

**SELECT DIMENSIONS OF PATENT MANAGEMENT
IN PHARMACEUTICAL INDUSTRY IN INDIA:
MOTIVE, COMMERCIALIZATION,
RENEWAL AND OPEN INNOVATION**

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by

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Submitted

in fulfillment of the requirements of the degree of Doctor of Philosophy

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Dedicated to My Papa

Dr. Onkar Krishna

Who was a visionary,

Who dreamt about future

Who lived by example and most importantly

Who inspired his daughters to believe in “sky is the limit”

CERTIFICATE

The thesis entitled ”**Select Dimensions of Patent Management in Pharmaceutical Industry in India: Motive, Commercialization, Renewal and Open Innovation**”, being submitted by Ms. Vinita Krishna to the Indian Institute of Technology Delhi for the award of DOCTOR OF PHILOSOPHY (Ph.D.) is a record of bona-fide research work carried out by her under our guidance and supervision. She has fulfilled the requirements for the submission of the thesis which has attained the standard as required for a Ph.D. degree of the Institute. The results presented in this thesis have not been submitted elsewhere for award of any other degree or diploma.

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I wish, I was H G Wells and could rather turn back the time and reach out to my papa with the copy of my thesis. With all hopes that he is watching from above!!

(Vinita Krishna)

ABSTRACT

The growing importance of intellectual property rights (IPRs), the surge in patenting and their recognition in the economics and management literature reiterates IP as one of the building blocks of a firm's superior performance. However, questions remain as to how managers should create, use and exploit intangible resources that are difficult to codify and less amenable to managerial manipulation and measurement. In this backdrop and motivated by the anecdotal evidences in the seminal work of Arrow (1962); Lemley & Shapiro (2005), this research project was planned, taking cues from Griliches (1990) that patents are a research repository, especially in the absence of detailed data on R&D. It was further fine-tuned with the help of thought-provoking paper by Hall & Harhoff (2012) offering multi-dimensional perspective on recent research on economics of patents, to explore the area of patent management.

Depending on the firm's activities, patent management system is categorized as a series of value-generating activities, referred to as the "value chain, conferring patent-based competitive advantage. Quite a number of literature raise the concern on understanding how the pharmaceutical firms plan their patent filing strategies, what use is made of patent renewal data through patent characteristics for value creation and what barriers and modes of commercialization exist for firms? The challenges in Open innovation in course of managing IP has also been pointed out as important dimension of patent management (PM).

This research project is based on a microeconomic perspective where the behaviour of firms is studied in context to its patent management activities, being examined from a multidimensional perspective. The selected dimensions are studied in literature mostly in isolation or in a group of two but not in this selected group of four.

The first dimension is patenting motive. It is studied with a view to examine the strategic motives of the firms in the wake of changing business models and the diversifying role of patents. Parallel to the emerging literature on strategic patenting, numerous authors have concentrated on the analysis of patent-based indicators to determine the economic value of patents. The patent characteristics have been used for studying the next two dimensions: patent commercialization and patent renewal. These are taken up for exploratory and inductive analysis whereby the attitudinal

perspectives of the firms on these dimensions are captured. These three dimensions have been identified in literature as the primary activities and are the key value extracting activities in PM. Literature suggests, patent commercialization as the most important incentive for monopolistic appropriation, whose external path often requires protocols for ownership, (co-patenting/exclusive ownership), the use of the generated IP and their licensing/ transfer.

The third dimension, patent renewal is studied next to patent commercialization, whereby firms' behavior towards maintaining patents and the decision to renew them is analyzed. OI is studied as the fourth dimension to understand firms' readiness for knowledge exchange in times of changing business models and IP regime, tightening IP/ regulatory environment. OI study has been recommended by OECD project (2009), as necessary in order to partially fill the gap on "the knowledge on firms' innovative behaviour and its determinants" to "design effective innovation policies". This study attempts to arrive at few inputs for such policies.

