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INTRODUCTION

REVIEW OF LITERATURE

NEED/IMPORTANCE OF THE STUDY

STATEMENT OF THE PROBLEM

OBJECTIVES

HYPOTHESES

RESEARCH METHODOLOGY

RESULTS & DISCUSSION

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- Always indicate the date that the source was accessed, as online resources are frequently updated or removed.

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- Garg, Bhavet (2011): Towards a New Natural Gas Policy, Political Weekly, Viewed on December 17, 2011 http://epw.in/user/viewabstract.jsp

INDIAN PATENT (AMENDMENT) ACT 2005 BOON OR BANE TO SMALL SCALE DRUG INDUSTRY IN INDIA

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ABSTRACT

The main objective behind of this study is to analyze, whether the growth of Small Scale Drug industry, employment opportunities in the rural areas has been affected or improved by the introduction of new patent regime 2005.This study is concerned with the small scale pharmaceutical sector. The study used primary data collected through a structured questionnaire assessing the behavior of the small-scale drug entrepreneurs during the period 2005-2010. This study found out that most of the industrial population comes under very positive ATTITUDE, stating that they are favorable to the Indian patent (amendment) act 2005. Some of the small scale drug entrepreneurs are not in favor of IPA 2005 because it restricts the SSDI business. Some of the Non industrial respondents argue that this law is in favor of monopoly.

KEYWORDS
Small Scale Drug Industry, Indian Patent Act, primary data, Entrepreneur.

PRE- INDEPENDENCE PERIOD

In 1911, the Indian Patents and Designs Act, 1911, (Act II of 1911) was brought in replacing all the previous legislations on patents and designs. This Act brought patent administration under the management of Controller of Patents for the first time. This Act was amended in 1920 to provide for entering into reciprocal arrangements with UK and other countries for securing priority. In 1930, further amendments were made to incorporate, inter-alia, provisions relating to grant of secret patents, patent of addition, use of invention by Government, powers of the Controller to rectify register of patent and increase of term of the patent from 14 years to 16 years. In 1945, another amendment was made to provide for filing of provisional specification and submission of complete specification within nine months.

PERIOD FROM 1947 TO 1970

After Independence, it was felt that the Indian Patents & Designs Act, 1911 was not fulfilling its objective. It was found desirable to enact comprehensive patent law owing to substantial changes in political and economic conditions in the country. Accordingly, the Government of India constituted a committee under the chairmanship of Justice (Dr.) Bakshi Tek Chand, a retired Judge of Lahore High Court, in 1949, to review the patent law in India in order to ensure that the patent system is conducive to the national interest.

The Committee submitted its interim report on 4th August, 1949 with recommendations for prevention of misuse or abuse of patent right in India and for amendments to sections 22, 23 & 23A of the Patents & Designs Act, 1911 on the United Kingdom Acts of 1919 and 1949.

The time period prescribed for making the applications was "at any time after expiration of three years from the date of sealing." The application could also be made by the licencee the term, 'patented article' the application could also be made by a patented process. insecticide, germicide or fungicide and a process for producing substance or any invention relating to surgical or curative devices, through Act LXX of 1952.. The compulsory licence was also available on notification by the Central Government. Based on the recommendations of the Committee, a bill was introduced in the Parliament in 1953 (Bill No.59 of 1953). However, the bill lapsed on dissolution of the Lok Sabha.

In 1957, the Government of India appointed Justice N. Rajagopala Ayyangar Committee to examine the question of revision of the Patent Law and advise government accordingly. The report of the Committee, which comprised of two parts, was submitted in September, 1959. The first part dealt with general aspects of the patent law and the second part gave detailed note on the several clauses of the lapsed bill of 1953. The first part also dealt with evils of the patent system and solution with recommendations in regard to the law. The committee recommended retention of the patent system, despite its shortcomings. This report recommended major changes in the law which formed the basis of the introduction of the Patents Bill, 1965. This bill was introduced in the Lok Sabha on 21st September, 1965, which, however, lapsed. In 1967, an amended bill was introduced which was referred to a Joint Parliamentary Committee and on the final recommendation of the Committee, the Patents Act, 1970 was passed. This Act repealed and replaced the 1911 Act so far as the patents law was concerned. However, the 1911 Act continued to be applicable to designs. Most of the provisions of the 1970 Act were brought into force on 20th April, 1972 with the publication of the Patents Rules, 1972.

In 1970, concerned about the dominance of foreign pharmaceutical firms and the high price of medicines, India changed course, passing a patent law prohibiting product patents on medicines. At the time, foreign firms controlled about 70 percent of the Indian market, and Indian drug prices were among the highest in the world. Colonial era patent laws were an important factor: foreign firms used them to their advantage, winning victories in court that helped suppress competition from local companies.

