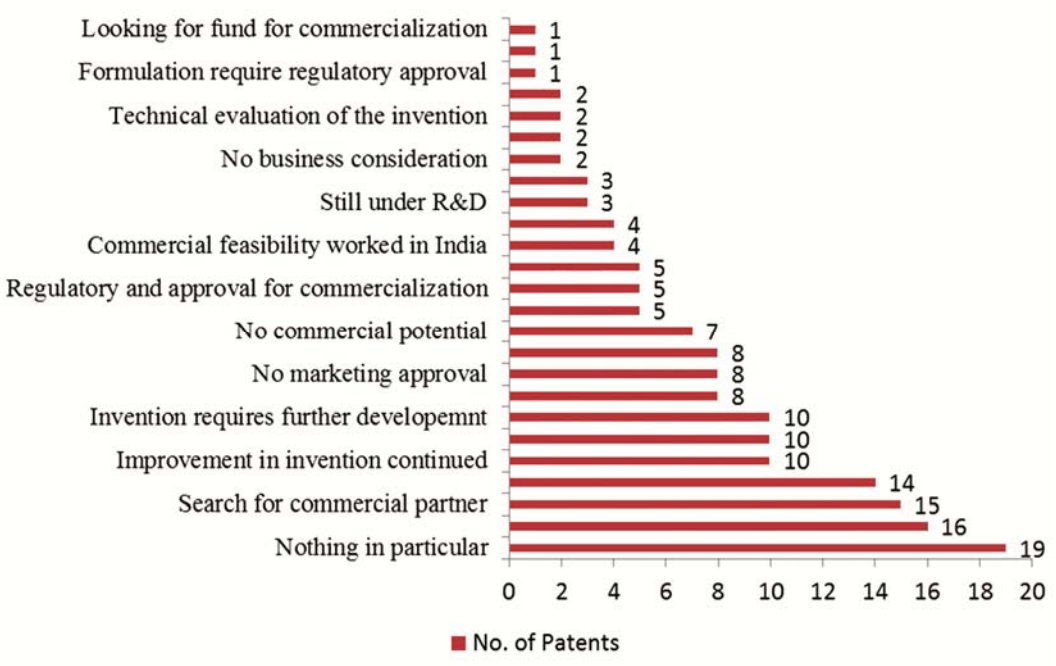

Fig. 2 — Reasons for non-working of the patents (extracted manually from Form-27)

Table 6a — Correlation between patent ownership and status of patent commercialization

			Working status		
			Patent not worked(N)	Patent worked(Y)	Total
Renewal status	Patent ownership-Non-resident (1)	% within the working status	89.6%	10.4%	100%
	Patent ownership-Resident(2)	% within the working status	52.7%	47.3%	100%
(N=218)		% of Total	80.3%	19.7%	100%
2×2 tables					

Table 6b — Measures of significance between the groups

	Value	df	Asymptomatic. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Yate's Continuity Correction	32.966	1	0.000		
^Phi (for strength of correlation)	0.402		0.000		

p- Value is significant at 5% (2-tailed)
^ indicates the strength of correlation

Linkage between Patent Commercialization and Patent Renewal

Correlation between Status of Patent Commercialization and Patent Maintenance Duration

The assumption that patents which are maintained for longer duration are more likely to be commercialized or vice versa has been tested empirically by quite a few scholars and has been found to be positive with varying degree of association between the two variables.[10,15,40] This linkage has been explored mostly in the case of patents in health and semi-conductor sector with studies concentrated in the geographical regions of Europe and US. Whether the same holds true for pharmaceutical patents in India, is being tested. The correlation between these two dimensions has been studied using the sample of 300 granted patents. This was accomplished in two stages:

Due to missing data on both the variables, only 200 complete cases were analyzed to check for correlation between the two variables (Table 7). A weak (r=0.2) but significant correlation (p=0.005) between patent maintenance duration and patent commercialization

Table 8 — Rating of the reasons for maintenance and non-maintenance of patents

S.No.	Reasons for non-renewal	Mean score	S.N	Reasons for renewal	Mean score
1	No potential for technology transfer/licensing	3.43	1	For enhancement of reputation	3.64
2	No commercial utility	3.35	2	To increase the strength of the company portfolio	3.53
3	Technology obsolescence	3.13	3	Potential future use	3.42
4	Company's policy on maintaining for limited period	2.64			
5	Left for public use	2.43			
6	Lack of finance for payment of maintenance fees	2.16			