These four dimensions are part of an exploratory research, using both primary and secondary data at the firm and patent level using the descriptive statistics and statistical techniques: Mean, Pearson's correlation, Independent sample t-test, Pearson's chi-square test, one-way ANOVA, Linear regression, Binary logistic regression, Factor analysis and Multiple imputation. Data on granted patents were sourced from Indian Patent Office for the year 2005-2014 and have been used in conjunction with firm-level data from Ace Equity data base and survey response from 60 Resident firms. Questionnaire had items measured on 5-point Likert-scale.

The key findings capture the pharmaceutical firms' behaviour in context to these four dimensions. With respect to their patenting motive strategy, protection of invention and preventing imitation have emerged as the predominant motives in India as well. Licensing and secure finance models are the best fit models of all individual motives pursued by the firms in the studied sample. Patent characteristics as claims and patent renewal data can serve as proxy for value /quality determination of patents through non-monetary method, especially in the absence of a uniform monetary valuation method for IP.

In terms of patent renewal behaviour, there is no inter-firm variation in the renewal pattern of small and large firms but there is a significant difference in maintenance duration of patents by small and large firms, the size of firm measured by number of granted patents. The legal scope of invention (claims), team collaboration (number of co-inventors) and number of granted patents are significant predictors of patent renewal while maintenance duration and patent ownership are significant predictors of the probability of patent commercialization. However, claims are not significant for the same. Findings from both, Form-27 and survey have shown in-house manufacturing as most common mode of working the patent and search for commercial partner as the major barrier to patent commercialization.

The positive linkage between these two dimensions echoes the existing findings that patents maintained for a longer duration are more likely to be commercialized. Pharmaceutical patents in India too expire on an average by ten years; the likely reasons for their non-renewal are lack of potential technology transfer, commercial utility and technology obsolescence as observed from the survey findings. Firms however, renew their patents mostly for enhancing their reputation and building portfolio strength. In the OI practice, Resident firms show similar extent of collaboration as the Non-resident firms as evident from the number of co-inventors from the patent data. However, there is inter-firm variation with respect to their collaboration in the form of M&A activity i.e. Non-resident firms are more active than the Resident firms of India.

This work has significant contributions for academic research: the importance of human capital (co-inventors), the critical use of resources (patents) for competitive advantage, especially the domestic firms. The policy implications for the government/IP authorities lies in adopting more effective measures, compatible to the comfort of pharmaceutical firms in regular disclosure of information in Form-27. The managerial implications lie for the top-level management of very young firms in taking cues from the well-established Intellectual Property Management Systems (IPMS) of large firms to draft their IP policy based on their needs. The use of patent characteristics as claims and patent renewal data can serve as proxy for value /quality determination of patents through non-monetary method, especially in the absence of a uniform monetary valuation method for IP.

सार

बौद्धिक संपदा अधिकारों (आईपीआर) के बढ़ते महत्व, पेटेंटिंग में वृद्धि और अर्थशास्त्र और प्रबंधन साहित्य में उनकी मान्यता आईपी को फर्म के श्रेष्ठ प्रदर्शन के निर्माण ब्लॉकों में से एक के रूप में दोहराता है। हालांकि, प्रश्न प्रबंधकों को बनाने, उपयोग करने और प्रबंधन के लिए मुश्किल बनाने के लिए प्रबंधनीय हेरफेर और माप को कम करने के लिए मुश्किल है जो अमूर्त संसाधनों का निर्माण, उपयोग और शोषण के रूप में बने रहेंगे। इस पृष्ठभूमि में और एरो (1962) के महत्वपूर्ण कामों में एक्टिटल रिकॉर्ड्स द्वारा प्रेरित; लेम्ले एंड शापिरो (2005), इस शोध परियोजना की योजना बनाई गई, ग्रिलिस (1990) से संकेत लेते हुए कि पेटेंट एक शोध भंडार हैं, खासकर आर एंड डी पर विस्तृत डेटा के अभाव में पेटेंट प्रबंधन के क्षेत्र का पता लगाने के लिए, पेटेंट के अर्थशास्त्र पर हालिया शोध पर हॉल एंड हार्फ (2012) द्वारा हॉल और हार्वफ (2012) के द्वारा हालांकि, प्रोपोजिंग पेपर की सहायता से इसे और अधिक बेहतर बनाया गया था।