The 1970 Act served as a substantial driver of three decades of growth in the domestic pharmaceutical industry. In the years that followed it, the number of patents granted in India dropped precipitously. Although the law permitted process patents related to medicines, they were very limited in scope and rarely sought. The law thus created significant space for the entry of local pharmaceutical firms, and they rapidly increased their share of the Indian market.

This Act remained in force for about 24 years till December 1994 without any change. An ordinance effecting certain changes in the Act was issued on 31st December 1994, which ceased to operate after six months. Subsequently, another ordinance was issued in 1999. This ordinance was later replaced by the Patents (Amendment) act, 1999 that was brought into force retrospectively from 1st January, 1995. The amended Act provided for filing of applications for product patents in the areas of drugs, pharmaceuticals and agro chemicals through such patents were not allowed. However, such applications were to be examined only after 31st December, 2004. Meanwhile, the applicants could be allowed Exclusive Marketing Rights (EMRs) to sell or distribute these products in India, subject to fulfillment of certain conditions.

The second amendment to the 1970 Act was made through the Patents (Amendment Act, 2002 (Act 38 of 2002). This act came into force on 20 th May, 2003 with the introduction of the new Patents Rules, 2003 by replacing the earlier Patents Rules, 1972.

The third amendment to the Patents Act, 1970 was introduced through the Patents (Amendment) Ordinance, 2004 w.e.f. 1st January, 2005 (Act 15 of 2005) on 4th April, 2005 which was brought into force from 1st January, 2005.

After introduction patent ordinance, large scale drug industry has been geared up to new environment to the domestic market and as well as international market. Their revenue has been increased in the domestic market as well as international market since 2005. When large scale drug industry are joining with patent regime, what about feelings, thoughts, their perception of the small scale drug industry who actually contributing 30% of the market share to the Indian pharmaceutical market in connection with acceptance of product patent, as a result of new patent regime whether the growth of SSDI, employment opportunities in the rural areas has been affected or Improved. This is the main objective of the study.

REVIEW OF LITERATURE

Alkachanda (National University, Singapore) and Zhiliang Ying (Columbia University) studied on TRIPs, Innovation and Survival of Indian pharmaceutical firms. In their study they examined survival of Indian pharmaceutical industry in the light of TRIPSs requiring a shift towards a stronger patent regime. They found that the survival of firms has been adversely affected due to TRIPs after controlling for other firm characteristics like size, experience, ownership, group membership and innovation.

Hemant N Joshi PhD (2003) (Associate Director of pharmaceutical research and development at Bar Laboratories, Pomona, New York) analyzed the Indian Pharmaceutical industry with emphasis on opportunities in 2005. In his article he found when many countries will start honoring patent law from 1sr January 2005, and India is among the countries that will be affected. The study also found that the second largest population in the world, a highly educated population that is fluent in English, and well developed buying power, India has great potential for industrial growth.

Sing Surrendar (2003) in their article have focused up on the strategies used by the small and medium scale pharma companies to meet the challenges of the patent regime. The larger companies like Ranbaxy and Cipla etc, were preparing for the new patent regime since 1995 onwards, however the small and medium scale pharma companies did not make much of an effort and now realizing that their top lines and bottom lines are going to be impacted because of product patent they have devised few strategies: Toll Manufacturing, Bottom fishing, In-licensing. Niche plays, and Contract Manufacturing. This article is based on the interviews with top executives of small and medium pharma companies who have implemented with success the above mentioned strategies.

Sampath (2005), in her research paper analysis his survey of 103 Indian pharmaceutical firms. The scope of his study was limited to analyzing emerging firm strategies of Indian firms as a response to gradual transitions protect patent protection. The survey found that Indian firms are adopting a combination of cooperative and competitive strategies, in order to adapt and as well as capitalize an opportunities created by new patent regime. The Indian domestic pharma companies have faced the international competition and although protect patent has thrown up lot of opportunities, still consolidation will happen in the industry in coming years. The study also finds a high correlation between export intensity and R&D investments in the Indian pharma sector. Firms that had greater revenues from export were able to invest a larger amount on R&D.

Jaya Prakash Pradhan (2007) in his study, "New Policy Regime and Small Pharmaceutical Firms in India" pointed out the factors that contributed to the growth of pharmaceutical firms prior to new industrial policy and what are unfavorable condition like a long-term product patent regime, withdrawal of exemption from price controls, implementation of good manufacturing practices etc. based by the SSDI due to new policy regime. These new policies have number of implications for the survival and growth of small pharmaceutical firms today.

