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Design and Development of Patent System in Pharmaceutical Industry

Mr. Aritra Chatterjee[1]* Dr. Munish Rastogi[2]

[1] Research Scholar, Chhatrapati Shahu Ji Maharaj University, Kanpur University, India

[2] Department Head, Chhatrapati Shahu Ji Maharaj University, Kanpur University, India

Abstract – This thesis aim is to study the design and development of pharmaceutical industry in India with respect to its patent system, analyse the opinion of experts/professionals regarding the effectiveness of the existing Patent Act and Rules in policing and enforcing safeguards against abuse of Patents and identify the problems pertaining to enforcement of patents specifically with respect to pharmaceutical industry. The present study focuses on the design and growth of the pharmaceutical industry in relation to its patent system. It is evident from the frequency test that majority of respondents (73.14 percent) suggested that disclosure of source and origin of genetic material should be mandatory.

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INTRODUCTION

Patents are exclusive ownership rights in the human mind's intangible creations. They only occur in compliance with sovereign state legislation and can only be applied to the degree that an application has been filed and a patent issued protecting the territories of a single state (1). Patent privileges are restricted in length, with the global norm being 20 years from the date of filing. Patents benefit businesses that may otherwise be uninterested. In the electronic industry, patents are often pooled or cross-licensed by competitors. This sharing is necessary because many patented technologies are often contained in a given product (2, 3).

Promising developments are emerging in countries such as India and Brazil, which are starting to use patents to develop commercial pharmaceutical industries that produce local disease products and are available at a price that can be afforded by patients in those countries. Such efforts are supported by foundations and nonprofit organisations such as the Bill and Melinda Gates Foundation and OneWorld Health, Inc (4). These efforts demonstrate the ability of developing countries to build research-intensive pharmaceutical industries capable of operating profitably in local market conditions (5-9).

Instead of attempting to pass the expense of drug production to others, the risk of drug development should be borne equitably among customers in all countries by paying for drugs at a price range that is compatible with their means. The aim of this study is to study the pharmaceutical industry's design and development with respect to its patent system.

Visanko, H. E. (2016) aim of the thesis is to find out what kinds of issues arise from the patent monopolies granted to drugs and how they can be addressed. As the flexibilities have done so much good for the access issue, they can also be seen as part of the problem causing the lack of medication availability. Several solutions have been suggested to solve the problems of access and availability and to encourage medical innovation in ways other than patent exclusivity. These solutions range from awards to patent pools and the development of non-profit drugs. These solutions, however, have not been able to generate new medical innovations as much as they were hoped for and needed. This thesis therefore introduces a new solution to solve the availability problem. The R&D Financing Pool for Neglected Disease combines the best features of existing solutions and creates a unique approach to solving the issue (10).

Tyron Stading (2014), When cash turns out to be tight, organisations search for choices to build their income and find two ways to I) innovate items, and ii) case. A few organisations that dismiss innovation or innovation protection for cutting costs or keeping away from risk will be off guard both in current downturn advertisements and, to a more noteworthy degree, once again when the economic tempest passes and exchange exercises increase. Organizations that keep focusing in the midst of the downturn on their IP assets will pick up an aggressive edge after it. The majority of pharmaceutical organisations were assembled in the field of R&D regions during the retreat season. The IP approach states that, as a research and

technology-driven association, they firmly trust IP creation, maintenance and respect (11).

RESEARCH METHODOLOGY:

- **Data Source**

Two different questionnaires were constructed for the purpose of the requested data. The first questionnaire is used to collect data primarily from Mumbai from lawyers, company secretaries, patent agents, attorneys, regulators, academics and post-graduate law students. The second questionnaire is used to gather data from staff working in the legal department, the R&D department, senior executives and company secretaries working in the pharmaceutical industry, patent department staff, pharmaceutical industry management trainees. Secondary data was collected from standard textbooks, journals, judgments, Government of India committee reports, websites, newspapers, etc.

- **Sampling Design**

A sample size is a component of the population selected for a survey. The primary data was gathered from two separate groups of respondents for whom two separate questionnaires were prepared. The population was 7685 for the first questionnaire and 523 for the second questionnaire.