फर्म की गतिविधियों के आधार पर, पेटेंट प्रबंधन प्रणाली को मूल्य-सृजन करने वाली गतिविधियों की शृंखला के रूप में वर्गीकृत किया जाता है, जिसे "मूल्य शृंखला के रूप में संदर्भित किया जाता है, पेटेंट आधारित प्रतिस्पर्धात्मक लाभ प्रदान करता है बहुत सारे साहित्य यह समझने पर चिंता पैदा करते हैं कि फार्मास्यूटिकल कंपनियां अपने पेटेंट दाखिल करने की रणनीतियों की क्या योजना बना रही हैं, पेटेंट नवीनीकरण के डेटा से मूल्य सृजन के लिए पेटेंट की विशेषताओं और फर्मों के लिए बाधाओं और व्यावसायीकरण के तरीकों के कारण क्या उपयोग किया जाता है? आईपी प्रबंधन के दौरान ओपन नवाचार की चुनौतियों को भी पेटेंट प्रबंधन (पीएम) के महत्वपूर्ण आयाम के रूप में बताया गया है।

यह शोध परियोजना एक सूक्ष्म आर्थिक परिप्रेक्ष्य पर आधारित है, जहां पेटेंट प्रबंधन गतिविधियों के संदर्भ में फर्मों के व्यवहार का अध्ययन किया जाता है, जिसे बहुआयामी परिप्रेक्ष्य से जांच की जा रही है। चयनित आयामों को ज्यादातर अलगाव में या दो समूह के साहित्य में पढ़ाया जाता है, लेकिन चार के इस चयनित समूह में नहीं।

पहला आयाम उद्देश्य पेटेंट कर रहा है। बदलते कारोबारी मॉडल और पेटेंट की विविधतापूर्ण भूमिका के चलते फर्मों के रणनीतिक उद्देश्यों की जांच के लिए इसका एक अध्ययन है। सामरिक पेटेंटिंग पर उभरते साहित्य के समानांतर, कई लेखकों ने पेटेंट के आर्थिक मूल्यों को निर्धारित करने के लिए पेटेंट आधारित संकेतकों के विश्लेषण पर ध्यान केंद्रित किया है। पेटेंट की विशेषताओं का उपयोग अगले दो आयामों का अध्ययन करने के लिए किया गया है: पेटेंट व्यावसायीकरण और पेटेंट नवीनीकरण ये खोजी और आवेशपूर्ण विश्लेषण के लिए उठाए गए हैं जिससे इन आयामों पर फर्मों के दृष्टिकोण संबंधी दृष्टिकोण पर कब्जा कर लिया गया है। साहित्य में इन तीन आयामों को प्राथमिक गतिविधियों के रूप में पहचाना गया है और प्रधान मंत्री में गतिविधियों का मुख्य मूल्य निकालना है। साहित्य का सुझाव है, एकाधिकार एकाधिकार के लिए सबसे महत्वपूर्ण प्रोत्साहन के रूप में पेटेंट व्यावसायीकरण, जिसका बाहरी पथ अक्सर स्वामित्व के लिए प्रोटोकॉल (सह-पेटेंट / अनन्य स्वामित्व) की आवश्यकता होती है, उत्पन्न आईपी और उनका लाइसेंसिंग / स्थानांतरण का उपयोग।

तीसरे आयाम, पेटेंट व्यावसायीकरण के बगल में पेटेंट नवीनीकरण का अध्ययन किया जाता है, जिससे पेटेंट बनाए रखने के लिए फर्मों के व्यवहार और उनके नवीनीकरण के निर्णय का विश्लेषण किया जाता है। ओआई का अध्ययन व्यापार मॉडल और आईपी शासन के समय, आईपी / नियामक वातावरण को कसने के समय ज्ञान विनिमय के लिए कंपनियों की तत्परता को समझने के लिए चौथे आयाम के रूप में किया जाता है। ओईसीडी परियोजना (ओएफसी) द्वारा (ओईसीडी) परियोजना (200 9) के लिए ओआईसी अध्ययन की सिफारिश की गई है, क्योंकि प्रभावी नवाचार नीतियों को डिजाइन करने के लिए "फर्मों के नवप्रवर्तन व्यवहार और उसके निर्धारकों पर ज्ञान" के अंतर को आंशिक रूप से भरने के लिए आवश्यक है। इस अध्ययन में ऐसी नीतियों के लिए कुछ निविष्टियाँ आने का प्रयास किया गया है।