METHODOLOGY OF THE STUDY

SAMPLING FRAME

The Indian pharmaceutical industry is highly fragmented and can be grouped into two main sectors namely organized and unorganized. This study is concerned with the small scale sector (unorganized sector) in Tamilnadu and the Union territory of Puducherry. There are 205 small-scale drug industrial units in Tamil Nadu and Puducherry (136 in Tamil Nadu and 69 in Puducherry). Stratified convenient sampling was used. A sample of 100 small-scale industries (63 from Tamil Nadu and 37 from Puducherry) was included in the study. Though respondents are only from Tamil Nadu and Puducherry, the main issue of the study is the dilution of the drug price control order and its effect on the small scale drug industry, which is having an the nation as a whole. Hence the perception of the respondents is likely to be the same irrespective of the state chosen.

The study is purely based on the primary data collected from the 200 samples on Rensis Likert Scale 1932. To obtain the primary data, questionnaire method has been adopted. Out of the total 200 samples, 100 samples have been collected from the proprietors of the small-scale industry. In order to avoid the bias, another 100 samples has been collected from the non-industrial respondents who are mostly connected with the drug industry and familiar with IPA-2005 & drug policies. The non industrial respondents are further classified into four categories each represents 25 members. The non industrial respondents are further classified into four categories each represents 25 members. They are: 1) Wholesale drug distributors 2) Industrial workers (production managers, Quality control managers, Quality assurance managers) 3) Association/ academicians 4) Sales Representatives.

PERIOD OF STUDY

The study used primary data collected through a structured questionnaire assessing the behavior of the small-scale drug industry during the period 2005-2010. Since the study based on after the introduction of IPA 2005, some of the information relevant for the study are also collected from the secondary sources from the year 2005 to 2010 .

ORGANIZING DATA

SCALING TECHNIQUE: A five-point **Likert scale** has been used. Letters indicating choices such as 'SD' (Strongly Disagree), 'D' (Disagree), 'N' (No comment), 'A' (Agree), 'SA' (Strongly Agree), rather than numbers, were used.

SCORING RENSIS LIKERT SCALE

In order to avoid bias there are two statements having the same concepts, one positive and another negative, used in this study, the points given for each response depends on whether the statement is positive or negative. The person who 'strongly agrees' with a positive statement gets maximum points (5). One who 'strongly disagrees' with a positive statement gets the minimum points (1). For a five-point scale, the scoring would be as follows for positive statement: SD=1, D=2, N=3, A=4, SA=5.

The person who 'strongly agrees' with a negative statement gets minimum points (1), while the one who 'strongly disagrees' with a negative statement gets the maximum points (5). For a five- point scale, the scoring would be as follows for a negative statement: SD=5, D=4, N=3, A=2, SA=1.

STATEMENTS IN THE QUESTIONNAIRE

GENERAL STATEMENT

Indian government was compelled to introduce the Indian patent act on the basis of the WTO agreement, are you favor of this Indian Patent Act 2005?

TABLE-1

Are you in favor of Indian Patent Act		
Response	Frequency	
	Industrial respondents	Non-industrial respondents
Yes	86	90
No	14	10
Total	100	100

Table-1 shows the response of both industrial and non industrial respondents about the general question, "Are you in favor of this Indian Patent Act 2005?" 86 percent of industrial population said they are favor to Indian patent(Amendment) act 2005 in pharmaceutical industry .The rest of population(14%) not supporting new patent act. More or less similar opinion found in non industrial respondent also.

	Positive Statement
Statement 1(S1)	The growth of small scale industry in India is in an increasing trend after Indian Patent Act 2005.
Statement 2(S2)	Employment opportunities have been increasing in rural and urban areas after introduction of Indian Patent Act 2005
Statement 3(S3)	The Product Patent Act 2005 has helped the small scale pharmaceutical industry to compete in the market.
Statement 4(S4)	After 2005, contribution of the Small Scale Drug Industry (SSDI) towards research in the clinical and pre-clinical field has increased.

TABLE 2: INDUSTRIAL AND NON-INDUSTRIAL RESPONDENTS IN RELATION WITH POSITIVE STATEMENT SCORE

Respondents	Frequency							
	Industrial Respondents				Non-Industrial Respondents			
	S1	S2	S3	S4	S1	S2	S3	S4
Strongly Disagree	2	6	3	7	1	3	4	7
Disagree	9	11	12	11	8	8	6	12
No Comment	2	0	6	17	7	4	5	18
Agree	49	47	48	44	34	53	38	41
Strongly Agree	38	36	31	21	48	32	47	22
Mean Value	4.12	4.13	3.92	3.61	4.16	4.03	4.18	3.59
Std Deviation	.967	.837	1.061	1.145	1.061	.979	1.048	1.164
Coefficient of Vari	.235	.203	.271	.317	.2555	.243	.251	.324
Minimum Score	100	100	100	100	100	100	100	100
Actual Score	412	396	392	361	414	401	418	359
Total Score	1561				1592			
	2000				2000			

Table2: shows the response of both industrial and non-industrial respondents about the positive statements: Each statement is valued on a five point Likert scale and scored.