- **Sample Size**

A Stratified Proportionate Random Sampling Method has been used for the sample design. With the help of the Raosoft calculator, the population has arrived. The questionnaire's sample size was 366 and 220, respectively. Stratified Proportionate random sampling was taken to gather data from the participants. Only 350 responses were considered out of 366 responses received as the remainder of the responses were incomplete and had some errors that were not fit to be considered.

- **Pilot study**

In the beginning, a pilot study with the restricted respondents was conducted and necessary modifications were made in the light of the suggestions received. After their pre-testing, the questionnaire was finalized. The pre-test was carried out with the help of the Cronbach Alpha Test. The reliability of the likert scaling used in the questionnaire is applied to find out.

- **Statistical technique**

To analyse the first questionnaire, statistical tools such as One Sample T test, Friedman test, Kendalls W Test, Factor Analysis, Multiple Regression, Correlation analysis, Mean Score and simple percentage analysis were used. Weighted Average Method, One way ANOVA, Factor Analysis, Mann-Whitney 'U' test, Friedman test Factor analysis and simple percentage were used for the second questionnaire.

- **Analysis of Data**

For data collection, the field survey and individual interview method were adopted and data collected was tabulated and assisted by diagrams, tables and graphs. In showing and breaking down the data, both descriptive and inferential statistics were used.

DATA ANALYSIS

- **Demographic profile of the respondents**

Results reveal that majorities (65 percent) of the respondents are males and rests of the respondents are females. 40.91 percent of the respondents belong to the age group of 25 to 35 years, 38.18 percent are from 36 to 45 years, 14.09 percent of the respondents are from 46 to 55 years and remaining 6.82 percent of the respondents belong to the age group of above 55 years. 50 percent of the respondents are employees from legal department, 25.9 percent are employees from R&D department, 8.6 percent are senior executives, 8.18 percent are employees of Patents department and remaining 7.27 percent are trainee in pharma companies.

- **Opinion of the respondents**

Table 1 shows respondents' views on the "Indian Patents Act Fosters Research and Development." The findings reveal that most respondents (47.73%) agree with the statement below.

Table 1: Indian Patents Act Promote Research and Development

Particulars	Percentage	No. of Respondents
Strongly Agree	35.46	78
Agree	47.73	105
Neutral	5.45	12
Strongly Disagree	5.00	11
Disagree	6.36	14
Total	100	220

- Growth (GR) of Pharmaceutical Industry in India-One way ANOVA

Table 2 shows respondents' views on whether demand from the export market has increased rapidly due to Indian Players' ability to manufacture cost-effective drugs with world-class production. The findings show that the majority of respondents (74.55 percent) agree with the statement above.

Table 2: The potential of Indian players to manufacture cost-effective medicines with world-class production has resulted in a dramatic rise in demand from the export sector

Particulars	Percentage	No. of Respondents
Strongly Agree	17.72	39
Agree	74.55	164
Neutral	1.36	3
Strongly Disagree	4.09	9
Disagree	2.28	5
Total	**100**	**220**

- **Prospects in Clinical Trials and Exports in Pharmaceutical Sectors in India- Friedman Test**

Table 3 shows the respondents' responses to pharmaceutical industry patent research and development and technology advancement in India. Responses to each variable ranging from 1 to 5 were given by respondents regarding research and development and technology advancement. In the opinion of the respondents, generic opportunities in the overseas market, growing domestic market, R&D orientation, opportunities for CRAMs (Contract Research and Manufacturing Services) would keep the pharmaceutical industry on a high growth path, and it is expected that SMEs will play a critical role.

Table 3: Research and development and technology advancement in patent of pharmaceutical sector in India

Research and Development and Technology Advancement	SA	A	N	DA	SDA	Total
Going forward, R&D would be the key growth driver and survival strategy for SMEs	71 (32.27)	131 (59.55)	8 (3.64)	5 (2.27)	5 (2.27)	220 (100)
The generic opportunities in the overseas market, growing domestic market, orientation towards R&D, CRAMs (Contract Research and Manufacturing Services) opportunities would keep the pharmaceutical industry on a high growth trajectory, and SMEs are expected to play a critical role	36 (16.36)	159 (72.27)	12 (5.46)	7 (3.18)	6 (2.73)	220 (100)
Exports, with a reported growth in the last five years, will continue to remain the biggest opportunity for pharmaceutical companies	55 (25)	131 (59.55)	25 (11.36)	8 (3.64)	1 (0.45)	220 (100)
The industry has seen tremendous progress in terms of infrastructure development, technology base and the wide range of Products manufactured	66 (30)	111 (50.45)	28 (12.73)	4 (1.82)	11 (5)	220 (100)

Table 4 shows respondents' opinion that "The Indian bio pharmaceutical industry does not have the monetary resources to develop new drugs; it requires financial support or cooperation with other businesses." The results show that the majority of respondents (59.09%) strongly agree with statement.