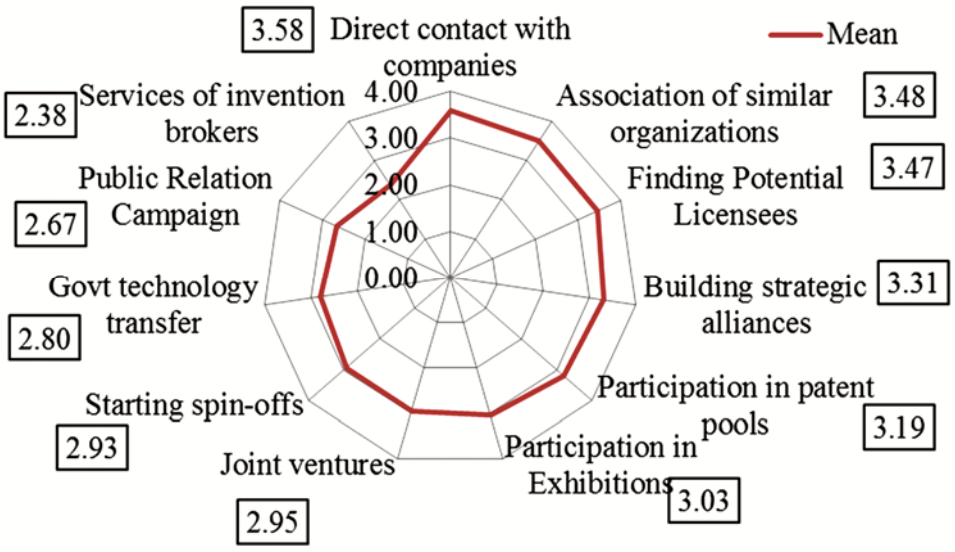

Fig. 3 — Mean score analysis for the different modes of patent commercialization

status (measured by working status of patents) was found. This explains that patents maintained for longer duration are likely to be commercialized and *vice-versa*, keeping other factors in mind like other non-strategic uses of patents, which might also be responsible for long duration of maintenance. The finding partly aligns with the existing co relational studies in earlier literature.[15,16]

Analysis of Primary Data

The findings from the patent data were complemented from survey findings in order to firm up the perspectives on these two dimensions. The survey was designed to elicit responses from either the intellectual property managers or research scientists of the pharmaceutical firms in India, based on one respondent per firm as the criterion. The content of the questionnaire was a mix of closed-ended, open-ended items with few dichotomous and multiple choice questions. Items were measured with the 5-point Like rt scale (strongly disagree=5 to strongly agree =1). The items were validated with the help of experts in intellectual property management, pilot tested and finalized. After minor modifications (by omitting items which were less likely to generate responses or were ambiguous),it was administered to the respondents between March, 2014 to September, 2015.

The questionnaire was sent by mail/post or handed in person to the respondents from a total of 400 firms. Only 82 forms were returned from which those with incomplete responses (15) and blank forms (5) were discarded. From the remaining 62 usable forms, only 60 were used to get a homogenous sample of domestic firms. The 2 forms from non-resident firms were discarded. A response rate of 20.50% (82/400) was observed.

Sample Profile and Survey Findings

The respondent firms had a fairly good geographical spread over India with practically no

Table 9 — Ranking of the barriers to commercialization (Mean analysis)

S. No.	Barriers to Commercialization	Mean score
1	Blocking motive of other firms	4
2	Economic evaluation of invention in patents	3.24
3	Nature of invention	3.2
4	Field of invention	3.2
5	Potential demand for technology	3.17
6	Technical and technological evaluation of invention	3.17
7	Underdevelopment of technology	3.1
8	Lack of professional expertise and expert knowledge	3.08
9	Difficulty in identifying partners	3.02
10	Lack of markets for technology	3
11	Ownership issue while developing technology	2.67
12	Cost of drafting and negotiating contracts	2.53

firm from the North-East zone, which actually is not even a pharmaceutical hub. The mean age of the respondent firms was found to be 36.65 years while the mean experience of the respondents was more than 10 years. The respondent firms were neither too old nor too young as the average age of the firms is 20 years and the average experience of the respondents was 10 years. Keeping in mind, the two decades of TRIPS Agreement (1995) and the product patent regime[54] implementation in India in 2005, the firms' experience with age and the respondents' knowledge about the IP issues justifies their selection as key informants. For their selection, purposive sampling technique[55] was employed since respondents with expertise in a specific domain were required. The IP managers with their business expertise, research scientists with their knowledge of the invention and both being a part of the decision on maintenance and commercialization of patents in most of the organizations, were suitable enough to respond to the questionnaire.

Findings on Maintenance of Patents

The ranking of the reasons for maintenance and non-maintenance of patents have been presented in Table 8. Firstly, the reasons for non-maintenance were evaluated, where the respondents showed highest preference for "potential for technology transfer" which along with "no commercial utility of the invention" emerged as the two most important reason. "Lack of finance for payment of fees" and "patents left for public use" was ranked as the least important factors for reasons of non-maintenance of patents by the pharmaceutical firms. Lack of finance is not a deterrent factor in patent renewal process in the Indian context.

Secondly, the reasons for maintenance were analyzed. "Enhancement of reputation" with the highest mean score of 3.64 emerged as the topmost reason while "building strength of the portfolio" with a mean score of 3.53 was rated as second. This is quite logical from the perspective of capturing market share in their technology area to maintain their competitive edge.[57] "Potential future use" is the least important reason for maintaining the patents, perhaps due to the fact that technology obsolescence has not as much impact in the pharmaceutical industry as in the other hi-tech industries, electronics and mobile.