Each statement attitude score ranges from 100 to 500, which is arrived by the formula Minimum score/maximum score × number of questions × number of respondents. Here there are only one question and 100 respondents; so a low score of 100 (1×1×100) and a high score of 500 (5×1×100). Altogether for industrial respondents there are four statements hence the score ranges from 400 (1x4x100=400) to 2000(5x4x100=2000).

First we computed total score of each statement for industry and non industry respondents separately and then we computed the score of all statements (2000 possible), and respondents together to see the overall points on this scale (4000 possible).

In this process the industrial respondents, the total aggregate score of each statement ranging from 361 to 412 points on this scale (500 possible); Where as in the case of non industrial respondent ranging from 359 to 418 points on this scale (500 possible), Hence we conclude that most of the industrial population come under very positive ATTITUDE, that means they are favorable to the Indian patent (amendment) act 2005. By taking both industry and non-industrial respondents the total scores comes 3153 points on this scale (4000 possible). Coefficient of variation is ranging from .203 to .317, and .243 to.324 for industrial respondent and non-industrial respondents respectively.

NEGATIVE STATEMENT

	Negative Statement
Statement 1	Despite the growth of Pharma industry, the market share of the small scale pharma industry has not increased significantly
Statement 2	The Product Patent Act 2005 does not provide enough incentives for R&D towards the progress of small scale pharmaceutical industry.
Statement 3	Since the introduction of Indian Patent Act 2005, the local human resources are not being utilized to the expected level.
Statement 4	Uncertain climate prevails after 2005 due to implementation of IPA 2005

TABLE 3: INDUSTRIAL AND NON-INDUSTRIAL RESPONDENTS IN RELATION WITH NEGATIVE STATEMENTS SCORE

Respondents	**Frequency**							
	Industrial Respondents				**Non-Industrial Respondents**			
	S1	**S2**	**S3**	**S4**	**S1**	**S2**	**S3**	**S4**
Strongly Agree	4	15	3	6	7	15	4	4
Agree	13	25	12	13	17	31	10	13
No Comment	30	25	11	18	31	19	15	11
Disagree	41	16	51	35	34	14	43	37
Strongly Disagree	12	19	23	28	11	21	28	35
Mean Value	3.44	2.99	3.79	3.66	3.25	2.95	3.81	3.86
Std Deviation	.998	1.337	1.028	1.191	1.086	1.381	1.080	1.155
Coefficient of variation	.290	.447	.271	.325	.334	.468	.283	.299
Minimum Score	100	100	100	100	100	100	100	100
Actual Score	344	299	379	366	325	295	281	386
Maximum Score	1388				1287			
	2000				2000			

Table3: shows the response of both industrial and non-industrial respondents about the negative statement: Each statement is valued on a five point Likert scale and scored.

Each statement attitude score will range from 100 to 500, which is arrived by the formula Minimum score/maximum score × number of questions × number of respondents. Here there are only one question and 100 respondents; so we get a low score of 100 (1×1×100) and a high score of 500 (5×1×100). In total there are four negative statements the scores ranges from 400 (1x4x100=400) to 2000(5x4x100=2000). First we computed total score of each statement for industry and non industry respondents separately and then added both industrial and non industrial respondent together to see the overall points on the scale (4000 possible).

In the case of industrial respondents the total aggregate score for each statement ranging from 299 to 379 and for non-industrial respondents from 281 to 386 for negative statements (500 possible); here the total scores lies just above to no comment level. We conclude that both industrial non industrial respondents are mediocre situation. By considering both positive statement score (3153/4000) and negative statement score (2675/4000) the total score comes 5828 points on this scale (8000 possible). This clearly shows most of the population favor to Implementation of Indian Patent (Amendment) Act 2005. Coefficient of variation was ranging from .271 to .447 and .283 to.468 for industrial respondent and non-industrial respondents respectively. This was higher than the positive statements.