Table 4: The Indian bio-pharmaceutical industry does not have the financial resources to develop new drugs; financial support or cooperation with other companies is required.

Particulars	No. of Respondents	Percentage
Strongly Agree	130	59.09
Agree	42	19.09
Neutral	7	3.18
Strongly Disagree	21	9.55
Disagree	20	9.09
Total	**220**	**100**

Three factors-the people, environment, and infrastructure are critical for a healthy environment for business collaboration, especially in the bio-pharmaceutical sector," are presented in Table 4 by respondents' opinion." The findings show that the majority of respondents (63.64 percent) agree with the statement above.

- **Government Role on Patent Management-KMO and Bartlett's Test**

In this case, the KMO value - 0.793 is above the 0.6 benchmark value. The Sphericity Bartlett test is .000, which is also important. It is therefore helpful for further factor analysis.

Table 5: Role of the government in patent management -KMO and Bartlett's Test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		**0.793**
Bartlett's Test of Sphericity	Approx. Chi-Square	**200.960**
	Df	**15**
	Sig.	**.000**

All statements have extraction values above 0.5, which means that the correlation relationships between the statements are above 50%. It is therefore helpful to continue with all the declarations for factor analysis.

Percentage Analysis

Table 5 shows respondents' views on the "Indian Patents Act Fosters Research and Development." According to the findings, the majority of respondents (57.43 percent) agree with the statement above.

Table 5: Indian Patents Act promote Research and Development

Particulars	Percentage	No. of Respondents
Strongly Agree	26.86	94
Agree	57.43	201
Neutral	12.00	42
Strongly Disagree	2.00	7
Disagree	1.71	6
Total	100	350

Factors Related with the Provisions and Legislations regarding Patent-KMO and Bartlett's Test

Two such tests for data suitability for carrying out factor analysis are the Kaiser-Meyer-Olkin (KMO) test and the Bartlett test. The KMO value -0.703 indicates that an analysis of the factor is useful for the current data because it is above the 0.6 benchmark value. Bartlett's Sphericity test determines whether the correlation matrix is an identity matrix, indicating that the variables are unrelated. The level of significance gives the test's outcome. The significant value here is 0.001, which indicates that significant relationships exist between the variables. The resulting KMO test value and the Bartlett test value indicate that the current data is useful for factor analysis.

Table 6: Factors Associated with Patent Law Provisions and Legislation -KMO and Bartlett's Test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		0.703
Bartlett's Test of Sphericity	Approx. Chi-Square	584.826
	Df	45
	Sig.	.001

Communalities show the correlation between the variables. The variable correlation should be greater than 50%+.

Pearson Correlation between the Factor Variables

It is inferred from Table 7 that the provision of Section 92 A has a positive relationship with the Bolar provision of .158 (15. 8 percent), which means that both move in the same direction. It rejects the null hypothesis. Bolar Provision has a negative relationship with the TRIPS-related provision of -33.0 (-33 percent), which means both are moving in the opposite direction.

Table 7: Correlation between the factor variables

Variables	Section 92A provisions	Bolar Provision	TRIPS Related Provision
Section 92A provisions	1.000	.158	.055
Bolar Provision		1.000	-.330
TRIPS Related Provision			1.000

Challenges of Indian Pharmaceutical Industry-Friedman Test

It is therefore concluded that there is a significant difference between the average ranks given by the respondents in relation to the Indian pharmaceutical industry's patent challenges. The new pharmaceutical pricing policy (4.03) is the Indian pharmaceutical industry's most important patent challenge on the basis of the average rank, followed by delays in clinical trial approvals (3.88), uncertainties about the FDI policy (3.71), uniform code of sales and marketing practises (3.47), strict regulations on manufacturing and quality practises (3.11) and compulsory licencing (3.11) (2.80).