Findings on Patent Commercialization

The respondents were asked to give their preferences for a) modes and b) barriers to commercialization. For the pharmaceutical firms, direct contact with the companies (mean =3.58), association with similar organizations (mean =3.48), finding potential licensees (mean=3.47) and building strategic alliances (mean=3.31) were the top four preferred mode of patent commercialization. Public relation campaigns (mean=2.67) and services of invention brokers (mean=2.38) were the least important routes of commercialization for the sample firms. Other modes, participation in patent pools, exhibitions joint ventures and starting spin-offs were accorded mid-way ranking among all the items.

Among the barriers to commercialization (Table 9), blocking motive (mean=4) has emerged as the topmost deterrent, which is at the policy level. However, the next three important barriers: economic evaluation of the invention (mean=3.24), nature of invention (mean=3.2) and the field of invention (mean=3.2) are other important barriers which are at the level of invention. Potential demand for technology, technical evaluation (mean=3.17) and technological evaluation of the invention (mean=3.17) are found to be the next level of barriers faced by the firms in the sample.

Discussion

The findings on patent renewal show that a majority of pharmaceutical patents expire by the age of 10 which is indicative of not reaching the full term of 20 years. Literature suggests private value of patents is linked with the renewal process and thus predict fast depreciation of patents with low value.[13,27]

In practicality, however expiry and underutilization of patents could be due to the company's financial constraints, policy reasons, no potential commercialization, patents left for public use or technology obsolescence as has been observed from survey findings. Lack of finance especially is not a deterrent for patent renewal process for the sample firms which could be ascribed to major share of pharmaceutical patents being owned by the non-resident firms which often possess strong patent portfolio. However, this result contradicts the findings from US sample where expiry of almost 60% is reported due to non-payment of renewal fees. This particular finding needs careful interpretation, with caution since the reasons for failure to pay could be company's policy or finance.[27]

In context to patent commercialization in this sector, both resident and non-resident firms show a large percentage of non-working patents, which could be due to multiple reasons: technical, administrative, regulatory. These findings can also be justified in the backdrop of an important study from US and Japan where strategic holding of patents has been found to be the basic reason for non-commercialized patents.[34]

Form-27 disclosure shows that reveals a miniscule proportion of granted patents is being worked/ commercialized while majority of the patents are in the embryonic stage[19] in search for suitable market conditions or partners. The sample consists primarily of very early stage inventions which are undergoing further development, or are being tested for efficacy or are also undergoing clinical trials. Consistent with the work of other scholars who have examined invention commercialization,[57,59] the inventions in Form-27 sample are either at the proof of principle or proof of concept stage, and are rarely prototypes that are ready for manufacture or production. Therefore, they require further development to reach the commercialization stage.[58]

For the study of modes of commercialization, two different perceptions have emerged: (a) In Form-27 disclosure, the most preferred route of commercialization for the pharmaceutical patents in India has been found to be the in-house route of manufacturing and sale of products, while licensing takes a back seat; firms which lack complementary assets (marketing or distribution channel), mostly make in-house use[59] of patents, however, these firms have a competency for using the technology in-house; technological uncertainty could also be one of the likely reasons for in-house manufacturing; (b) From the responses to items on modes of commercialization, direct contact, association with similar organizations and finding potential licensees have emerged as the most important routes of commercialization.

The survey responses on barriers overlap with Form-27 findings to quite an extent.The findings from Form-27 can only be partially cross-validated with those from survey due to two reasons: Firstly, the modes of commercialization identified through Form-27 disclosure are only 5 (due to a large-scale secrecy or procedural complications in working of the patents) against the 12 items in survey questionnaire. Besides, the sample of respondent firms in survey is 60 while in case of Form-27, disclosure of 150 firms (accounted for 265 patents) have been analyzed. Thus, the unequal sample size might be partly responsible for a fully conclusive result.

Conclusion

This paper has tried to capture some aspects of patent management from the perspective of developing countries. Accordingly, the conducted study has identified the existing barriers to commercialization, high rate of expiry of patents and reasons for not working the patents. The sensitivity of pharmaceutical sector to IPR has also been confirmed through the lack of adequate disclosure on the part of the firms, either in Form-27 or in survey. The findings from patent data have been complemented with those of survey findings on these two dimensions. Findings from both sources overlap to quite an extent, with search for potential partners and licensing as the topmost reasons for not commercializing the invention. In terms of rank, "search for potential partner" is same, *i.e.* it is topmost in both cases.

Similar studies can be replicated for different industries using advanced econometric techniques to offer wider perspective on these topics. The small sample size of respondent firms which are exclusively domestic firms restricts the scope of generalization of findings from survey. Missing data especially in the case of Form-27 upload or missing renewal information on some patents due to missing record are some of the limitations of this study. However, due to heterogeneity of patents across industries and IP laws across countries, a single industry focus is able to provide a comprehensive and new perspective on pharmaceutical patents granted in India. This work opens up further avenues to supplement findings from in-depth interviews and case studies. The managerial

implications of this study lie in reassessment of the firms' strategy for tackling the challenges in these two dimensions for optimization of patents as well as to unlock the economic resources in these intangible resources.

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