REASONS WHY THE ENTREPRENEURS FAVOR INDIAN PATENT ACT 2005

General views collected from the small scale entrepreneurs during interaction towards the acceptance of product patent Act 2005, their growth in terms of production, competitiveness and providing employment opportunities in the rural areas. During this period we visited small Scale Drug Industries situated in Tamilnadu and Puducherry with a questionnaire. The interaction with SSDI for collecting the data was encouraging. Salient information collected on the basis of the questionnaire from industrial and non-industrial people regarding Indian Patent Act 2005 is given below.

Fifty five percent of the industrial population depends upon large scale domestic industries and MNCs in the form of contract manufacturing and loan licensing. Only 42 percent of the industries depend neither on large scale domestic industries nor MNCs. They advocate the Indian patent act helps the SSDIs for the creation of employment opportunities to the public and also helpful for the nation to improve infrastructural facilities. Majority of the population favor Indian product patent act 2005. The patent law recognizes the exclusive right of a patentee to gain commercial advantage out of his invention. This has to encourage inventors to invest more on the new drug for their creative facilities, knowing that their inventions would be protected by law and accordingly no one else would be able to copy their inventions for a certain period. On the other hand some of the entrepreneurs have said that the patent act 2005 allows producer to produce quality and new innovative drugs. Patent helps SSDI to take their products to the global market because SSDI's give quality drugs. The growth of the small scale drug industry is in an increasing trend and it has reflected that the human capital is the key competitive factor in pharmaceutical sector. After implementation of IPA 2005, SSDI have progressed towards a positive route and the government is also supporting the SSDI's for R&D. Although India has constituted patent enforcement in every technological field since 2005, Indian SSDI has been positively benefited. This is good for our country in future.

NEGATIVE STATEMENTS OF INDUSTRIAL RESPONDENTS

Small number of population is not in favor of the Small Scale Drug Industry. They said that after IPA was enacted most of the SSDI were affected. In their view, only the foreign companies and large scale Companies are benefited under IPA.

SSDI could not compete with big companies. Indian SSDI is aware of its ability to provide very low cost drugs with the old format, but the introduction of Patent Act 2005 restrictions has totally affected the SSDI. This IPA 2005 was a heavy dose for the SSDI. Government should understand the SSDI's ability whether it can sustain or not and accordingly do something in favor of SSDI.

Some of the small scale industries are not in favor of IPA 2005, because it restricts the SSDI business. Before IPA they have manufactured many drugs without getting permission from the owner of the innovation. Now they all come under royalty. After IPA many innovator's get royalty for their products hence, it is difficult for the SSDI to get royalty and as a result profit has reduced. Further, it is bad news for the small scale manufactures. Patent period is also long and patent holders have a possibility to earn more money. So the low income public's life has become questionable.

POSITIVE STATEMENTS OF NON INDUSTRIAL RESPONDENTS

We believe that human capital is the key competitive factor in pharmaceutical as well as other sector. But after implementation of IPA 2005 Indian SSDI has faced some positive trend towards contribution of human capital in pharmaceutical manufacturing especially in knowledge base. The skilled human capital produces quality innovational drugs and also gets patent for that product. This will create good image about India in the international market.

We strongly argue that as an invention involves a great deal of time, money and effort and includes a large element of risk, the exclusive use of the invention must be reserved for a period of time so that it could be benefited by the inventor and thereafter the same drugs can be coming under the category of generic drugs and can be manufactured by SSDI.

Although India has constituted patent enforcement in every technological field since 2005, it is the only member country in the World Trade Organization which excludes incremental innovation from patent protection scope. Indian SSDI is aware of its ability to provide very low cost drugs, during old format, but after introduction of Patent Act 2005 restrictions totally encourage the SSDI. Government should understand the SSDI's ability whether it can sustain or not. This IPA restriction is good for the Pharma Industries.

NEGATIVE STATEMENTS OF NON INDUSTRIAL RESPONDENTS

This Act will seriously affect the availability of new life saving drugs at affordable costs. The reason is the drug manufacturer is monopoly for that product so they are ready to fix their own price for that drug. Another bad news is the fixation of royalty by one agency can be easily violated and made in favor to the monopoly holder. This law is in favor of the monopoly.

The act has been created in favor of the multinational companies. They want to secure their product and do not care for the public. If once got the royalty for a particular product they became the monopoly for that product, No one can manufacture the medicine due to higher royalty. We understand that they have spent huge amount for R & D but we feel the royalty is high and finally public will suffer.

After implementation of IPA 2005 the local human resource has not been utilized to the expected level in the form of new innovation. It has been created because of high restriction made by the government. This has imposed a negative trend in the Indian pharmaceutical Industry.

Indian Patent Act created unfavorable situation to the SSDI. Previously we have done all type of new manufacturing activities, but now it is not possible. Some innovators don't have fund to get patent for their product.

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