Table 8: Challenges of Indian Pharmaceutical Industry on patents -Friedman Test

Particulars	Mean Rank	Chi-Square	Df	Significant Level at 0.05 (N=350)
a) Delays in clinical trial approvals	3.88	162.030	5	.001
b) Uncertainties over the Foreign Direct Investment (FDI) policy	3.71			
c) New pharmaceutical pricing policy	4.03			
d) Uniform code for sales and marketing practices	3.47			
e) Compulsory licensing	2.80			
f) Strict regulations on manufacturing and quality practices	3.11			

Factors hindering the growth of the pharmaceutical industry-The W test by Kendall

Based on the Kendall's W value .027 means that the agreement level of the respondents towards the factors hampering the growth of pharmaceutical industry is lesser. This implies that there is an important agreement between the respondents' responses to the factors hindering the growth of the Indian pharmaceutical industry. Low public spending on healthcare (3.31) has a significant negative impact on the growth of the Indian pharmaceutical industry based on the average rank, followed by poor healthcare delivery system (3.14), lack of healthcare infrastructure (2.92), low health insurance system penetration for all sectors of society (2.84) and lack of 'Universal Health Coverage' (2.80).

Table 9: Factors hampering the growth of pharmaceutical Industry-Kendall's W Test

Factors hampering the growth	Mean Rank	Kendall's W Value	Chi-Square	Df	Significant Level at 0.05 (N=350)
a) Low public spending on healthcare	3.31	.027	37.086	4	.001
b) Lack of healthcare infrastructure	2.92				
c) Low penetration of health insurance system for all strata of society	2.84				
d) Poor healthcare delivery system	3.14				
e) Absence of 'Universal Health Coverage'	2.80				

The opinion of respondents on "Whether High "Out of Pocket" (OoP) expenditure limiting access to medicines" is shown in Table 10 below. The findings show that most respondents (62.86 percent) strongly agree.

Table 10: High "Out of Pocket"(OoP) expenditure limiting access to medicines

Particulars	Percentage	No. of Respondents
Strongly Agree	62.86	220
Agree	29.43	103
Neutral	4.28	15
Strongly Disagree	0.86	3
Disagree	2.57	9
Total	**100**	**350**

Table 11 shows respondents' views on the statement that "India's pharmaceutical companies have been forced to live with continued government and civil society focus on 'reasonably affordable' medicines regardless of whether they are generic or patented." According to the findings, the majority of respondents (73.43 percent) agree with the statement above.

Table 11: In India, pharmaceutical companies have been forced to focus on 'reasonably affordable medicines' with continued government and civil society focus, regardless of whether they are generic or patented.

Particulars	Percentage	No. of Respondents
Strongly Agree	12.00	42
Agree	73.43	257
Neutral	9.71	34
Strongly Disagree	2.57	9
Disagree	2.29	8
Total	100	350

Indian Pharmaceutical Industry Opportunities- KMO and Bartlett's Test

The KMO sampling adequacy measure should be greater than 0.6 and closer to 1 and the P value should be lower than 0.055. (5 percent level of significance).

Here, the KMO value -0.861 is above the value of the 0.6 benchmark. The Balrtlett sphericity test is .000, which is important as well. It is therefore helpful for further factor analysis.

Table 12: Indian Pharmaceutical Industry Possibilities- KMO and Bartlett's Test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		0.861
Bartlett's Test of Sphericity	Approx. Chi-Square	1052.601
	Df	55
	Sig.	.000

The extraction value of all statements is above 0.5, i.e. the correlation relationship is above 50 percent between the statements. It is useful to proceed with all the factor analysis statements

CONCLUSION:

The Patent Management in the sub-continent, particularly in India is undergoing a paradigm shift. The pharma sector has witnessed thumping progress in the recent times and the trend precisely started from the year 2005. In the present work, we focused on the design and development of the pharmaceutical industry with regard to its patent system. The real reason for descriptive research is to portray the situation as it currently exists. A Stratified Proportionate Random Sampling Method will be used for the sample design. It is concluded from the study that majority of respondents (73.14 percent) suggested that disclosure of source and origin of genetic material should be mandatory.

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Corresponding Author

Mr. Aritra Chatterjee*

Research Scholar, Chhatrapati Shahu Ji Maharaj University, Kanpur University, India