ये चार आयाम एक खोजपूर्ण शोध का हिस्सा हैं, जो फर्म और पेटेंट स्तर पर वर्णनात्मक आंकड़ों और सांख्यिकीय तकनीकों का उपयोग करते हुए दोनों प्राथमिक और द्वितीयक डेटा का उपयोग करते हैं: मीन, पियरसन का सहसंबंध, स्वतंत्र नमूना टी-परीक्षण, पियरसन के ची स्क्वायर टेस्ट, एक-तरफा एनोवा, रैखिक प्रतिगमन, बाइनरी रोधक प्रतिगमन, फैक्टर विश्लेषण और एकाधिक अभिकथन। दी गई पेटेंट के डेटा को वर्ष 2005-2014 के लिए भारतीय पेटेंट कार्यालय से प्राप्त किया गया था और इसका उपयोग एस इक्विटी डेटा बेस के फर्म-स्तर डेटा के साथ और 60 निवासी फर्मों से सर्वेक्षण की प्रतिक्रिया के साथ किया गया है। प्रश्नावली में मदों की गणना 5 सूत्री Likert-scale पर की गई थी।

महत्वपूर्ण निष्कर्ष इन चार आयामों के संदर्भ में फार्मास्यूटिकल फर्म के व्यवहार को पकड़ते हैं। उनके पेटेंटिंग मकसद की रणनीति के संबंध में, आविष्कार की रक्षा और नकली को रोकने के लिए भारत में भी प्रमुख उद्देश्य के रूप में उभरा है। लाइसेंस प्राप्त और सुरक्षित वित्त मॉडल फलितों द्वारा अध्ययन किए गए नमूने में अपनाई गई सभी व्यक्तिगत उद्देश्यों का सबसे अच्छा मॉडल हैं। दावों और पेटेंट नवीनीकरण डेटा के रूप में पेटेंट की विशेषताओं को गैर-मौद्रिक विधि के माध्यम से पेटेंट के मूल्य / गुणवत्ता निर्धारण के लिए प्रॉक्सी के रूप में सेवा प्रदान की जा सकती है, खासकर आईपी के लिए एक समान मौद्रिक मूल्यांकन पद्धति की अनुपस्थिति में।

पेटेंट नवीकरण व्यवहार के संदर्भ में, छोटी और बड़ी कंपनियों के नवीकरण पद्धति में कोई अंतर-फर्क नहीं है, लेकिन छोटी और बड़ी कंपनियों द्वारा पेटेंट की रखरखाव अवधि में एक महत्वपूर्ण अंतर है, दी गई पेटेंट की संख्या से मापा फर्म का आकार। आविष्कार (दावों), टीम सहयोग (सह-आविष्कारों की संख्या) और अनुदानित पेटेंट की संख्या पेटेंट नवीनीकरण के महत्वपूर्ण अनुमान हैं जबकि रखरखाव की अवधि और पेटेंट स्वामित्व पेटेंट व्यावसायीकरण की संभावना के महत्वपूर्ण भविष्यवक्ता हैं। हालांकि, उसी के लिए दावे महत्वपूर्ण नहीं हैं फॉर्म -27 और सर्वेक्षण दोनों के निष्कर्षों में पेटेंट व्यावसायीकरण के लिए प्रमुख बाधा के रूप में पेटेंट काम करने और वाणिज्यिक साझेदार की खोज के लिए घर के निर्माण का सबसे आम तरीका दिखाया गया है।

इन दो आयामों के बीच सकारात्मक संबंध मौजूदा निष्कर्षों की गूंजता है कि एक लंबी अवधि के लिए पेटेंट बनाए रखा जा सकता है और वे व्यावसायिक रूप से वाणिज्यिक होने की संभावना रखते हैं। भारत में फार्मास्यूटिकल पेटेंट भी दस साल की औसत पर समाप्त हो जाती हैं; उनके गैर-नवीकरण के संभावित कारणों में संभावित प्रौद्योगिकी हस्तांतरण, वाणिज्यिक उपयोगिता और

प्रौद्योगिकी अप्रचलन की कमी है, जैसा कि सर्वेक्षण निष्कर्षों से देखा गया है। हालांकि फर्मों ने अपनी प्रतिष्ठा बढ़ाने और पोर्टफोलियो की ताकत बढ़ाने के लिए अपने पेटेंट को नवीनीकृत किया है। ओआई अभ्यास में, निवासी फर्म, पेटेंट डेटा से सह-अन्वेषकों की संख्या से स्पष्ट रूप से अनिवासी कंपनियों के सहयोग के समान हद तक दिखाई देते हैं। हालांकि, एम एंड ए गतिविधि के रूप में उनके सहयोग के संबंध में अंतर-फर्म भिन्नता है, अर्थात् गैर-निवासी फर्म भारत के निवासी फर्मों से अधिक सक्रिय हैं।

इस काम में अकादमिक अनुसंधान के लिए महत्वपूर्ण योगदान है: मानव पूंजी (सह-अन्वेषक) के महत्व, प्रतिस्पर्धात्मक लाभ के लिए संसाधनों (पेटेंट) का महत्वपूर्ण उपयोग, विशेष रूप से घरेलू कंपनियां सरकार / आईपी अधिकारियों के लिए नीति के निहितार्थ, फॉर्म -27 में नियमित रूप से जानकारी देने वाले फार्मास्यूटिकल कंपनियों के आराम से संगत अधिक प्रभावी उपाय अपनाए जाने में निहित है। बड़ी कंपनियों की अच्छी तरह से स्थापित बौद्धिक संपदा प्रबंधन प्रणाली (आईपीएमएस) से अपनी जरूरतों के आधार पर अपनी आईपी नीति का मसौदा तैयार करने के लिए प्रबंधकीय प्रभाव बहुत युवा कंपनियों के शीर्ष स्तर के प्रबंधन के लिए हैं। दावों और पेटेंट नवीनीकरण डेटा के रूप में पेटेंट विशेषताओं का उपयोग गैर-मौद्रिक विधि के माध्यम से पेटेंट के मूल्य / गुणवत्ता निर्धारण के लिए प्रॉक्सी के रूप में कार्य कर सकता है, खासकर आईपी के लिए एक समान मौद्रिक मूल्यांकन पद्धति के अभाव में।

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ABBREVIATIONS

API	Active Pharmaceutical Ingredients
BRICS	Brazil, Russia, India, China, South Africa
BSE	Bombay Stock Exchange
CGPDTM	Controller General of Patents, Designs & Trademarks
CRAMS	Contract Research and Manufacturing Services
DIPP	Department of Industrial Policy and Promotion
EPO	European Patent Office
EU	European Union
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GIR	Geographical Indications Registrations
IBEF	India Brand Equity Foundation
IC	Intellectual Capital
IPA	Indian Patent Act
IPAIRS	Indian Patent Information Retrieval System
IPC	International Patent Classification
IPI	Indian Pharmaceutical Industry
IPO	Indian Patent Office
IPRs	Intellectual Property Rights
M&A	Mergers and Acquisitions
MNC	Multi-national Corporation
OECD	Organization for Economic Cooperation and Development
OLS	Ordinary Least Squares
OTC	Over the Counter

PCT	Patent Cooperation Treaty
PDF	Portable Document Format
PIS	Patent Information System
R&D	Research and Development
RGNIIPM	Rajiv Gandhi Institute of Intellectual Property Management
RSI	Relative Specialization Index
RTI	Right to Information
SIPO	State Intellectual Property Office
TRIPS	Trade Related Aspects of Intellectual Property Rights
USA	United States of America
USD	US Dollar
USPTO	United States Patent and Trade Mark Office
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization