INTELLECTUAL PROPERTY RIGHTS AND THE IMPACT OF TRIPS AGREEMENT WITH REFERENCE TO INDIAN PATENT LAW

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LETTER OF TRANSMITTAL

It is presented with a deep sense of gratitude that this report of the major research project titled **"A Study on the Intellectual Property Rights and the Impact of Trips Agreement with Reference to Indian Patent Law"** has been funded by the Planning Commision(SER Division) New Delhi(No. O-15012/3/02-SER dated:02.05.2002) The project with a tenure of 1 year was carried out by me in the Department of Coporate Secretaryship, Alagappa University,Karaikudi from July 2003. Ten copies of the report are submitted to the Planning Commission,New Delhi.

Dr.V.MANICKAVASAGAM
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CERTIFICATE

This is to certify that the research Project entitled **"A Study on the Intellectual Property Rights and the Impact of Trips Agreement with Reference to Indian Patent Law"** is a bona fide research work carried out in the Department of Corporate Secretaryship, Alagappa University, Karaikudi sponsored by the Planining Commision, New Delhi.

December 2007
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Dr.V.Manickavasagam
Project Director

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V. MANICKAVASAGAM
Project Director

CHAPTER - I

INTRODUCION AND DESIGN OF THE STUDY

1.1 INTRODUCTION

The TRIPS Agreement which came into effect on 1 January 1995, is to date the most comprehensive multilateral agreement on intellectual property. The areas of intellectual property that it covers are : copyright and related rights (i.e. the rights of performers, producers of sound recordings and broadcasting organizations); trademarks; geographical indications; industrial designs; patents, including the protection of new varieties of plants; and undisclosed information including trade secrets.

The Three main features of the Agreement are :

♦ **Standards:** In respect of each of the main areas of intellectual property covered by the TRIPS Agreement sets out the minimum standards of protection to be provided by each Member. Each of the main elements of protection is defined, namely the subject-matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection. The Agreement sets these standards by requiring, first, that the substantive obligations of the main conventions of the WIPO, the Paris convention for the protection of industrial property (Paris convention) and the Beme Convention for the protection of literary and Artistic Works (Beme Convention) in their most recent versions must be complied

with. With the exception of the provisions of the Beme convention on moral rights, all the main substantive provisions of these conventions are incorporated by reference and thus become obligations under the TRIPS Agreement between TRIPS member countries. The relevant provisions are to be found in Articles 2.1 and 9.1 of the TRIPS Agreement, which relate, respectively, to the paris convention and to the Beme Convention. Secondly, the TRIPS Agreement adds a substantial number of additional obligations on matter where the pre-existing conventions are silent or were seen as being inadequate. The TRIPS Agreement is thus sometimes referred to as a Beme and Paris – Plus agreement.

♦ **Enforcement :** The second main set of provisions deals with domestic procedures and remedies for the enforcement of intellectual property rights. The Agreement lays down certain general principles applicable to all IPR enforcement procedures. In addition, it contains provisions on civil an administrative procedures and remedies, provisional measures, special requirements related to border measures and criminal procedures, which specify, in a certain amount of detail, the procedures and remedies that must be available so that right holders can effectively enforce their rights.

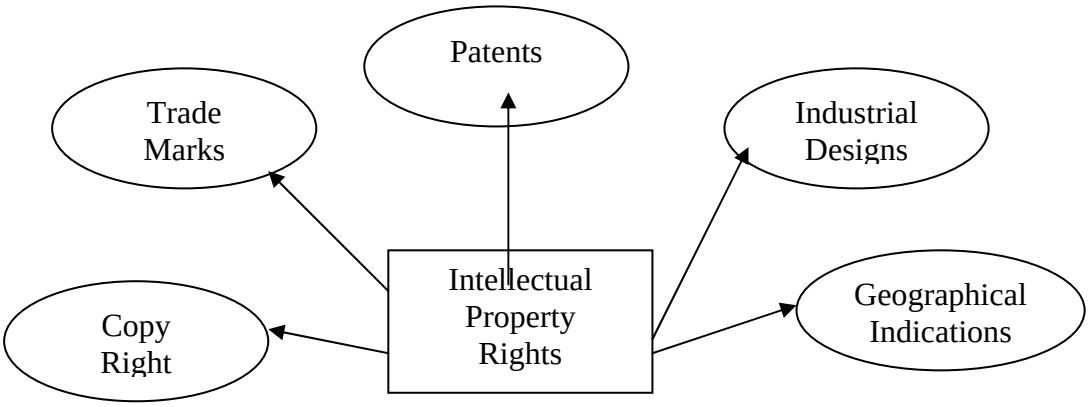
♦ **Dispute settlement** : The Agreement makes settlement procedures of disputes between WTO members about the respect of the TRIPS obligation subject to the WTO's dispute.

In addition the Agreement provides for certain basic principles, such as national and most- favoured-nation treatment and some general rules to ensure that procedural difficulties in acquiring or maintaining IPR do not nullify the substantive benefits that should flow from the Agreement. The obligations under the Agreement will apply equally to all member countries, but developing countries will have a longer period to phase them in. Special transition arrangements operate in the situation where a developing country does not presently provide product patent protection in the area of pharmaceuticals.

The TRIPS Agreement is a minimum standards agreement, which allows members to provide more extensive protection of intellectual property if they so wish. Members are left free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice.

DIAGRAM-1.1

DIVISIONS OF INTELLECTUAL PROPERTY RIGHTS



Certain General provisions

As in the main- existing intellectual property conventions, the basic obligation on each member country is to accord the treatment in regard to the protection of intellectual property provided for under the Agreement to the persons of other members. Article 1.3 defines who these persons are. These persons are referred to as "nationals" but include persons , natural or legal, who have a close attachment to other Members without necessary being nationals. The criteria for determining which persons must thus benefit from the treatment provided for under the Agreement are those laid down for this purpose in the main pre-existing intellectual property conventions of WIPO, applied of course with respect to all WTO members whether or not they are party to those convention. These conventions are the paris Convention, the Beme convention, international convention for the protection of Performers, producers of phonograms and Broadcasting Organization (Rome Convention), and the Treaty on intellectual property in respect of integrated Circuits (IPIC Treaty)

Articles 3,4 and 5 include the fundamental rules on national and most favoured- nation treatment of foreign nationals, which are common to all categories of intellectual property covered by the Agreement. These obligations cover not on the substantive standards of protection but also matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in the Agreement. While the nation treatment clause forbids discrimination

between a member's own nationals and the nationals of other members, the most-favoured –nation treatment clause forbids discrimination between the nationals of other members. In respect of the national treatment obligation, the exception allowed under the pre-existing intellectual property conventions of WIPO are also allowed under TRIPS. Where these exceptions allow material reciprocity, a consequential exception to MFN treatment is also permitted (e.g. comparison of terms for copyright protection in excess of the minimum term required by the TRIPS Agreement as provided under Article 7(8) of the Beme convention as incorporated into the TRIPS Agreement). Certain other limited exceptions to the MFN obligation are also provided for.

The general goals of the TRIPS Agreement are contained in the preamble of the Agreement, which reproduces the basic Uruguay Round negotiating objectives established in the TRIPS area by the 1986 Punta del Este Declaration and the 1988/89 Mid-Term Review. These objectives include the reduction and impediments to international trade, promotion of effective and adequate protection of intellectual propert rights, and ensuring that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade. These objectives should be read in conjunction with Article7, entitled "objectives" according to which the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological

knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. Article 8, entitled “Principles” recognizes the rights of Members to adopt measures for public health and other public interest reasons and to prevent the abuse of intellectual property rights, provided that such measures are consistent with the provisions of the TRIPS Agreement.

Patents

The TRIPS Agreement requires Members countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced (Article 27.1)

There are three permissible exceptions to the basic rule on patentability. One is for inventions contrary to “ordre public” or morality : this explicitly includes inventions dangerous to human, animal or plant life or healthy or seriously prejudicial to the environment. The use of this exception is subject to the condition that the commercial exploitation of the invention must also be prevented and this prevention must be necessary for the protection of “ordre public” or morality (Article 27.2)

The second exception is that members may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals (Article 27.3(a)).

The third is that members may exclude plants and animals other than micro- organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

However, any country excluding plant varieties from patent protection must provide an effective "sui generic" system of protection. Moreover, the whole provision is subject to review four years after entry into force of the Agreement (Article 27.3(b)).

The exclusive rights that must be conferred by a product patent are the ones of making, using, offering for sale, selling, and importing for these purposes. Process patent protection must give rights not only over use of the process but also over products obtained directly by the process. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts (Article 28).

Members may provide limited exceptions to the exclusive rights conferred by a patents, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties (Article 30)

The term of protection available shall not end before the expiration of a period of 20 years counted from the filing date (Article 33)

Members shall required that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may required to indicate the best mode for carrying out the invention known to the inventor known to the inventor at the filling date or, where priority is claimed, at the priority date of the application (Article 29.1).

If the subject-matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process, where certain conditions indicating likelihood that the protected process was used are met (Article 34)

Compulsory licensing and government use without the authorization of the right holder are allowed, but are made subject to conditions aimed at protecting the legitimate interests of the right holder. The conditions are mainly contained in Article 31. These include the obligation, as a general rule, to grant such licence only if an unsuccessfully attempt has been made to acquire a voluntary licence on reasonable terms and conditions with in a reasonable period of time; the requirement to pay adequate remuneration in the circumstances of each case, taking into account the

economic value of the licence and a requirement that decisions be subject to judicial or other independent review by a district higher authority. Certain of these conditions are relaxed where compulsory licences are employed to remedy practices that have been established as anticompetitive by a legal process. These conditions should be read together with the related provisions of Article 27.1, which required that patent rights shall be enjoyable without discrimination as to the field of technology, and whether products are imported or locally produced.

1.2 Need for the study

This study was initiated with an intention to understand the long-term orientation for survival and growth of the small and large pharmaceutical companies in the wake of WTO accord and research & development initiatives.

This industry boasts of huge fragmented players and the pharmaceutical companies who have followed the process patent and operating in all the therapeutic areas available in the market. With the product patent becoming imminent by 2005, companies with clear vision and understanding of the domestic and global markets will only be successfully.

In this context, the study was conceived to see such a focus from the player of the pharmaceutical industry. The impact of WTO on small and large scale companies was studied and the possible future framework of the pharmaceutical industry was also obtained from the respondents for ascertaining the suggestions for the industry to face the challenges after 2005, This study intends to add to the existing knowledge on the pharmaceutical industry and help the companies in careful application of this concept.

1.3 Scope of the study

This study has been conducted keeping in mind the top management professionals in the pharmaceutical industry, who can understand and provide information related to the product patent aspects concerning the industry. Hence, care has been taken to concentrate on the Chiet Executives of the small scale companies, the General Managers or the production Managers of medium and large scale companies.

Since, the pharmaceutical companies are wide spread all over the country, the executive of the companies who are amenable and accessible by the researcher in Tamilnadu (i.e)Chennai, Coimbatore, Trichy & Madurai were sent questionnaire through mail.

1.4 Objectives of the study

The study is proposed to be carried out to accomplish the following objectives:

a. To ascertain why has India followed TRIPS to grant 20 year monopolies to foreigners through patents?

b. To study how far the poor nations with ailing needs will be empowered to break corporate monopolies at will to meet their needs.

c. To investigate the concern of developing countries that the strengthening of JPR could cause problems for the affordability of medicines, particularly for the poor.

d. To suggest how the law should aim at striking a balance between a reward to the holder of trade secrets in the form of monopoly sufficient to encourage R & D to produce new inventions and to encourage disclosure of those inventions to the public to increase the stock of knowledge and on the other hand, not unduly fettering the liberty of members of the public or hindering competition.

e. To examine how for the Doha Meet's requirements such as Compulsory licensing provisions, fixed royalties of around 4% and better public interest provisions enabling a modified licence of right as scheduled by the Govt. for health, food and energy and research are implemented in India.

f. To analyse the impact that the TRIPS agreement will cause on the Indian companies in respect of patent matters.

1.5 Methodology

To obtain the primary data, questionnaire method was adopted. All the pharmaceutical companies in Tamilnadu represented the universe of the study which includes the organized as well as unorganized sector in the industry. Organized sector represent the companies whose activities are controlled and monitored by the Ministry of petroleum and Fertilisers, Government of India Unorganized are those companies which are small scale in nature and are under the control of the respective state Government.

There are 400 Companies in the organized sector and there are more that 17000 companies in the unorganized sector. With a view to get responses from both the sectors a sample of 50 pharmaceutical companies has been selected from both sectors for the purpose of this study. Among these 50 companies, 30 companies are manufacturing units 20 companies are trading units.

Judgment sampling method has been adopted for the selection of sample pharmaceutical companies. Table 1.1 shows the sampling distribution.

TABLE- 1.1

SAMPLE PHARMACEUTICAL COMPANIES

S.No	Place of pharma Ceutical companies	No.of units	Percentage
1	Chennai	30	60%
2.	Coimbatore	5	10%
3.	Trichy	10	20%
4.	Madurai	5	10%
	Total	**50**	**100%**

1.6 Data collection

Both Primary data and secondary data were collected for the present study.

First hand data were collected from the executives of the sample pharmaceutical companies by mailing the questionnaires to them. Since the study covers the responses from the executives from the executives or the top management professionals, the research found difficult to get the reply in time. Because of their busy schedule, it took long time to receive the responses from the executives. A specimen of the questionnaire is given in the appendix section of the present research report.

Secondary data were collected by referring the various magazines, journals, text books and also through the internet browsing.

1.7 Data Analysis

Statistical tools are used to interpret and analyse the primary data, so collected. The statistical tools are percentage analysis, and the charts, which were used for this study. As the percentage analysis is easily understood by all, It is used for the present study.

1.7 Geographical area of study

The geographical area of study is confined to the major cities in Tamilnadu like Chennai, Coimbatore, Madurai and Trichy. The pictorial representation of the geographical area of study is also given.

1.9 Period of Study

The study covers a period 3 years (ie) from 2002-2005. since the WTO agreement became operational fully in 2005, the study was conducted to elicit information from respondents 2005 (April –September)

1.10 Limitation of the study

This study was mainly based on the primary data collected through questionnaire method from various pharmaceutical companies situated in Tamilnadu. The researcher has collected the primary data by mailing one or two questionnaires after repeated reminders and also by visiting certain medical representative of the concerned

pharmaceutical companies. In several cases, the exact meaning of the questions (or) may be its impact were not understood by the respondents and they were left unanswered. Some companies responded that the questionnaire is too long to answer and time consuming also. And certain companies took long time to give their responses to the researcher.

1.11 **Chapter Arrangement**

The present research report is divided into 5 chapters.

The first chapter entitled “introduction and design of the study” deals with the introduction of intellectual property Rights and its certain general provisions, need, scope and objectives of the study, methodology, data collection and analysis, geographical area and period of study, and the limitations of the study.

The second chapter named, “patents Act 1970- An overview” deals with the provisions of the patents Act 1970.

The third Chapter tiled, “ Trade Relaged intellectual property Rights” Containing details about WTO agreement, intellectual property rights and wrongs and modifications in the patents Act 1970.

The fourth chapter entitled, “Analysis of the survey data” contains the detailed analysis of the primary data so collected.

The fifth chapter named “Summary of Findings, suggestion and conclusion presents the findings of the study and offers suggestions to the pharmaceutical companies with regard to the introduction of product patents in India.

CHAPTER –II

THE PATENS ACT 1970 – AN OVERVIEW

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2.2 purpose of patent system

2.3 Object of patent law

2.4 Application of patent

2.5 Non- patentable inventions

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CHAPTER –II

THE PATENETS ACT, 1970- AN OVERVIEW

2.1. Meaning of patent

Patent is ground in favour of the inventor conferring on him the right to use his invention to the exclusive of all others. It is granted for a time , (i.e) for a fixed period of five years where the product or process relates to food or medicine or for a period of 14 years in other cases. If the investo cannot use or work the invention by himself, he can do son in association with other or assign it to other or he can grant licences to other to work the invention for consideration or for fees which is called Royalty.

What is granted as patent is a privilege of making, manufacturing, selling or using the invention and also a right to authorise other to do so. Those who infringe the patent are liable to be restrained by injunction. They will be liable to compensate the inventor by paying damages ascertained in terms of the loss suffered by the investor or the profits gained by the infringer and not both.

2.2 purpose of the patent system

The purpose of the patent system is :

♦ To encourage research and promote the inventive genius

♦To Secure for investors awards for inventing useful inventions.

♦To give protection to inventors by conferring them a monopoly from commercial exploiting their inventions.

♦To induce industries to undertake research and development

♦ To maintain a flow of inventions, one invention leading to another .

♦Increasing both qualitatively and quantitatively, the production potential in the country, by creating new processes and new methods in production of goods and services.

♦To add the industrial growth of the country and improve the quality of life of the people.

♦To generate and promote scientific temper.

The patent system which has been in vague since the beginning of the 17th century in England and in India from 1856 has greatly helped the industrial growth. The principal of granting limited protection to the inventor for a period in consideration of his disclosing the invention, and thereafter releasing the invention to public use has improved production of goods and services on mass scale.

2.3 object of patent law

The object of patent law is to encourage scientific research and industrial progress. Grant of exclusive privilege to won, use or sell the method and product patented for a limited period stimulates new inventions of commercial utility. The price to the grant of monopoly is the disclosure of invention by the inventor at patent office which after the expiry of the fixed period of the monopoly, passes into the public domain.

The fundamental principle of patent law is that patent is granted only for an invention which must be new and useful. This is to say that it must have novelty and utility. Though the invention is not by itself new, the particulars use of it, for purpose described in combination with other elements of the system

Producing advantageous results, will be a sufficient element of novelty to support the patent. It is essential for the validity of the patent that it must be inventor's own discovery.

Gains to inventor

The gain are :

♦ Monetary rewards the inventor may get from the authorities and person who recognize his merit.

♦ Protection of his invention against pilferage, imitation and infringement.

♦ The law does not compel the inventor to take out patent for his invention. The inventor can keep his invention secret and work upon it himself if he has to keep the secret of invention for ever unkown to others.

♦ If the inventor has no financial resources adequate enough to work the invention he can transfer the patent for consideration to others who can work on the invention or assign it by granting licence to other on payment of fees or royalty.

♦ Invention becomes the property of the inventor when it is patented.

2.4 Application of patent

The following persons can make application for patent.

♦ Person claiming to be the true and first inventor of the invention.

♦The assignee of the person claiming to be the true and first inventor in respect of the right to make such application.

♦The legal representative of the deceased person who immediately before his death was entitled to make such application can make an application for patent.

Joint Application

If the application is made by the joint inventors, the patent is granted in their names jointly.

If the application is made by the assignee of the inventor, the patent is granted in the namely of the assignee, as the assignee of the inventor.

The inventor and his assignee can make joint application. The legal representative of the inventor along with the assignee or the licensee can make joint application.

There cannot be any question of licensee getting the patent in his name. His name will be shown or registered as the licensee in the patent after the patent is granted in the name of inventor or is assignee.

True and first inventor

Any person who in exercise of his mind and skill invents a new and novel things for the first time is the true inventor and such inventor who applies is the first inventor.

If two persons independently make an invention, one of them applies for the patent and the other keeps his invention to his breast, the one who applies is the true and first inventor entitled for patent.

The person who has idea of the invention can not claim to be the true and the first inventor when another to whom the idea is conveyed, gave a practical shape to that idea.

Application by film , company, Association, etc

Name of the above viz, the firm, company, joint family, co- operative society or association of persons can make an application as the true and first inventor of invention. However they can make an application for patent as assignee of the true inventor or as an assignee of right to apply.

Application by foreigner

A foreigner including a foreign national residing outside India can make an application for patent in India.

- In respect of an invention made by him in India
- In respect of an invention made by him outside India.
- In respect of an invention obtained by him as assignee or licensee made with India or outside India.
- In respect of an invention for which he applied for patent in any convention country.

Application by India citizen

An Indian citizen can apply for a patent in India for an invention made b him abroad in any country irrespective whether such country is a signatory of the convention

relating to intellectual property rights or not. The place where the invention is made is not relevant for the purposes of granting patent. Similarly, an Indian citizen can make an application for patent in any of the countries which are members of the conventions relating to the intellectual property rights in respect of his invention whether it is made in India or anywhere abroad. But he should obtain prior permission of the controller of patents for making such as application abroad.

2.5 Non- patentable inventions

The following are not inventions for purpose of the Act and the controller of patent will not grant any patent for these inventions.

- ♦ An invention which is frivolous
- ♦ An invention intended to be used contrary to law or morality or injurious to public health
- ♦ A mere discovery of scientific principle.
- ♦ A mere discovery of nay mew property or a mere use of a known process of the machine or apparatus unless ' such known process results in a new product or employs atleast one reactant.
- ♦Substance obtained from mere admixture
- ♦ Mere arrangement or rearrangement or duplication of a known device each functioning independently of one another in a known way.

- ♦Method or process of testing applicability during the process of manufacture for rendering the machine, apparatus or other equipment more efficient by or for improvement or for restoration of existing machine, apparatus or other equipments for improvement or control of manufacture.
- ♦ Method of agriculture or horticulture.
- ♦ Any process in medical, surgical, curative, prophylactic or other treatment of human being or any process for similar treatment of animals or plants to render them free of disease or to increase their economic value or of their products.
- ♦ Invention relating to Atomic Energy.

2.6 priority date and its purpose

Priority date is the date on which applicant makes his application for patent to the controller. The application should necessarily be accompanied by either provisional specification or by complete specification. Provisional specification describes the outline and gives all indications of the invention for which patent is applied. The complete specification described fully the invention. Since the patent is granted to the invention on the basis of complete specification which is continuation of the earlier provisional specification, the priority date for such invention has to be necessarily the date on which provisional specification is filed.

2.7 procedure for obtaining patent

1) Application for patent

The application shall be in the appropriate prescribed form only. Separate forms are prescribed for filing the application by the true and first inventor, and for the assignee or legal representative of the inventor. The application and all its enclosures shall be filed in triplicate. The fees shall be paid along with application. And the controller will not take any action on the application unless the fees is received by him.

Where the application is sent by post it shall be sent by the Registered post acknowledgement due. Unless the acknowledgement is produced the controller will not accept any other proof of service. The application shall be accompanied by provisional specification or complete specification as the case may be.

If the applicant is the assignee or legal representative, proof of applicant's right to make the application shall be filled along with the application for patent or within 3 months from the date of application. In all the cases the application should contain the name of the true and first inventor and applicant must also say that he is in possession of the invention. The application shall be confined to one invention only. The application shall be either in English or in Hindi.

2) Precautions to be taken

Patent office scrutinizes the application very carefully. Wherever the applicant is required to sign he shall sign in full. All the documents and all the copies required to be filed should be properly attested by the authority competent to attest. It may be noted that the seal of the attesting officer is put on all the pages. The Plans, design etc. which are required to be filed are drawn in paper of quality as may be prescribed and shall be in accordance with scale and size. Failure to satisfy the office in any of these matters will result in the return of the application and all the documents.

3) Stages of procedure

Only after the fees received in full, the controller will issue an acknowledgement mentioning the date on which the application is received at his office. The date of receipt of the application as mentioned in the acknowledgement is the date of priority of the application. And applicant shall be very careful and vigilant in securing the official acknowledgement and in preserving it till the patent is granted.

a) First stage- office objections

The office of the controller will then examine the application as to whether the application filed is in accordance with the procedures prescribed. If there are any deficiencies the applicant is required to make good the deficiencies. After the office objections are satisfactorily complied with, the controller will issue a direction that the application be kept pending for 12 months reckoned from the date of receipt of application. During this period the applicant shall file the complete specification. The lay- over period is statutorily fixed. This time is intended to enable the applicant to re-examine his invention, check and re-check the result, improve upon the invention and explore the possibilities, its usefulness and marketability. The 12 months lay-over period may be extended by 3 more months if an application is filed together with complete specification for its extension.

b) Second Stage: Examination by Examiner

After the complete specification is filed, the controller will refer the application to the examiner of the patent who examines the application thoroughly on merits of the application for patent and whether the applicant is entitled to the grant in accordance with the claims made in his complete specification. If there are any objections, the examiner of patents will communicate the same to the applicant requiring him to comply with the objections. On consideration of all the matters connected with the grant of

patent, the examiner finally submits his report to the controller. The Examiner of patents shall as far as possible submit his report with in 18 months from the date of reference or reference or such extended term as the controller may grant him to submit his report.

C)**This stage**: **Acceptance and proceedings in opposition**

On receipt of the report from the examiner of the patent, the controller will decide the issue of acceptance of the application. If accepted, the Controller will direct the publication of the patent application in the official gazette for information to all those who may be interested in opposing the grant of patent. If no objections from any of the interest parties are received and if the controller finds o ground for rejections of the application, he, by an order grants the patent.

In case any objections are received within 4 months from the date of publication, the controller will decide on the objection after giving full opportunity of making representation, adducing of evidence and hearing to all those who filed objections and the applicant. The Order made by the controller at the conclusion of the proceedings in opposition is a quasi judicial order. The controller himself functioning as a quasi judicial tribunal with power of a civil court in matters of reception of evidence and holding trial as if it is a suit. The proceedings before the controller finds that the objector himself is entitled to the patent he has the power to treat that person who files the objection as the real applicant and proceed accordingly.

d) Fourth stage : sealing of patent

With in 6 months from the date of the order disposing off the objection in the proceedings of opposition and grant to the applicant the patent, the applicant may apply to the controller to register the patent and grant him the Patent certificate and seal the patent. The applicant will there after will be called a patent holder or patentee.

e) Refusal to grant patent – consequence

If the controller ultimately refuses to grant the patent, it means that the applicant's request to grant him monopoly in his invention is rejected. In other words the knowledge about invention becomes public property as any other invention for which a patent is not either applied for or the patent the term of which has expired.

Protection period

The period between the date on which the application is made along with provisional specification and the date on which the patent is granted is called the protection period. During this period the inventor can make his invention known to the public, get published in journal and exhibit the process of the manufacture and the product which could be manufactured. Since the inventor has the advantage of protection period, it is very essential and necessary that he should first make the application for the grant of patent and then only think of publishing the invention.

2.8 Provisional specification

As the name itself shows that the provisional specification is a provisional intimation of the invention to the controller. The provisional specification should contain the outline of the invention and not necessarily be detailed. If should indicate the working and utility of the invention. There is no need to furnish any minute details thereof. There should be clear indication in the provisional specification which can be treated as having a fair reference to The claims to be incorporated in the complete specification. Provisional specification should commence with a title which should sufficiently introduce the subject matter of the invention. Then, it should follow the descriptive outline of the invention, its novelty, working and utility.

2.9 Complete specification

As with the provisional specification , complete specification will also commence with the title, and a paragraph may be devoted for defining and explaining various terms used in the specifications. The description of the invention which follows must be full and shall give all details. Simple and clear language shall be used and ambiguity should be avoided. The description shall follow a sequence of either events, thoughts, experiments or the progression of the invention.

It is necessary that a separate paragraph is set apart and devoted to the methods and procedures of working the invention. Insufficient description, lack of bona fids or avoidance to disclose fully will result in the rejection of application for patent. If there are different methods of working the patent, they may be described and included in the complete specification and the applicant is entitled to include all of them in his claims as covered with in the monopoly. The final paragraph in the complete specification shall be exclusively devoted to the claims in relation to which the applicant claims monopoly and claims that by virtue of this monopoly none else should be entitle to use or adopt the patent.

2.10 Ground of opposition

- The grounds on which one can oppose the grant of patent to the person who claims the patent are ;
- That the person claiming the patent has wrongly obtained the invention or the right to make the application for patent.
- That the invention for which patent claimed is already published.
- That there is already a prior claim in the complete specification earlier filed.
- That there was prior knowledge of the claim made in the complete specification from the date anterior to the date of its priority.
- That the invention suffers from obviousness and lacks inventive step.

♦ That the subject of the claim can not be treated as invention and is not patentable under the Act.

♦ That the complete specification does not sufficiently and clear describe the invention or the method by which it is to be performed.

♦ That the applicant for patent failed to disclose information required under the Act, or furnished information which in material particulars is false to his knowledge.

♦ That, the application which is a convention application is filed beyond time.

♦ The purpose of opposition proceedings is to assure that the person who is really entitled to the patent is only granted the patent and that a real patentable invention is only granted the patent.

2.11 Grant of Patent

After Controller has rendered his decision and ordered the grant of patent , the applicant has to make an application for the issue of patent and for sealing it. Such an application can be filed within six months from the date of the decision of the controller or within such extended time the controller may grant. On receipt of such request from the applicant, the controller will register the patent in the Register maintained at the office of the controller of patents and grants the patent with a number which was originally allotted to it on the date of the acceptance of the completed specification and dated also the same date on which it was numbered. The controller will on the date of

the issue of patent, seal the patent. Therefore, the patent will bear the number and date on which the complete specification is accepted and the sealing date is the date on which the patent is registered and sealed.

Significance of date of patent and date of sealing

The date of patent is relevant for purposes of calculating the term of the patent. The fourteen year term of patent commences from the date of patent. This also is the date relevant for purposes of calculating the amount of renewal fees which is traded upwards for each successive year and the due dates for payment of renewal fees.

The date of sealing is relevant for purposes of calculating the five year or seven year term of the patent which is the granted in relation to the processes of articles of food and drugs. The date of sealing is relevant also for purposes of determining the time after which compulsory licences of right can be granted

Obligations of patent holder

The first obligation is that the patent holder must work the patent. He should thus, fulfill the primary object of the grant of patent. He should act as model for further inventions. The next obligation is to pay renewal fees as prescribed in accordance with the scale on due dates every year. The third obligation of the patent holder is that he should report to the controller the progress of the working of the patent.

Renewal fees is not payable for the period during which a direction given by the controller to keep the patent secret in view of the security requirements, remains in force. If the direction is revoked in any year irrespective of the time at which the order of revocation was issued, renewal fees shall have to be paid for the full year. If in any year the patent holder fails to pay the renewal fees in time he may get extension up to six months and pay the renewal fees accordingly. If the renewal fees is not paid even after the period is extended, the patent ceases to have effect from the date when the renewal fee first fell due and not on the date when the extended period expires.

Register of patent

The patent office at Calcutta will maintain a Register of patent. It contains all relevant particulars about the patent as and when they are registered. All the additional entries relevant to the registration and all changes and amendments will be duly entered so that the register reflects the position up to date.

The following particulars are noted for each of the patent registered.

♦The name, address for service, nationality of the patent holder, the title of the invention including the category to which it belongs, the date of patent, and the date of sealing.

♦ All particulars and notifications about the assignments, transmissions, licences, amendments, extensions, and revocations are all recorded in the register.

♦Particulars of the payment of fees and renewals can be seen in the register. If there are any changes in the address of the patent holder or holders, the same will be recorded in the register.

The register of patent is maintained at the Head Office, Calcutta and the copy of the same is available with all the Branch Offices. They are available for inspection on payment of fees.

Rights of patent Holder

The right of the patent holder in his invention is called the monopoly right. Any person who has an invention with him has a right to use it, make articles out of it and deal with those articles. This right is a general and natural right common to all those having with them an invention or a secret formula. But what a patent holder of the invention is vested with is that he only shall be exclusively entitled to use the invention. This exclusive right is called monopoly.

Accordingly the patent holder has all the rights an owner has in any property. He can lease, assign, licence the patent in favour of other or otherwise in any manner part with any of the ownership rights. He can grant a Share to other in the patent. He can mortgage the patent. Patent

holder has a right to surrender the patent. The proposal to surrender will be notified in the Gazette. The controller will permit the surrender only after all objections to surrender are disposed off.

2.12 Types of patents

The types of patent granted by the controller of patents are

1) Ordinary patent
    a) product patent and process patent and
    b) patent of addition for improvement and modification
2) combination patent
3) selection patent
4) convention patent and
5) Pipeline patent or sealed box patent

All other except ordinary are called patent under special categories.

(a)product patent and process patent

The patent law in India makes distinction between the product patent and process patent. Where the invention relates to the manufacture of machine, article or substance which is new, novel and useful and the patent asked for is for the product, such patent is called product patent where by a new, novel and useful process a new better cheaper multi-active article or substance is made available the patent asked for is for the process, such patent is called process patent.

While both the process and product patents are available in all areas of manufacture, process patent only and not product patent are granted in India respect of the following substances.

♦Substances intended for use, or capable of being used as food or as medicine or drug, or

♦ Substances prepared or produced by chemical processes (including alloys, optical glass, semi- conductors and intermetellic compounds), no patent shall be granted in respect or claims for the substances themselves, but claim for the methods or processes of manufacture shall be patentable.

While the procedure for obtaining patent and all other matter are the same for both product and process patents, the only difference between them is that while the terms of the patent in all matters is 14 years, the term of patent for process patent in respect of substances intended to be use as food or medicine or drug is 7 years from the date of patent and 5 years from the date of sealing whichever is earlier.

(b) patent of addition

Patent of addition is granted to the applicant who was granted already a patent or whose application for patent is pending. Such patent may be for improvement over the original patent or may be a modification of the invention. The patent of addition can not be sealed unless the original patent is sealed.

The term of the patent of addition is same as that of the original patent and it runs simultaneously with that of the original patent and expires at the Same time as the original patent expires. There is no need to pay separate renewal fees for patent of addition. If for any reason the original patent is revoked, the patent of addition may be kept alive if so ordered by the controller. The patent of addition kept alive till the expiry of the un-expired period of the revoked original patent shall be subject to the payment of renewal fees.

2) Combination patent

It is accepted as a sound proposition that mere placing side by side of the known integers of a patent, each performing its own proper function in spite of combination, is not a patentable combination. When known integers placed together by an inventive step into a working inter-relationship producing a new article or a better or cheaper article, then there is a patentable subject matter. Mere collection of more than one integer not involving any inventive step is not patentable.

Even where the change is very slight but the result of combination is significant or significant improvement then there exists a patentable substance to be considered as a combination patent.

3) Selection Patent

When the selected members chosen out of patented substance and they are selected for their special characteristic and the inventive step results in a new substance, the patent that will be granted is selection patent. There are three characteristics which determine whether the patent asked for is a selection patent or a combination patent, they are :

♦Selection from members of the substance already patented must be based on some substantial advantage. The whole of selected members must posses the advantage. The selected members must have quality of special character which may be peculiar to the selected group.

♦The inventive step in selection patent consists in the exercise of intellectual faculty in choosing some of the advantages of the patented substances and bringing out a substance which is new and having special advantage.

♦The principles involved in combination patent and selection patent are applicable to mechanical patents also.

4) Convention patent

With a view to fulfill the treaty obligation incurred with the convention countries, the Government by a notification specifies the names of countries which give to Indian citizen the same facilities in relation to patents as they give to other nationals and offers to the nationals of those convention countries facilities in relation to patents. Such notification may cover the whole field occupied by the Indian patent Act or so much only of it is as is commensurate with the facilities granted by those convention countries to the Indian citizens.

The application made in accordance with the said notification by any national of a convention country in India for patent or for a licence for an Indian patent either by himself or in association with Indian citizens, is called convention application.

6) Sealed Box Patent

The expression sealed-box patent does not occur in the Indian Patents Act. It is a name popularly adopted to indicate the manner in which the application for the product patent for medicines and drugs in India is treated during the period of ten years from January, 1995 to 2005.Here, the application for patent is received and is not sent to the Examiner of patents in the manner in which it was so sent in all other cases. It is kept as though in a sealed-box without any further action. But in the meanwhile, if the applicant makes a request to grant him

Exclusive Marketing Rights for the product for which he made an application for product patent, he will be granted such a permission to sell his products in India for a period of five years or till he is granted or refused the patent. Since the application for the patent is kept in a sealed-box for a period of time and granted or refused a patent after the expiry of the period and the application in the meanwhile is granted Exclusive Marketing Rights to sell his product in India, this patent is called sealed-box patent. It is also called a pipe-line patent in the sense that the application for the patent is in the pipe-line for the ultimate grant or refusal of paten by 2005.

Countries which grant both process and product patent in pharmaceuticals

1. Arminia	2.Belarus	3.Brazil
4. Bulgaria	5. Czech Republic	6.Estonia
7. Finland	8. Jeorgia	9.Hungary
10. Kazakhastan	11.Kyrystan	12.latvia
13. Liberia	14. Lithuania	15.Medagskar
16.Maldova	17.Mangolia	18. Norway
19.Poland	20. Romania	21. Russian federation
22.Slovak Republic	23.Sloveuia	24. Swaziland
25. Tajikasthan	26. Ukraine	27.Uzbekistan

and 28. Vietnam

Countries which grant process patents only in pharmaceuticals countries : India

Since India provides process patent only in medicines and drugs, there arose a necessity of making a temporary law to enable the controller to receive application for product patent in medicines and drugs and also to grant Exclusive Marketing Rights.

2.14 Infringement

Rights of the patent holder are the rights of monopoly exclusive to him in the patent. He who breaches the monopoly, is said to infringe the rights of the patent holder. The rights of monopoly granted to the patent holder consists in his exclusive right, to make, use, exercise, sell or distribute the articles manufactured in accordance with the patent or manufactured in accordance with the patent process. Nobody else can use patented invention or patented process for manufacturing the articles or substances.

A person who uses the patented invention or a patented process or the person who produces the articles and substances, for which there exists a patent, commits infringement. A person or institution which uses the patented invention for research purposes does not commit any infringement. Infringement of patent Is not a criminal offence. The infringer is not liable to be prosecuted in any criminal court.

Relief

The patent holder cans sure the infringer for permanent injunction. He can also ask for ex parte interim injunction on the date of filing the suit which if granted will be in force initially for a period of one month and thereafter continued or withdrawn in accordance with the orders that may be made by the court. The patent holder can ask for damages or for a direction to render an account for profits. As a matter of fact the suit is only one in which all the relief can be asked for including delivery of and destruction of infringed articles.

The act does not require that any previous notice is necessary before action is taken against the infringer. If there are circumstances which warrant the issue of notice hopefully with a view that the defendant may settle the matter out of court, a notice may be issued. Where injunction is an immediate necessity there should not be any delay in filling the suit.

The first principle the court has no follow in granting injunction is that if there is a clear breach of right, it is permissible for the court to invoke any equitable bar to refuse injunction. The patent holder must first prima facie establish the legal title to the patent, his right to apply to the court, the balance of convenience where by he should show that the losses he will suffer are immeasurable and cannot be compensated and the damages, loss of business and market reputation he will suffer will be irreparable. Unless these essentials are satisfied the court will not issue injunction against the infringer.

CHAPTER-III

TRADE RELATED INTELLECTUAL PROPERTY RIGHT

3.1 WTO's Agreement

3.2 Criticisms on patents (Amendment) Act, 2005

3.3 Intellectual property Rights & Wrongs

3.4 Modifications in the patent Act, 1970

3.5 Pharma patents

3.6 Compulsory License

CHAPTER –III

TRADE RELATED INTELLECTUAL PROPERTY RIGHTS

3.1 WTO'S Agreement

The WTO's Agreement on TRIPS makes it mandatory for all countries to establish standards for intellectual property protection. This Agreement came into effect on 1995 of all developing nations including India, needed to fulfill the above requirements by 2000. While the developed countries were to implement this requirement by 1996, the schedule for the least developed ones gave then time till 2005.

The TRIPS solution suggests a wonderful new market will open up for nations like India, South Africa, Brazil and china which have domestic manufacturing capacity in pharmaceuticals. There are so many safeguards that few compulsory licence will actually be used not to mention the delivery and government problems that will plague exporters from India. It could make India and other developing countries think a big victory has been wrested & thus deflect attention from more important issues like agriculture.

3.2 Criticisms on patents (Amendment) Act,2005

The criticism centres especially on the re-introduction of product patents for foods, drugs and chemicals. A substantial part of the criticism is based on misconceptions. This is particularly true of claims that the Indian drug industry has been able to bring down the price of medicines as a result of the act, Which deleted the provisions for grant of product in the case of foods, drugs and chemicals alone.

The patent Act 1970, granting only process patent for drugs, enabled even small and medium Indian companies to produce indigenous versions of drugs developed abroad, especially in the U.S. and Europe and even export them. The low price of Indian drugs was because the material cost of the final product was very low, compared to the costs involved in the development of drugs.

Development costs include not just the wages of medical and scientific manpower involved in research, but also the infrastructure required for experimentation on animals and humans over a long period before a new drug is ready. This is followed by a lengthy and rigorous process of approval by the regulatory authorities.

It is in the nature of chemical products that their composition can be easily known and they can then be made through alternative processes. Any company that makes a drug developed and patented by somebody else but uses another process avoids the bulk of the development costs and thus able to produce and self it at a low cost.

The patent act, 1970, reflected the experience of the colonial era. The British rulers has used the Indian patent and Designs Act, 1911, to force products including drugs on this country – encouraging imports from Britain and discouraging manufacture in India.

At present, there is enormous scope for investment of capital, both indigenous and foreign for manufacturing within India. What's more, india's vast scientific manpower can be harnessed to make the industry an innovator of new drugs at low cost. This will help the Indian drug industry take advantage of product patents, instead of making it dependent on the development of drugs abroad for producing copies. The latter option, encouraged by 1970 Act is economic tailism, which a nation can embrace only at the risk of undermining its own technological potential.

Among the objections to the restoration of product patent for drugs are allegations that drug multinationals indulge in monopoly practices and that they exaggerate the cost of product development. The power of monopolistic companies is controlled by the Government through anti-trust legislation, price regulation, etc. The limited monopoly that a patent entails is a grant from the State to any innovator – Individual or business or institution. The patentee is entitled to compensation from anyone, including a big company or multinational company that puts his invents or innovation to commercial use.

Thus, the patent monopoly granted by the Intellectual Property right(IPRs) system is not only different from but also in a sense a counterweight to the power of big firms, especially in a developing country. Also, if the cost of research and development is exaggerated as well develop new drugs at non-exaggerated costs and capture markets.

However, one valid objection to the reform of the Indian Patent Law is the introduction of Exclusive Marketing Rights (EMRs) in the period of transition (10 years from 1995 to the product patent regime) in tune with the TRIPs agreement.

The new patent ordinance expands the patentability criteria from drugs and agro-chemicals to other fields of technology, such as embedded software. One of the major provisions introduced was regarding grant of compulsory licence, which means that Indian manufacturers will be able to manufacture and export patented medicines to countries, which have insufficient or no manufacturing capacity. The introduction of a provision to enable grant of compulsory licence for export of medicines to the countries that have insufficient or no manufacturing capacity to meet emergent public health situations, is in accordance with the Doha Declarations on Trade Related Intellectual Property rights (TRIPs) and public health.

The ordinance seeks to strengthen opposition proceedings by allowing for both pre-grant and post-grant opposition. Pre-grant opposition can be filed anytime after

publication. While earlier there was no time frame, the ordinance states that if a pre-grant application is filed close to a patent being granted then, in certain cases, it has to be cleared within 90 days. Rationalization of provisions relating to time-lines has been done with a view to introducing flexibility and reducing the processing time for patent applications, and simplifying and rationalizing procedures.

The Ordinance also seeks to simplify and rationalize the time-frame for process of patents. The time limit for giving requests for examination has been reduced to 36 months from 48 months earlier. Another important provision made in the Act, is that the patent will be available from the day when the patent is granted and not when it is published. This means that many Indian Companies will be saved from infringement cases by the multinational majors, who might get patents for drugs which Indian companies are selling.

What is most likely to happen is that the companies that have the patent for a particular drug may force the company producing a generic version of the same to stop production but they cannot bring a libel suit on the generic producer retrospectively. Another important provision relates to the extension of patents in case of incremental innovations. It means that the companies, which come up with new usage of the same product may not get patent for the new usage. Security provisions are also tightened, particularly, for dual-use patent applications. Such patents will now scrutinized by the patent office. While software

would continue to be copyright-protected, embedded software that has technical applications can now be patented.

The Act has strong provisions under chapter XVII for outright acquisition of the patent to meet national requirements. Since the icing mechanism for patented drugs in the Ordinance is not clear, we might see some improvement on that front in the actual law and that may define new products being launched by the multi-national pharmaceutical companies in the country. Patent applications for all inventions made by anybody resident in India (by Indians or otherwise) have to be now filed in India, first, before filling else where in the world.

Thus, patent applications based on collaborative research and research work being done in India has to be filed in India first, including the PCT. Some controversy arises related to the product patent regime. From an academic Point of view, product patent helps countries to develop and be self-reliant. But, from a humanitarian perspective, it will adversely af dedefect and life of poor people in developing countries. The argument from the product patent lobby is that most of the existing drugs became generic, so the regime won't affect much. Instead of reverse engineering or copying existing foreign drugs, Indian companies should provide more money for research and development. The government should also encourage more R&D, which helps increase employment opportunities.

3.3 Intellectual property rights & Wrongs

October 2004 the general assembly of the world intellectual property organization (WIPRO)decided to consider what a development- oriented intellectual property regime might look like. The current rules of the international economic games reflect the interests of the advanced industrial countries- especially of their big corporation- more than the interests of the developing world. Without intellectual property protection, but there are high costs associated with intellectual property. Ideas are the most important input into research, and if intellectual property slows the ability to use other' ideas, then scientific and technological progress will suffer.

By contrast, an intellectual property regime rewards innovators by creating a temporary monopoly power, allowing them to charge far higher prices than could if there were competition. In the process, ideas are disseminated and used less than they would be otherwise. The economic rationale for intellectual property is that faster innovation offsets the enormous.Costs of such inefficiencies. But it has become increasingly clear that excessively strong or badly formulated intellectual property rights may actually impede innovation – and not just by increasing the price of research.

Monopolists may have much less incentive to innovate than they would if they had to compete. Modern research has shown that the great economist Joseph Schumpeter was wrong in thinking that competition in innovation leads to a succession of firms. In fact, a monopolist, once established, may be hard to dislodge, as monopoly can use its market power to squelch competitors. Such abuses of market power discourage innovation. Moreover, so-called 'patent thickets' the fear that some advance will tread on pre-existing patent, of which the innovator may not even be, aware- may also discourage innovation.

The need to prevent excessive monopoly power has led anti-trust authorities to require compulsory licensing. Unfortunately, the trade negotiators who framed the intellectual-property agreement of the Uruguay trade round of the early '90s(TRIPS) were either unaware of all of this, or more likely, uninterested. Intellectual property is important, but the appropriate intellectual property regime for a developing country is different from that for an advanced industrial country. The TRIPs scheme failed to recognize this. In fact, intellectual property should never have been included in a trade agreement in the first place, at least partly because its regulation is demonstrably beyond the competency of trade negotiators.

Besides, an international organization already exists to protect intellectual property, Hopefully, in WIPO's reconsideration of intellectual property regimes, the voices of the developing world will be heard more clearly than it was in the WTO negotiations; hopefully, WIPO will succeed in outlining what a pro-developing intellectual property regime implies; and hopefully, WTO will listen; the aim of trade liberalization is to boost development, not hinder it.

3.4 Modifications in the patent Act, 1970

The patent (Amendment) Act, 2005 is presently in force. Subsequently, the central Government amended the patent Rules, 2003 and the rules were called the patent (Amendment) Rules, 2005. By a publication dated june 2005 in the gazette of India, further amendments to the rules were published, called the patent (Second Amendment)Rules, 2005.

With regard to the examination of the application and time for placing the application in order, section 11B of the patent (Amendment) Act, 2005 stipulates that the application will e examined only after filling the request for examination. Rule 24B prescribes various time limits for making the request. The Rule 24B (1)(i) also stipulates that the request for examination can be filed only after the publication of the application but within 36 months from the date of priority or the dale of filing of the application, whichever is earlier.

On the request for examination, according to the proposed amendment to Rule 24B (1)(v), in the cases of applications filed before January 1, ’05, the time limit for filing a request for examination shall be the period specified under section 11B before the commencement of the patent (Amendment) Act, 2005.While appreciating the amendments proposed, It would be appropriate if the extract period was stipulated in the rule itself, instead of making a reference as proposed. Rule 24B (4) is not clear as to the applications in respect of the period specified therein. It is presumed the applications are those which have been examined after the coming into force of the patent (Amendment) Act, 2005 and not those examined earlier. So, an order for a grant under section 21 in respect of the application, which are examined after the amended act, shall be 9 months from the date on which the first statement of objection is issued to the applicant to comply with requirements.

The applicant has a reduced time period to place the application in order for grant, namely within 9 months from the date of the first examination report. However, an extension up to maximum of three months is available in the case of the applications in respect of which the first statement of objections has been issued after the commencement of the patent (Amendment) act, 2005. But, this extension has to be made before the expiry of the nine-month period from the date of the first examination report. In other words, the applicant has to take a calculated risk in securing one or two months and not the maximum three months. In addition, the fees prescribed for such as

extension is very exorbitant, namely, for total fees for three months, the extension is Rs 6000,in case the applicant is an individual and Rs.24,000in case the applicant is a legal entity that is not an individual.

These provisions are intended to expedite the grant of patent and in principle, are a good provision and are appreciated. It is seen that after meeting the official requirements, the applicant has to wait for a considerable length of Time to receive another official action if any, for a considerable period of time. In other words, many a time, the patent office takes away majority of the period available. In the case of inspection and supply of published documents, in rule 27, there is a mention of “payment of fees” but the schedule does not prescribed any such fees. Hence, if any fees are to be paid, it has to be stipulated in the schedule of fees. On the other hand, if no fees are to be paid, then the above words have to be deleted. When it comes to opposition by representation against the grant of patent, in the proposed amendment to rule 55(1), no time period has been specified, though from the new Rule 55(1)a, it can be presumed that the period is six months from the date publication under section 11A. in order to make the rule clear and precise and not leave anything to presumption, the time limit may be specified in rule 55 (1) itself.

The patent (Amendment) act, 2005 also provides the constitution of an opposition Board, which will provide inputs to the controller. The Board will consist of three examiners, one of them acting as the chairman. When it comes to inspection of documents for the grant of patent, Rule 74 A, though specifies that for this, a written request has to be made along with the prescribed fees, though no fees have been prescribed. Therefore, in the schedule of fees, the prescribed fees have to be indicated. Section 153 deals with the request of information. In rule 134 (k), the words "official Gazette" should be substituted with the words" patent office journal". This amendment is required consequent to the discontinuance of the gazette of India with effect from January 1, o5 and the publication of the patent office journal instead.

No revision of the fees prescribed has been made. Though the fees than those indicated above are to be reviewed, so that it can be justified, as the proceedings are very few and far between and further, the situation may arise due to the negligence/ default of the applicants/ agents. Therefore, the high fees may make the applicant/ agent more vigilant. A revision or fee is required.

3.5 Pharma patents

Insofar as patentability of chemical molecules is concerned, it has been clarified that mere discovery of a new form of a known substance which does not result in the enhancement of the known efficiency of that substance is

not patentable. For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, isomers, mixtures of isomers and other derivatives of known substances are to be considered to be the same substances, unless they differ significantly in properties with regard to efficacy, (amendment to section 3(d) This amendment would alleviate fears amongst the Indian pharmaceutical industry and consumers with regard to the scope of product patent. What is not novel is now made clearer. A new form of a substance is patentable only if it results in enhancement of the know efficacy of such substance.

A new form of a new drug composition, such as an injectable or slow-release formulation is patentable only if it differs in efficacy or benefit the user. Another common and debated example is that of a salt. This was also considered in a US case, Pfizer vs Dr Reddy's where Dr Reddy's was trying to sell amiodipine maleate. Pfizar had a patent on amiodipine besylate, a different salt. The court declared that Dr.Reddy's composition did not differ in therapeutic value from amlodipine besylate. What is important to note is the Inclusion of "metabolites" this used to be a common element of strategies adopted by US drug companies to extend patent lifecycles. The company would first file a patent for a drug and the formulation and after sometime, a patent for a metabolite would be tiled. A metabolite is something that is created in a patient or body after consuming the drug. Since the metabolite patent would expire much later than the original drug patent, many companies were prohibited from making a drug that would

result in that particulars metabolite. The courts did, of course intervene and now metabolites are not patentable in the US. Reading section 3(d), it could be interpreted that metabolites are patentable if they have better efficiency.

3.7 compulsory license

Section 92A, which was inserted by the ordinance in pursuance of paragraph 6 of the Doha Declaration on TRIPS, has been further amended. Now, compulsory license to manufacture and export the patented product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector can also be granted if such country has allowed importation of the patented pharmaceutical products from India.

The amended provision will allow Indian companies to produce and export AIDS drugs to African and South East Asian countries.

The Amendment has greatly broadened the scope of opposition to the patent by introducing two changes; that is after its publication but before its grant and after the grant, within one year.

CHAPTER-IV

ANALYSIS OF SURVEY DATA

CHAPTER- IV

ANALYSIS OF SURVEY DATA

A manufacturing unit is one which produces its products or commodities by its own, while a trading unit is one which acts as a mediator between the manufacturing unit and the ultimate consumer. That is, these companies buy products from the manufacturing companies in a bulk and in turn, sell it to the final consumers. These companies may also be called as wholesalers or retailers.

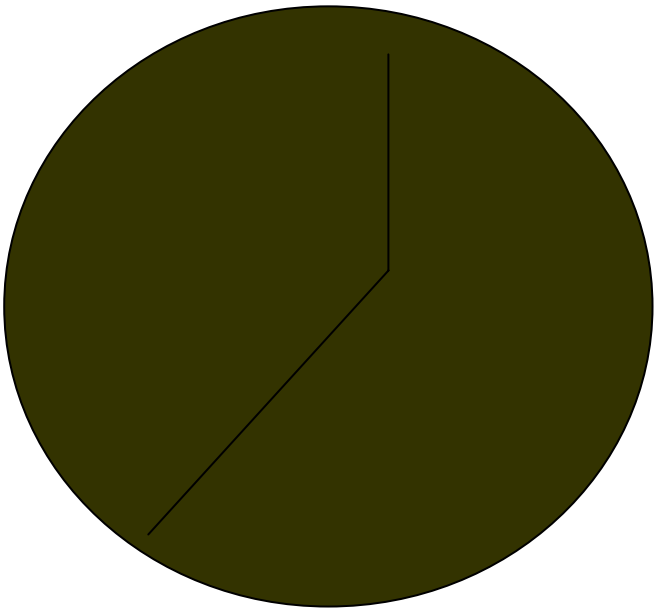
TABLE- 4.1
NATURE OF RESPONDENT UNIT

S.No	Nature	No.of units
1.	Manufacturing	30
2.	Trading	20
	Total	50

From the above table 4.1, it is clear that 30 out of 50 respondent units are manufacturing units, who produce the products by their own and the remaining 20 units are trading units who buy products from the former and sell it to the final consumers.

DIAGRAM – 4.1

NATURE OF RESPONDENT UNITS



The performance of every company is measured by its profit (or) turnover it earned, during a period (ie) yearly or half-yearly. So, the motto of every company will be earn more turnover only.

TABLE- 4.2

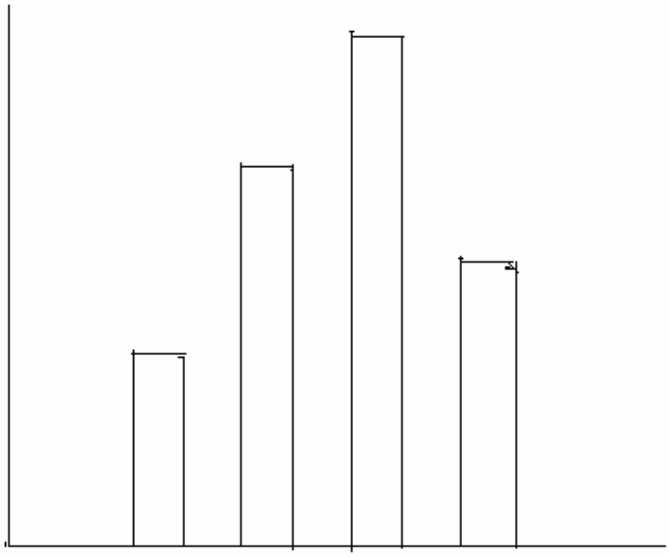
ANNUAL TURNOVER OF THE RESPONDENT UNITS

S.No	Annual Turnover	No.of units
1.	Below 1 crore	-
2.	1 crore- 3 crores	5
3.	3 crores – 5 crores	15
4.	5 crores – 10 crores	20
5.	10 crores & above	10
	Total	**50**

The above table 4.2 shows that only 10 out of 50 respondent units are earning Rs. 10 crores per annum, 20 companies are earning more than Rs. 5 crores & less than Rs. 10 crores, 15 companies are earning above Rs. 3 crores and below Rs. 5 crores, 5 units and earning an annual turnover of below Rs. 3 crores and above Rs. 1 crore.

DIAGRAM – 4.2

ANNUAL TURNOVER OF THE RESPONDENT UNITS



The size of the business, its running and its future are decided by the initial capital invested by the company. So it is correct to say, " capital is the life blood of the company". The capital may be raised by issuing the shares to the public and by the contribution of the promoters of Directors of the concerned companies.

TABLE- 4.3

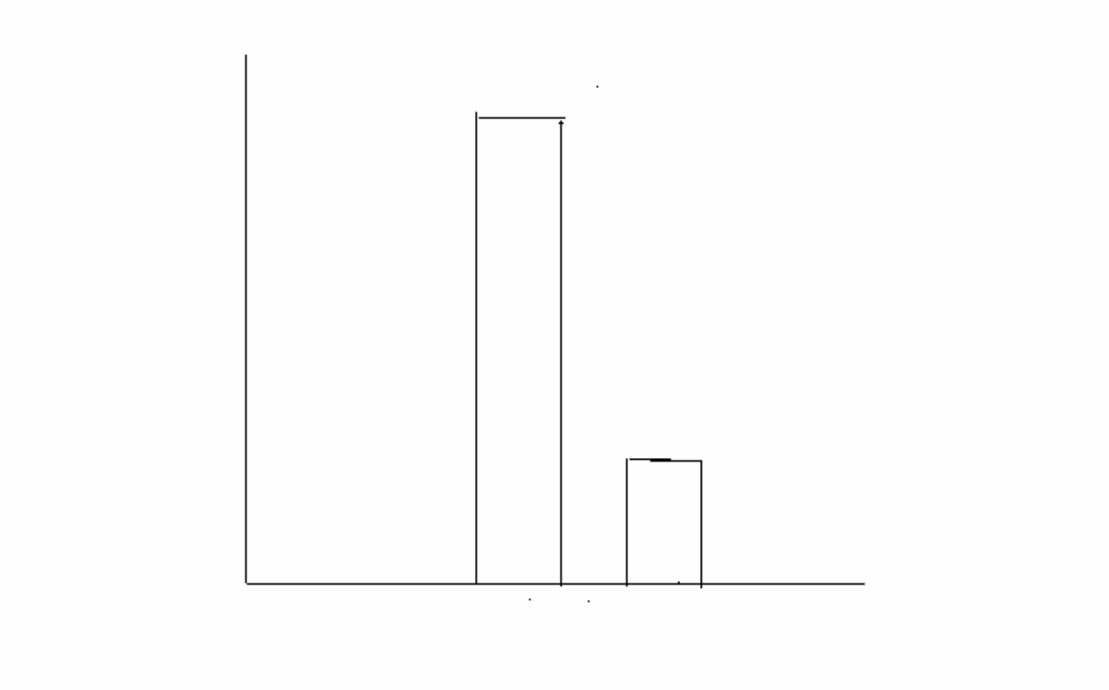
CAPITAL INVESTMENT IN RESPONDENT UNITS

S.No	Capital investment	No.of units
1.	Less than 1 crore	-
2.	1 crore – 3 crores	40
3.	3 crores – 5 crores	10
4.	5 crores & above	-
	Total	**50**

From the above table 4.3 it is known that out of 50 respondent units 40 units had invested the capital of above Rs. 1 crore and below Rs.3 crores and 10 units had invested within the margin of Rs. 3 crores and Rs. 5 crores and no respondent unit had invested above Rs. 5 crores as it capital.

DIAGRAM – 4.3

CAPITAL INVESTMENT IN RESPONDENT UNITS



It is an important one to be a member in the Associations of the respective companies in order to safeguard the interest of company and to have a cover over the disturbing factors. These Association or Unions will save the companies during the period of problem or crisis, legally. And the companies should pay some nominal amount as subscription a become a member of these associations and also they have to subscribe some money at regular intervals, usually yearly once, to retain their membership in the associations of pharmaceutical companies. Ex. Indian Drugs Manufacturing Association, Tamilnadu pharmaceuticals manufacturing Association etc.,

TABLE- 4.4

MEMBERSHIP IN ASSOCIATIONS OF PHARMACEUTICAL COMPANIES

S.No	Membership	No.of units
1.	Member	50
2.	Not a member	-
	Total	**50**

It is clear from the above table 4.4 that all the 50 respondent units are members of the Association of pharmaceutical companies.

The Association of pharmaceutical companies will meet periodically to discuss the not issues relating to the pharmaceutical industries and take decisions or steps to tackle the situation. The experts of the related fields may give their advices or suggestions to the members, attending the meeting. The queries or doubts will also re raised and the members may find the solution or the means to the solutions for their problems.

TABLE- 4.5

MEETING ON IMPACT OF WTO ACCORD

S.No	Attendance	No.of units
1.	Attended	5
2.	Not Attended	45
	Total	**50**

Above table 4.5 shows that only 5 companies had attended the meeting of the pharmaceutical companies Association on the impact of WTO and the remaining 45 units were not even attended the meeting. Organized by the Association of pharmaceutical companies.

Due to the absence of product patents in pharmaceutical industry in India, some companies may copy other companies products (ie) its composition (or) formula, and sell it in its own brand name. Thus, a drug with same composition or same formula may be sold at different rates at different places. And the consumers may get confused over the various brands of the some drug.

TABLE- 4.6

RESULT OF ABSENCE OF PRODUCT PATENT IN PHARMACETICUAL INDUSTRY

S.No	Result	No.of units
1.	Piracy lucrative	30
2.	Piracy not lucrative	20
	Total	**50**

Above table 4.6 shows that 30 out of 50 respondents unit have reported that copying or piracy are extremely lucrative of profitable due to the absence of product patent in pharmaceutical industry and the 20 units have responded that they are not as much lucrative or profitable in India.

Introduction of new products or improvements or innovations in the existing products will be made by the company through its Research & Development (R&D). So, it is an important department for the company to meet the competition in this modern and fast world, by its invention and innovations. The innovations in the existing products may be made in its composition (ie) its ingredients or in its formula or in its size or in its packing etc

TABLE- 4.7

RAISING THE INVESTMENTS IN R&D DUE TO THE INTRODUCTION OF PRODUCT PATENT

S.No	CAUSE	No.of units
1.	Introduction of products patents	30
2.	No product patent	-
3.	No idea	20
	Total	**50**

From the above table 4.7 it is clear that 30 out of 50 respondent units will raise its investment in research and development due to introduction of product patent 20 units have respondent that they have no idea about the investment in research and development.

The pharmaceutical companies are producing its products either from its own discovery or copying from other companies. The companies may choose the method of own discovery or copying of comparing the profitability of both the methods. While compounding the profitability of either methods, the cost factors and the non-cost factors should be considered.

TABLE- 4.8

Profitability from original discovery than copying

S.No	Profitability	No.of units
1.	Higher	40
2.	Not- Higher	-
3.	No idea	10
	Total	**50**

It is clear from the above table 4.8 that 40 units are earning more profit from their original own discovery than from copying from other companies and 10 units reported that have no idea about the profitability from original discovery or copying.

Introduction of product patent in India will be beneficial to various section of the society like the pharmaceutical industry, patent and the country as the whole. In the products patent regime as the copying of products are restricted, the companies of original discovery will be benefited much, the patent will be relieved from the confusion of various brand of drugs existing and as a result, its country as a whole, will be developed.

TABLE- 4.9

BENEFICIARIES FROM PRODUCT PATENT REGIME

S.No	Beneficiaries	No.of units
1.	Industry	20
2.	Patent	-
3.	Country	10
4.	No idea	20
	Total	**50**

Above table 4.9 shows that 20 units have responded that industry will be benefited from the product patents, 10 units responded that the country will be benefited and the 20 units responded that they have no idea.

The success of the pharmaceutical companies are clutched by different factors such as product quality, investment in research, exports, up-graduation etc. So, a company should give equal importance to all these factors while taking vital business decisions and also take necessary steps for its improvement like quality of products, more exports, up-gradation, etc.

TABLE- 4.10

FACTORS AFFECTING THE COMPANIES IN PRODUCT PATENT

S.No	Factors	No.of units
1.	Poor quality	-
2.	No investment in research	-
3.	No Exports	-
4.	No desire to upgrade	-
5.	All the above	30
6.	No idea	20
	Total	**50**

It is clear from the above table 4.10 that 30 out of 50 respondent units reported all factors such as poor quality, no investment in research and no exports & up-gradation, will affect the pharmaceutical companies in product patent regime and the remaining 20 units reported that they have no idea.

Due to the introduction of product patent in India, the copying of other companies' product will be decreased and the prices of own discovered products may go up. Treatment may become unaffordable for AIDS, heart & diabetic patients and those affected with mental ailment belonging to the low income and even middle income group as new drug inventions would get product patent and the patent holders would charge royalty to recover the research and development costs.

TABLE- 4.11

HIKE IN PRICES OF DRUGS IN THE PRODUCT PATENT REGIME

S.No	Effect	No.of units
1.	Hike in price	30
2.	No hike in price	20
	Total	**50**

It is known from the above table 4.11 that 30 companies replied that there will be hike in the price of drugs in the product patent regime and 20 companies replied that there will be no hike in the price of drugs.

Small pharmaceutical companies are the ones creating the bogey of prices where it is obvious that patent will affect only the new products, but not the existing products. And they would be the loser with no investment in research, poor quality, no exports and no desire to globalise and upgrade. And most of them were not even formed the department of Research & Technology. Since many small pharmaceutical companies are copying from others, they would be the losers.

TABLE- 4.12

CAPABILITY OF SMALL PHARMACEUTICAL COMPANIES TO FACE CHARLLENGES

S.No	Capability	No.of units
1.	Yes	15
2.	No	35
	Total	**50**

From the above table 4.12 it is clear that 15 units responded that small pharmaceutical companies can face the challenges of product patent and 35 units responded that they don't have the ability to face the challenges of product patents.

Foreign companies are much interested in coming to India and to work here in order to earn more profit because of various factors viz. cheap & intelligent labours in India, huge investment of capital, highly technological based and finally may be product patents in India. The Indian Government also inviting the foreign companies to start their companies here by minimizing the much legal formalities in order to earn more foreign exchange.

TABLE- 4.13

INTEREST OF FOREIGN COMPANIES IN COMING TO AND WORKING IN INDIA

S.No	Position of foreign companies	No.of units
1.	Interested	45
2.	Not interested	-
3.	No idea	5
	Total	**50**

Above table 4.13 shows that majority of respondent units (ie) 45 out of 50 units felt that the foreign companies are interested to come and work in India and 5 units responded that they have no idea.

The term ‘ polymorphism’ means the same compound that has different structures. Some there apeutically active ingredients present polymorphic forms, that is, they may crystallize in diverse forms, which may have different properties that are more or less significant in terms of their therapeutic use. Some companies have sought to use patentability of polymorphs as a means to extend the monopoly protection of a known active ingredient.

TABLE- 4.14

PATENTABILITY OF POLYMORPHISM

S.No	**Patentability**	**No.of units**
1.	Patentable	30
2.	Not patentable	-
3.	No idea	20
	Total	**50**

From the above table 4.14, it is known that 30 respondent units reported that polymorphism is patentable and the remaining 20 respondent units reported that they have no idea about polymorphism.

The term 'Optical Isomers' means the compounds that have the same chemical formula, but are structurally different in three dimensional forms. Optical Isomers are 'Stereo Isomers' where the molecules are mirror images of each other. The two mirror images are known as 'Enantiomers'. Isomers are molecules that have the same molecular formula, but have a different arrangement of the atoms.

TABLE- 4.15

PATENTABILITY OF OPTICAL ISMOERS

S.No	Patentability	No.of units
1.	patentability	30
2.	Not patentable	-
3.	No idea	20
	Total	**50**

It is clear from the above table 4.15 that 30 out of 50 respondent units replied that the optical isomers are patentable and the 20 respondent units replied that they have no idea about the optical isomers.

Some countries have permitted patenting of non-novel process (Sometimes called analogy processes') if the resulting chemical is novel and displays unexpected properties. The united states has held " analogy process" claims to be non-patentable unless they are invention in themselves, but has carved out an exception for biotechnology. The products and processes of biotechnology have posed hard problems for applying the inventive step standard. Since much biotechnology "inventions" repeat previously invented processes in slightly different contexts.

TABLE- 4.16

PATENTABILITY OF ANALOGY PROCESSES

S.No	Patentability	No.of units
1.	Patentable	25
2.	Not patentable	-
3.	No idea	25
	Total	**50**

Above table 4.16 shows that half of the respondent units (ie) 25 units responded that analogy processes are patentable and the remaining half of the respondent units responded that they have no idea about the analogy processes.

The term of every patent granted under Patents Act, 1970 Shall, in respect of process of manufacturing of food or medicine or drug, be five years from the date of sealing of patent or 7 years from the date of patent, whichever is shorter and in other cases it is fourteen years. And the patent granted may be extended or renewed on payment of renewal fees and in case of failure to make such payment, six months extension will be given, to pay the renewal fees.

TABLE- 4.17

MEANING OF PATENT EXTENSION TECHNIQUE

S.No	Meaning	No.of units
1.	Renewal of patent rights	5
2.	Visiting of patent rights with an inventor for some period	5
3.	No idea	40
	Total	**50**

From the above table 4.17, it is known that 5 units replied that the meaning of patent extension technique is the renewal of patent rights, 5 units replied that it is vesting of patent rights with a company for a particular period and the remaining 40 units replied that they have no idea.

Additives are substances that become part of a food product when added during the processing or production of that food. The 5 functions of additives are,

♦Maintain product consistency.
♦Improve or Preserve the nutrient value.
♦Maintain the wholesomeness & palatability of foods.
♦Control the acidity.
♦Provide color & enhance flavour.

TABLE- 4.18

PATENTABILITY OF COMPOSITION INCLUDING ADDITIVES

S.No	Patentability	No.of units
1.	Patentable	20
2.	Not Patentable	10
3.	No idea	20
	Total	**50**

It is known from the above table 4.18 that 20 units reported that the composition including the additives are patentable, 10 companies reported that they are not patentable and the 20 units reported that they have no idea.

Physicians define pro-drugs as “Active drugs when misused, it becomes pro-drugs”. When metabolized in the body, inactive compounds can produce a therapeutically active ingredient, called “pro-drug”. Countries must determine whether the patent on the compound covers the pro-drug, and the extent to which claims relating to certain compounds should also be allowed to include their pro-drugs.

TABLE- 4.19

PATENTABILITY OF PRO-DRUGS

S.No	Patentability	No.of units
1.	Patentable	10
2.	Not Patentable	-
3.	No idea	40
	Total	**50**

It is clear from the above table 4.19 that the 10 out 50 respondent units replied that the pro-drugs are patentable and the remaining 40 companies replied that they have no idea about the pro-drugs.

Prior – heart drugs are used for more than 30 years for the treatment of heart ailments such as high blood pressure, chest pain, heart attack and heart beat irregularities. It is reduce the stress on the heart patients and gives protection to brain and its functions, during surgery. These drugs are advised for the patients of by pass heart surgery.

TABLE – 4.20

PATENTABILITY OF PRIOR – HEART DRUGS

S.No	Patentability	No.of units
1.	Patentable	45
2.	Not Patentable	-
3.	No idea	5
	Total	**50**

Above table 4.20 indicates that the majority of the respondent companies (ie) 45 companies felt that the prior-heart drugs are patentable and 5 units replied that they have no idea.

The competition between the companies in the pharmaceutical industry is pushed by various factors, especially affordable price and better quality of the products. A company can win the hearts of the consumers by quoting the lower price for the medicines or drugs are inseparable. Today, every consumer is very vigilant about and also highly expecting the quality of products, especially medicines or drugs, as they are their life savers.

TABLE – 4.21

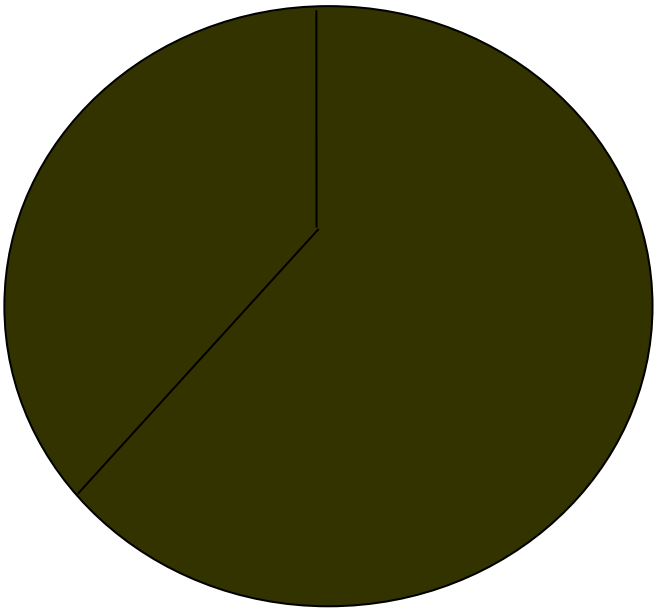
MAIN DRIVER OF COMPETITION

S.No	Factors	No.of units
1.	Price	20
2.	Quality	30
3.	No idea	0
	Total	**50**

From the above table 4.21 it is clear that 30 units responded that the quality will be the main driver of competition in the pharmaceutical industry and the 20 units responded that the price will be the main driver of competition.

DIAGRAM – 4.4

MAIN DRIVER OF COMPETITION



The large pharmaceutical companies like Ranbaxy, Dr.Reddy's Lab, etc,are now in favour of product patent, as they are making large investment in Research & Development (R&D) and producing drugs through their own original discovery. They will be the main competitors for the foreign companies or Multi National companies (MNCs) having business in India, as formers are equally strong in technology and in huge capital investment.

TABLE – 4.22

POSITION OF LARGE PHARMACEUTICAL COMPANIES

S.No	Position	No.of units
1.	Preparing for 2005	30
2.	Not preparing for 2005	20
	Total	**50**

It is obvious from the above table 4.22 that the large pharmaceutical companies are preparing for 2005, as reported by 30 companies and not preparing for 2005, as reported by 20 companies.

Though the patents Act, 1970 is existing already, the Government has kept the pharmaceutical companies out of the ambit of the product patents, since 1970. And took no steps to introduce product patent for pharmaceutical products till now, while the product patents are existing in other developed countries.

TABLE – 4.23

STEPS TAKEN BY GOVERNMENT FOR PRODUCT PATENT

S.No	Steps by Government	No.of units
1.	Deliberate	40
2.	Quick	-
3.	No idea	10
	Total	**50**

The above table 4.23 clarified that the majority of respondent units (i.e) 40 units felt that the Government has acted deliberately as regards product patents for pharmaceutical products and 10 units responded that they have no idea.

There is an alarm that the Indian pharmaceutical companies may lose the market, since all the developing nations are switching to product patent regime by 2005 and many of the Indian companies have been exporting bulk drugs. No need for any Indian pharmaceutical company to worry, who are producing best quality drugs at reasonable price from their own discovery, about the product patents.

TABLE – 4.24

MARKET TREND OF INDIAN PRODUCTS BY 2005

S.No	Market Trend	No.of units
1.	Lose the market	25
2.	Don't lose the market	25
	Total	**50**

From the above table 4.24, it is known that half of the respondent units (ie)25 units voted that Indian companies would lose the market and the remaining half (ie) 25 units voted that the Indian pharmaceutical companies would not lose the market.

A generic drug is identical or bio- equivalent to a brand name drug in dosage form, safety and strength, route of administration, quality performance, characteristics &intended use. Although generic drug are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.

TABLE – 4.25

PRICE OF GERERICS IN PRODUCT PATENT REGIME

S.No	Price position	No.of units
1.	Downward position	15
2.	Upward position	10
3.	No idea	25
	Total	**50**

Above table 4.25 indicates that 15 companies replied that the prices of Generics will go in a download trend, 10 companies replied that it will go in an upward trend and 25 companies replied that they have no idea.

Reverse engineering as the process of taking something (a device, an electrical component, etc) apart analyzing its workings in detail, usually with the intention to construct a new device or program that does the same thing without actually copying anything from original. Reverse engineering is commonly done to avoid copying from desired functionality, though this is a bit risky. Patents apply to the functionality not a specific implementation of it.

TABLE – 4.26

EFFECT OF RESTRICTIONS ON REVERSE ENGINEERED PATENTED PRODUCTS

S.No	Level of production	No.of units
1.	Top line	-
2.	Bottom line	-
3.	Both	35
4.	No idea	15
	Total	**50**

Above table 4.26 shows that 35 units reported that the restrictions on Reserve Engineered patented products will impact both the top line and bottom line of the levels of production and 15 units reported that they have no idea.

The experts felt that the number of pharmaceutical companies in India will come down drastically from over 20,000 today, as in the case of china, where the pharmaceutical companies have come down from over 6000 to just about 600 today. The reason may be the inability of small pharmaceutical companies to cope-up with the rules & regulations of product patent regime, the companies manufacturing drugs by copying from others, etc.

TABLE – 4.27

TOTAL NUMBER OF INDIAN COMPANIES IN PRODUCT PATENT REGIME

S.No	No.of companies	No.of units
1.	Increase	20
2.	Decrease	30
	Total	50

From the above table 4.27 it is known that 20 out of 50 respondent units responded that the number of companies will increase in the product patent regime and 30 units responded that the number of companies will decrease in the product patent regime.

The intellectual property Rights Department is created to look after the activities of industrial and commercial interests such as inventions, creations, new products, processes of manufacture, new design or model and a distinctive mark for goods, etc. so, it is considered as an important thing to set up the intellectual property right department by the companies, who are manufacturing drugs by their own original discovery.

TABLE – 4.28

CREATION OF INTELLECTUAL PROPERTY RIGHTS DEPARTMENT IN PHARMACEUTICAL COMPANIES

S.No	Creation of Department	No.of units
1.	Created	-
2.	Not created	50
3.	No idea	-
	Total	50

It is clear from the above table 4.28 that all the 50 respondent units have not yet created “intellectual property Rights Department” in their organizations, for 2005.

The Government of India inserted new chapter IV A in the patents Act, 1970, by the patents (Amendment) act, 1999, on Exclusive Marketing Rights (EMR) which means an approval to drug markers to sell the drug exclusively while the patent application is still pending.

TABLE – 4.29

ASSURANCE OF EXCLUSIVE MARKETING RIGHTS

S.No	Assurance	No.of units
1.	No.of copies of products	20
2.	Copies of products	5
3.	No idea	25
	Total	**50**

It is known from the above table 4.29 that 20 units replied that the EMR would assure the innovator company, a market free of copies of its products, 5 units replied that there may be copies of its products and 25 units replied that they have no idea.

The process of granting patent is expected to be transparent to the applicant, in order to ensure that the procedures and rules& regulations are lawful. The transparency in granting the period patent will make it a clean & legal process.

TABLE – 4.30

PRODUCT PATENT GRANT PROCESS

S.No	Grant process	No.of units
1.	Transparent	-
2.	Not transparent	30
3.	No idea	20
	Total	**50**

From the above table 4.30 it is obvious that 30 respondent units reported that the process of granting product patent will not be a transparent one, 20 units reported that they have no idea and to be noted that, no company responded that it will be a transparent process.

Since there arose a necessity of making a temporary law to enable the controller of patents to receive application for product patent in medicines and to grant Exclusive Marketing Rights, the redressal mechanism for the EMR holder will be an elaborate process. So, this elaborate process may discourage the Exclusive Marketing Rights holders to apply for redressal with the controller of patents.

TABLE – 4.31

REDRESSAL MECHANISM FOR EMR HOLDER

S.No	Redressal Mechanism	No.of units
1.	Elaborate process	30
2.	Reasonable process	15
3.	No idea	5
	Total	**50**

Above table 4.31 shows that 30 out of 50 respondent units responded that the redressal mechanism for the EMR holder will be elaborated, 15 units responded that it will be a reasonable one and 5 other units responded that they have no idea.

The two Government bodies, Drugs Controller General of India (DCGI) and the patent office should maintain a balanced network and there should be proper communication of vital information between these Government bodies, in grant of product patents and also in grant and also of Exclusive Marketing Rights.

TABLE – 4.32

NETWORK BETWEEN DCGI AND PATENT OFFICE

S.No	Network	No.of units
1.	Balanced network	10
2.	Imbalanced network	30
3.	No idea	10
	Total	**50**

From the above table 4.32 it is clear that 10 companies reported that the network between DCGI and the patent office will be balanced one, 30 units reported that it will be an imbalanced one and 10 companies reported that they have no idea about their network.

The Government of India has its role in grant of EMR, by verifying the composition of drugs, which will not be harmful to those who are going to use it, its price and if the prices of drugs are unaffordable, by notifying the reasonable prices for drugs covered by Exclusive marketing rights, and the Government may ask for any alteration or modification of the composition of drugs in public interest, etc

TABLE – 4.33

ROLE OF GOVERNMENT IN GRANT OF EMR

S.No	Role of Government	No.of units
1.	Have role in EMR	15
2.	No role in EMR	25
3.	No idea	10
	Total	**50**

It is known from the above table 4.33 that 15 units replied that the Government may have the role in the grant of Exclusive Marketing Rights and 25 units replied that the Government shall have no role in the grant of Exclusive Marketing Rights and 10 units replied that they have no idea.

The domestic pharmaceutical companies that take the aggressive patent challenge route into the US market will be forced to rethink the strategies, following the recent high profit set back to Dr.Reddy's Lab (DRL) with pfizer.

TABLE – 4.34

STRATEGY FOR ENTERING US MARKET

S.No	Strategy	No.of units
1.	Change needed	25
2.	Change not needed	10
3.	No idea	15
	Total	50

Above table 4.34 shows that 25 units reported that there is a need for changes in the strategy for entering US market, 10 units reported that no change is needed in the strategy to enter US market and 15 units reported that they have no idea.

The impact of patenting the pharmaceutical products in India may be the monopoly of products or increase in the prices of pharmaceutical products etc.

TABLE – 4.35

IMPACT OF NEW PRODUCT PATENT REGIME

S.No	Impact	No.of units
1.	Monopoly	20
2.	Increase in prices	15
3.	To wait & see	15
	Total	**50**

The above table 4.35 clarified that 20 units responded that there will be monopoly of products in the product patent regime, 15 units responded that there will be increase in the products prices and 15 units are in the position to wait and see the impact of product patent regime.

The experts said that only less than 5% of drugs available in the Indian market are copies of the patented products and hence the Indian pharmaceutical companies need not agonize over the product patents. Most of the drugs in the Indian market are manufactured through original own discovery or through reverse engineered process.

TABLE – 4.36

ONLY FEW INDIAN DRUGS ARE COPIES OF PATENTED PRODUCTS

S.No	Result	No.of units
1.	Yes	25
2.	No	15
3.	No idea	10
	Total	**50**

From the above table 4.36 it is clear that 25 units responded that only very few Indian Drugs are copies of patented products, 15 units responded that there may be many drugs which are copies of patented products and 10 units responded that they have no idea.

The large pharmaceutical companies in India are earning more only through the export of medicine & Drugs to other countries which will also earn foreign exchange to our country. If an Indian pharmaceutical company has not undertaken the exercise of patenting its product or some other change in its strategy, it could be barred entry into US market.

TABLE – 4.37

NO PRODUCT PATENT- NO US MARKET

S.No	Result	No.of units
1.	Yes	20
2.	No	20
3.	No idea	10
	Total	**50**

Above table 4.37 shows that 20 units reported that if there is no product patent, the products could be barred to enter US market, 20 units reported that there is no such position like the above and 10 units reported that they have no idea.

As the large pharmaceutical companies in India are manufacturing the medicines and drugs from their own original discovery and some other companies are manufacturing the drugs through Reverse Engineered process, there is no need to stop their investment in Research and Development, till 2005. it is only the small pharmaceutical companies, who are producing drugs by copying from patented products, should think about the product patent.

TABLE – 4.38

INVESTMENT I N RESEARCH & DEVELOPMENT

S.No	Investment in R&D	No.of units
1.	Stopped	15
2.	Not stopped	35
	Total	**50**

From the above table 4.38, it is clear that 15 units responded that the pharmaceutical companies stopped the investment in R& D till 2005 and 35 units responded that they have not stopped the investment in R & D.

With the introduction of product patents in India, the prices of the Indian pharmaceutical products may go up due to the huge investment in research and development by the manufacturing companies and the people will be unable to purchase certain drugs (atleast new drugs)

TABLE – 4.39

ECONOMICS AFFORDABILITY OF PEOPLE

S.No	Affordability	No.of units
1.	Affordable	5
2.	Not affordable	30
3.	No idea	15
	Total	**50**

From the above table 4.39 it is known that 5 units replied that the prices of drugs under products patent regime, will be affordable to the people to buy it, 30 units that they will not be affordable and 15 units reported that they have no idea.

CHAPTER –V

SUMMARY OF FINDINGS, SUGGESTIONS AND CONCLUSION

CHAPTER –V
SUMMARY OF FINDINGS, SUGGESTIONS AND CONCLUSION

5.1 Introduction

TRIPS agreement is regarded by developing countries as having been forced upon them by the united states. This is not entirely a fair claim in the case of India, where the government and some of the successful generic drug companies recognized in the early 1990s that an eventual transition to a regime allowing pharmaceutical patent might be in the nation's long-term interest.

The TRIPS agreement, informed by both the classical arguments for patent and the developing country – argument, made a distinction among three classes of nation. Developed countries were required to bring patent regimes into immediate compliance with the agreement.

Developing countries, India and Brazil among them were given ten years, and the least developed countries, mostly those in Africa and the Middle East, were given more time. This differentiated timetable makes sense for both developing and the least developed countries, and, specifically, for India.

Three factors may be suggested (1) india's growing size in relation to markets (2) its increased capacity to innovate, and (3) the flexibility inherent in the TRIPS agreement that will allow India to avoid most of the adverse consequences envisioned by the opponents of reform. Let us discuss earch of these factor's in turn

First, india's rapid growth rate and its large and rapidly expanding middle class is likely to create a preference among some consumers for branded as opposed to generic that simply wasn't present in 1970.

Moreover, as the Indian market grows, the previously negligible effect of an Indian patent system on the incentives of foreign innovators becomes measurable. This incentive effect could be especially important in including foreign investment on drugs aimed at treating previously neglected diseases prevalent in India and similarly situated developing countries.

Second, even more significant than India's growing market is its increased capacity for indigenous innovation. India's largest pharmaceutical firms and some of its research institutes now have the scale, the trained personnel, and technical capacity to develop new drugs, either alone or in partnership with foreign firms.

New opportunities

The availability of domestic patents, combined with low cost of performing research and development in India, could help to make india's largest pharmaceutical companies very successfully globally.

Moreover, a number of government Institute and private enterprises have developed the capacity to do large scale, highly cost-effective clinical trials. With product patent in place, India is likely become a major centre for "outsourced" clinical trials undertaken by the US and European pharmaceutical giants.

Without domestic, patent protection, neither india's potential for indigenous discovery nor its potential to become a leaning centre for clinical trials will be fully realized.

Third, some of the adverse impacts feared by opponents of reforms are likely to be less severe than imagined, and other can be mitigated and other can be mitigated by effective use of the flexibility permitted under the recent Doha declaration.

The notion that drug prices and the overall cost of health care will skyrocket as a consequence of the government ordinance is exaggerated, because 90 per cent of the drugs

currently classified by India as essential medicines are either unpatented or the patent has expired.

The prices of drugs patented before 1995 (including some of the most important anti retroviral treatments for HIVIAIDS) will not be affected, because these drugs will not be eligible for Indian patents and generic substitutes produced domestically are likely to continue to dominate the market.

It is true that those domestic producers that have been successful in copying foreign drugs without developing a capability for independent research are likely to be hurt, but the largest firms are likely to benefit from the opportunity that domestic patent protection will provide.

Finally, there is little substance to the concern that india's conformity with TRIPS will seriously hamper the battle against the HIV/ AIDS pandemic in Africa and parts of Asia. Under the exception recently created during the Doha round, countries are free to impose compulsory licenses to deal with public Health emergencies and to export such drugs to countries lacking manufacturing facilities

5.2 Objectives

The study is proposed to be carried out to accomplish the following objectives:

a. To ascertain why has India followed TRIPS to grant 20 year monopolies to foreigners through patents?
b. To study how far the poor nations with ailing needs will be empowered to break corporate monopolies at will to meet their needs.
c. To investigate the concern of developing countries that the strengthening of JPR could cause problems for the affordability of medicines, particularly for the poor.
d. To suggest how the law should aim at striking a balance between a reward to the holder of trade secrets in the form of monopoly sufficient to encourage R & D to produce new inventions and to encourage disclosure of those inventions to the public to increase the stock of knowledge and on the other hand, not unduly fettering the liberty of members of the public or hindering competition.
e. To examine how for the Doha Meet's requirements such as Compulsory licensing provisions, fixed royalties of around 4% and better public interest provisions enabling a modified licence of right as scheduled by the Govt. for health, food and energy and research are implemented in India.
f. To analyse the impact that the TRIPS agreement will cause on the Indian companies in respect of patent matters.

5.3 **summary of findings**

The advent of WTO era coupled with the effectuating of the TRIPS agreements has indeed ushered in essence new horizons for the pharmaceutical industry in India and as an inevitable outcome, every player in the Industry ought to be geared up to face new endeavours in an arena of heightened regulation and competition. The management of change under the new product patent regime is a reality that the Indian pharmaceutical industry ought to accept rather innocuously and nonchalantly. The management of change, especially when it is viewed within an increasingly regulated product patent regime, would inevitably throw up a lot of foreboding and even whilst these prospects have to be effectually handled, one ought to necessarily contemplate on the inherent aspects of the new product patent regime and thereafter devise perspicacious strategy for effectuating a comprehensive plan of action to face the new realities.

Jurisprudence, vis a vis, product patents, has been constantly evolving and the process has involved much ingenuity in developing the state of law as it is today from the state of flux in which it was not too long ago – the necessary outcome of much jurisprudential deliberation both by the legislatures and the courts have worked in cohesiveness to bring about the present stage .. wherein a platform has been created .. that could eventually provide

for a level playing field. The developing world should comprehend that plagiarizing pharmaceutical formulae tantamounts to grand larceny under criminal law and as an inevitable outcome, a suit for un - liquidated damages can be maintained in action under the law of torts coupled with an inevitable contractual suits that might also be plausible. In the United States there have been cases wherein pharmaceutical companies that have allowed their R & D division to indulge in formulae plagiarizing have inevitably come a cropper and the common law courts have come down very heavily in terms of awarding ' just compensation' and in some cases the companies had to be wound up as a result of suits in terms of the plagiarizing and the inevitable class action suits of the stakeholders. It could even end up as a 'winding up petition' under federal laws of the United States . In the Indian scheme of things, at the present time, there are just a hand few of companies that are aware of the consequences of the product patent regime, and as a sad commentary of the prevailing state of affairs, many Indian pharmaceutical companies are entirely unfamiliar with much of the legality involving patents. As a cardinal and primordial first step the Ministries responsible should first and foremost conduct relevant training for the Industry as a preventive first step towards familiarising the average industry player. The fact of the matter is that in the WTO era that has been ushered in post the TRIPS agreements is essentially an era that would encapsulate free mobility of information and the norms that have standardised have necessary to be complied with in no uncertain terms. The issues pertain to compliance of regulations in terms of

safeguarding patents across the globe, and Indian pharmaceutical companies have to effectuate a compliance regime wherein the norms are complied with in certitude, and more importantly, the court system should be thoroughly aggrandised to handle eventualities in the matter. Compliance regulations are of crucial importance and as the WIPO increasingly monitors compliance issues, it is reckoned that pertinent issues are to be articulated in cogent terms in order to bring forth much alacrity with respect to compliance issues. Issues such as Evergreening involving the patent term extension strategies and the sheer Implications of Compulsory Licensing provisions are to be cogently studied in detail:

Product Patent Regime & Pharmaceutical Product patent regime and the Industry In India

The Prologue With the nearing of the TRIPS deadline, the pharmaceutical industry in India is gearing up to face new challenges. The product patent regime is no longer the challenge - it is a reality that the Indian pharma industry has accepted.

The new set of challenges stem from the deeper implications of the imminent product patent regime. With the exception of a few, most Indian pharma companies are unfamiliar with the nuances of complex patent prosecution strategies. The research-based pharmaceutical companies, on the other hand, have first hand knowledge of successfully designing and implementing, sophisticated patent prosecution strategies. Therefore, the first hurdle for the Indian pharma

industry is unevenness in the domain knowledge on patents. One of the ways to overcome this is to learn the use of patents as a business tool. The unrealistic defence against the global norms on patents is perhaps the most critical post-TRIPS challenge faced by the Indian pharmaceutical industry.

This section attempts to analyze the implications of the TRIPS compliant patent regime. The key issues takenup in this section are:

a) The scope and extent of patentability of pharmaceutical products;
b) Evergreening – the patent term extension strategies; and
c) Implications of Compulsory Licensing provisions.

Scope and Extent of Patentability - Pharmaceutical products

Article 27 of the TRIPS Agreement harmonizes the subject matter of patent in a broad manner. However, the exclusions permitted under the TRIPS Agreement have created wide variance in the Indian Patent Act, 1970 ('the Act'). Complying verbatim with Article 27, Section 2(1)(j) of the Act provides that 'invention means a new product or process involving inventive step and capable of industrial application'. Section 3 of the Act explicitly excludes certain categories of inventions from the scope of patentability. Critical categories include-plants, animals, parts of plants and/or animals, seeds, essentially biological processes,

mathematical or business methods, computer program per se, inventions based on traditional knowledge, methods of treatment, diagnostic, therapeutic, and surgical methods. Section 2(1)(j) and Section 3 are inextricably linked with each other; any addition in the latter would result in the constriction of the former.

While Section 3 per se poses a direct conflict with the general mandate of Article 27 of the TRIPS Agreement, some of these restrictions can in fact stay on, provided they come under the general exceptions under the TRIPS, as provided in Art. 27 (2) and (3). One needs to closely watch the dialectics of Section 2(1) (j) and Section (3) of the Act in view of the substantive provisions contained in Art. 27(1) and the exceptions to patentability provided under Article 27(2) and (3) of the TRIPS Agreement.

Patentability of Pharmaceutical & Related Inventions

A general reading of Section 2(1) (j) (which defines patentable inventions) with Section 3 of the Act (that provides the list of subject matters excluded from patentability) do not clearly indicate if it is possible to interpret these provisions to exclude certain aspects of pharmaceutical inventions from the scope of patentable subject matters. A section of the Indian pharma industry even today argues that a distinction has to be drawn between primary and secondary patents in the field of pharmaceutical inventions. According to them, primary patents are the ones directed at new molecules and

secondary patents cover new combinations, optical isomers, active metabolites, polymorphs, 'prodrugs', new uses and so on. The question here is whether it is permissible under the TRIPS to draw such a distinction.

The Government of India seems to be adopting a balanced approach in addressing this issue. In the proposed Patent (Amendment) Bill, 2003, it is proposed to substitute the words "new use of known substance" with the words "mere new use of a known substance" in Section 3(d) of the Act. The interpretative scope of this is yet to be seen. It could eventually lead to the acceptability of 'Swiss-type' new use claims.

Findings of the study :

Understanding how things work, in terms of patents, and comprehending the opportunity it would provide Indian entities is the quintessential first steps towards any meaningful articulation of patents with respect to the Indian Pharmaceutical Industry. Whilst one ought to readily envisage a harmonious construction in terms of interpretation of the TRIPS agreement whence it is read with the Indian Patents Act of 1970, it must necessarily as a corollary denote effectuating patent issues in a perspicacious manner in accordance with pragmatic approaches. As an elucidative reference, albeit in hypothetical terms, if one were to study the concomitant issues pertinent to Article 27 of the TRIPS agreements, and then if we were to juxtapose it with specific sections of the Indian Patents Act of 1970, one could readily decipher that

whence construction of the relevant statues are done in a harmonious way, the effectuation, albeit subliminal, necessitates pragmatic solutions. Nevertheless, the TRIPS agreements, as a stand alone international agreement has inevitably provided for much interpretation and as a direct spin off much contumaciousness has inevitably followed in the developing world. Prudent research provides for handling he issues in a holistic manner for implementing agreements must go hand in hand ... harmoniously with the average citizens' compulsions to comply with regulations in place. Much of the calumny of the recent past has been largely the result of un - researched verbose, and the need of the hour is clearly in the recognition of need to conduct awareness campaigns throughout much of the developing world, even whilst anti – trust laws have to be innately be made efficacious. Countries like India should recognise the need to develop on patents indigenously and locally in order to benefit from inherent human capital advantages and as a rather innocuous commentary of the recent past we are yet to formulate a cogent policy for taking advantage of the new patent product regime as there are many opportunities or India primarily in research and in outsourcing possibilities. The Act defines invention as denoting an invention of a new product or process that integrally is also capable of innate industrial application'. Section 3 of the Act explicitly excludes certain categories of inventions from the scope of patentability and these represent such critical areas like that of plants, animals, parts of plants and/or animals, seeds, essentially biological processes, mathematical or business methods, computer program per

se, inventions based on traditional knowledge, methods of treatment, diagnostic, therapeutic, and surgical methods. Quintessentially, Section 2(1)(j) and Section 3 are inextricably linked with each other

And whilst Section 3 per se poses a direct conflict with the general mandate of Article 27 of the TRIPS Agreement, some of these restrictions can in fact stay on, provided they come under the general exceptions under the TRIPS, as provided in Art. 27 (2) and (3). Therefore the elemental issue lies in one requiring to decipher the language of Section 2(1) (j) and Section (3) of the Act in view of the substantive provisions contained in Art. 27(1) and the exceptions to patentability provided under Article 27(2) and (3) of the TRIPS Agreement.

The absolute basis of patents law rests in the fact that patents are granted only for an invention that ought to be new and useful. In the case of pharmaceutical products it is simply no different and the reward for the inventor is monopoly over the life of the patent which is 14 years in the case of product patent and 7 ears in the case of process patents - however we are placed with an obligation of recognising patent protection for a time horizon of 20 years under the provisions of the TRIPS agreement. The special protection provided for the pharmaceutical industry and earmarking them exclusively for process patents is really a departure from English law , and as a matter of fact, the US Drug Corporations have for long been completely agitated over the rather slack patent protection in India – this is especially true because ‘process patents' meant and

encouraged 'reverse engineering' ... and this could mean manufacturing the same product under a different process. It is respectfully submitted that the relentless pressure from the US authorities has brought forth amendments in our patent laws in 1999 and 2002 in order to provide for product patents in the pharmaceutical industry and to usher in exclusive marketing rights for five years from 1999.

Pharmaceutical Industry In India – myriad issues.

The elemental definition of a patentable invention ought to readily provide an acceptable criteria that is intelligible and as a necessary corollary it ought to provide a cogent list that denotes patentable inventions and the core criteria in the determination ought to be centre around the novelty, utility and implementation criteria – the very blithe spirit of scientific ingenuity should in a sacrosanct way encapsulate the inherent ingenuity of the patentable invention. An antithetical stance by boorish western pharmaceutical companies has always to be anticipated as essentially the patents are granted for the scientific processes/ molecular dispensations inculcated in a process and the logical methodology ingrained as an inherent part of the process would necessarily entail the ingenuity much sought after – take the neem case for example, where the WIPO norms had to be read in to effectuate geographical indicators as an intrinsic issue. The postulates that go in to the making of the processes are of primordial significance and the aspects of scientific reasoning that perpetuate these pharmaceutical inventions have to be fostered with much alacrity as essentially these revolve around pristine thought

processes that enunciate these pragmatic processes. Ingenuity, is the name of the game, and formulations are necessarily a natural consequence of ingenuity – our research reckons that a general reading of Section 2(1) (j) (which defines patentable inventions) with Section 3 of the Act (that provides the list of subject matters excluded from patentability) do not clearly indicate if it is possible to interpret these provisions to exclude certain aspects of pharmaceutical inventions from the scope of patentable subject matters. Of core and critical importance to the Indian Pharmaceutical Industry is the major perceptive issue revolving a segmented approach towards primary and secondary inventions and the inevitable categorisation eventually denotes that primary patents are the ones directed at new molecules and secondary patents are essentially the ones that cover new combinations, optical isomers, active metabolites, polymorphs, … et al ; The 64 $ question here is whether it is permissible under the TRIPS to draw such a distinction.

The Government of India has indeed promulgated an ordinance pertinent to the patents (third) amendment. ….. and as a matter of fact, it is only a culmination that was started on ten years ago. It is completely necessary to read into the ordinance along with the two amendments of 1999 and 2002 as India's patent Act always provided for process patent in all fields and product patents in most fields albeit excluding Pharmaceuticals. Therefore the act had to be amended to provide for product patent in Pharmaceuticals from 01.01.2005. In certitude, it fulfilled the legal

obligations within time and as an inevitable outcome brought forth an equitable regime, vis a vis, Intellectual property norms juxtaposing public health as well – this is bound to help India unlock vast export markets even whilst it clinical research outsourcing and bio – technology would get a boost.

The patentability of diagnostic methods under Section 3 (i) of the Act poses another important question with respect to the possible distinction between 'in vitro' and 'in vivo' methods of diagnostics. The Patents Amendment Bill, 2003 has not introduced any distinction between 'in vitro' and 'in vivo' methods of diagnosis. While 'in vitro' methods of diagnosis would involve tests on samples taken from the body and performed outside the body, (like taking blood samples and testing for diagnosis of a disease like malaria), the 'in vivo' methods of diagnosis would include performing the methods on the human body (like CT scanning of the body). Section 3(i) of the Act provides that any process for the diagnostic or other treatment of human beings or any process for a similar treatment of animals is not patentable. In view of this, 'in vitro' diagnostic methods may be considered as a patentable subject matter.

The above being the position, the exact nature and scope of patentable inventions in the field of pharmaceutical arts will become clear only when the amended law is put to use, and possibly reviewed by the Courts of Law. Hopefully the textual law will acquire more clarity in the days to come when the Judges opine what it means and contains.

Patent Term Extension Strategies (referred to as 'Evergreening of Patents')

"Evergreening' or what the pharmaceutical companies often refer to as 'life cycle –management plans' refers to patent term extension strategies. Using the intricacies of patent prosecution procedures, pharmaceutical companies develop 'bullet proof' patent portfolios around million dollar drug molecules. Typically, multiple patents are secured covering a variety of inventive aspects in respect of a basic invention without attracting double patenting rejections. This plurality of patents directed at divergent inventive aspects can at times lead to the extension of patent terms, provided the national patent law allows such flexibilities.

On a rough estimate, the Mail Box contains over 5000 patent applications filed under Sec. 5(2) of the Act. Therefore, these 5000 patent applications presumably contain claims directed at 'substances capable of being used as food, medicine or drug'. The number of new drug molecules discovered in the last 5 years is roughly estimated at 40-45. That being the case, a certain section of Indian pharma industry argues that a majority of these patent applications are claiming secondary inventive aspects. Here again the basic question is, the extent to which, the patent statute can declare inventive aspects as unpatentable, while complying with the obligations under Art. 27 of the TRIPS Agreement.

According to the TRIPS Agreement, the term of protection for patent is 20 years counted from the filing date. As a patent prosecution and management strategy, 'Evergreening' enables patent term extension by developing a portfolio of patents around a basic invention. The child patents may be directed at any one of the various ancillary inventive aspect explained in the earlier section.

Adding new claims to a basic patent disclosure is permissible in certain jurisdictions. This is achieved by the effective use of patent prosecution routes including continuation patent application, divisional patent application, continuation-in-part patent application, and application for patent of addition. It is also possible to build on chains of priority from a basic patent disclosure to preserve novelty. The limitations or restrictions in the criteria of patentability and the exclusions of certain subject matters from the scope of patentability can impose serious limitations on patent prosecution strategies aimed at 'Evergreening'.

A number of fundamental issues come in sharp interplay when structuring patent prosecution aimed at 'Evergreening'. Unless the later applications disclose independent inventions (or inventive aspects), though linked to the invention disclosed in the basic application, the allowance of the later application(s) can lead to double patenting. On the other hand, inclusion of multiple inventive aspects (consequently multiple independent claims) in a single application can lead to 'unity of invention'

issues. In India , the Patents (Amendment) Act, 2002 brought in an amendment to Section (10)(5) introducing 'single inventive concept'. However, the Indian patent offices are yet to start allowing multiple independent claims. Consequently, dividing out applications is considered a normal patent prosecution step. As the effective date of filing of a divisional application is the same as the date of filing of the basic application, this may not contribute to patent term extension or 'Evergreening'.

In the absence of multiple prosecution avenues, where the applicant has the scope of working around various prosecution routes, the Indian Patents Act is rather rigid as to the time lines for priority, patent term and patentable subject matters. Hence, 'Evergreening' may not acquire serious dimensions in India .

Compulsory Licensing

In the thirty years of the working of India 's patents system, Compulsory Licensing provisions were never invoked. However, today it is the most widely debated topic in India. The Government of India and a number of other stakeholders consider Compulsory License as a statutory tool to effectively protect 'public interest' from possible abuse of monopoly. One step ahead, many consider that Compulsory License will ensure a level playing ground between the owners of Intellectual Property Rights and their competitors.

The Patents (Second Amendment) Bill, 1999 (which later became the Patents (Amendment) Act, 2002 brought in substantial amendments in the provisions concerning Compulsory Licenses. The Patents Act, 1970 originally contained a Chapter titled 'Working of Patents, Compulsory Licences, Licenses of Right and Revocation'. The legislative intent behind the inclusion of Compulsory Licensing provisions was evident from Section 83 of the 1970 Act. The Section contained the general principles applicable to the working of a patent aimed at curbing the potential abuse of monopoly by the patentee.

The local working of inventions to the fullest extend and on commercial scales and preventing the patentee from creating import monopolies were the two fundamental principles recognized in the original Act. The recent amendment added clauses (c) through to (g) to the original set of principles.

The new principles are addressed at striking a balance of interests between the technology owners and technology users, promoting socio-economic progress by technological development, protection of public health and the Government of India's rights in that regard prevention of unfair trade practices by abuse of monopoly rights by the patentee and the availability of the patented invention at affordable prices to the public.

The Act originally contained two important grounds for invocation of Compulsory Licenses. Any interested person could approach the Controller of Patents seeking a Compulsory License on grounds that (a) the reasonable requirements of the public with respect to the patented inventions have not been satisfied, and (b) patented invention is not available to the public at reasonable prices. The amended provision contained in Section 84 of the Act has included a third ground of 'local working' for seeking Compulsory Licenses. If the patented invention is not worked within the territory of India , it can be a ground to seek Compulsory License by any interested person. While explaining the meaning of 'reasonable requirements of the public', the law as it originally stood did contain a provision that the reasonable requirements of the public is deemed not to have been met, if for reason of the default of the patentee to manufacture in India the patented study, or not to give a license for the manufacture of the patented study the interests of the existing trade or industry is adversely affected. In addition to the above, under Section 92 (1) the Central Government can issue notification for the grant of compulsory licenses, at any time after the sealing of patent, in the case of 'national emergency' or 'extreme urgency' or 'public non- commercial use'. The Controller of Patent is required to endeavor to ensure that the patented invention is available at the lowest price consistent with the patentees deriving reasonable advantage from their patent rights. Further, subsection (3) of the same Section provides that in circumstances of 'national emergency', 'extreme urgency' or 'public non-commercial use' including health crisis relating

to AIDS, HIV, tuberculosis, malaria or other epidemic, the controller is not required to afford an opportunity of opposition to the patentee.

Difficulties may arise in the interpretation of the meaning and extent of the grounds on which Compulsory Licenses can be sought. . The expressions 'National Emergency' and 'Extreme Urgency' are nowhere defined though it can be safely inferred that these terms refer to situations of grave magnitude.

National emergency can take the form of 'perceived terrorist attack using biological warfare'. For instance, in the year 2001 Canada overrode Bayer Corporation's patent over Ciprofloxacin and ordered production of a million tablets of generic version from a Canadian company. Ciprofloxacin was stockpiled as an antidote for any attack on the nation using the deadly Anthrax.

The amended provisions have in general broadened up the grounds for seeking Compulsory Licenses. Also the amendments have re-emphasized some of the basic principles behind the inclusion of Compulsory Licenses. The amendments are, therefore, a combination of policy statements and a set of substantive augmentation of the earlier provisions respecting Compulsory Licenses.

While some implications of the Compulsory Licensing provisions are direct and predictable, some others are indirect, and far less apparent. The law says that Compulsory License can be granted to any interested person

if the patentee does not make the invention 'available to the public' at 'reasonable prices'. What would be the nature and extent of 'making the invention available to public' for purposes of invoking Compulsory Licenses may lead to a contentious issue. These indirect and less apparent issues are likely to surface once the TRIPS compliant product patent regime comes into existence. Here again, the Courts of Law may play a decisive role in explaining the pith and substance of the textual law.

♦ The study reveals that 30 out of 50 respondent units are manufacturing units, who produce the products by their own and the remaining 20 units are trading units who buy products from the former and sell it to the final consumers.

♦ The study divulges that only 10 out of 50 respondents units are earning Rs.10 crores per annum, 20 companies are earning more than Rs.5 crores & less than Rs 10 crores, 15 companies are earning above rs 3 crores and below Rs. 5 crores, 5 units are earning an annual turnover of below Rs 3 crores and above Rs 1crore.

♦ A stark revelation of the study is that out of 50 respondent units 40 units had invested the capital of above Rs. 1 crore and below Rs. 3 crores and 10 units had invested within the margin of Rs. 3 crores and Rs 5 crores and no respondent unit had invested above Rs. 5 crores as its capital.

♦The study shows that all the 50 respondent units are members of the Association of Pharmaceutical companies.

♦ The study indicates that only 5 companies had attended the meeting of the pharmaceutical companies' Associations on the impact of WTO and the remaining 45 units were not even attended the meeting, organized by the Associations of pharmaceutical companies.

♦ The important finding of the study is that 30 out of 50 respondents unit have reported that copying or piracy are extremely lucrative or profitable due to the absence of product patents in pharmaceutical industry and the 20 units have responded that they are not as much lucrative or profitable in India.

♦The study clarifies that 30 out of 50 respondent units will raise its investment in research and development due to introduction of product patents and 20 units have responded that they have no idea about the investment in research and development.

♦It has been found out from the study is that 40 units are earning more profit from their original own discovery than from copying from other companies and 10 units reported that have no idea.

♦ A hall mark of the study is that 20 units have responded that industry will be benefited from the product patent, 10 units responded that the country will be benefited and the 20 units responded that they have no idea.

♦The study discloses that 30 out of 50 respondent units reported that all the factors such as poor quality, no investment in research and no exports & up-gradation, will affect the pharmaceutical companies in product patent regime and the remaining 20 units reported that they have no idea.

♦ An important revelation of the study is that according to the opinions expressed by 30 companies there will be hike in the price of drugs in
the product patent regime and according to the opinions of 20 companies there will be no hike in the price of drugs.

♦An important disclosure of the study is that as per the views of 15 respondents units the small pharmaceutical companies can face the challenges of product patent and as per the views of 35 units they don't have the ability to face the challenges of product patents.

♦The study reveals that majority of respondent units (ie) 45 out of 50 units felt that the foreign companies are interested to come and work in India and 5 units responded that they have no idea.

♦ 30 respondent units reported that polymorphism is patentable and the remaining 20 respondent units reported that they have no idea about polymorphism.

♦ It has been known from the study that as per the responses of 30 out of 50 respondent units the optical isomers are patentable and the 20 respondent units replied that they have no idea about the optical isomers.

♦ Half of the respondent units (ie) 25 units responded that analogy processes are patentable and the remaining half of the respondent units responded that they have no idea about the analogy processes.

♦5 units replied that the meaning of patent extension technique is the renewal of patent rights, 5 units replied that it is vesting of patent.
right with a company for a particular period and the remaining 40 units replied that they have no idea.

♦20 units reported that the composition including the additives are patentable, 10 companies reported that they are not patentable and the 20 units reported that they have no idea.

♦10 out 50 respondent units replied that the pro-drugs are patentable and the remaining 40 companies replied that they have no idea about the pro-drugs.

♦The majority of the respondent companies (ie) 45 companies felt that the prior-heart drugs are patentable and 5 units replied that they have no idea.

♦30 units responded that the quality will be the main driver of competition in the pharmaceutical industry and the 20 units responded that the price will be the main driver of competition.

♦The highlight of the study is that the large pharmaceutical companies are preparing for 2005, as reported by 30 companies and not preparing for 2005, as reported by 20 companies.

♦The majority of respondent units (ie) 40 units felt that the Government has acted deliberately as regards product patent for pharmaceutical products and 10 units responded that they have no idea.

♦Half of the respondent units (ie) 25 units voted that Indian companies would lose the market and the remaining half (ie)25 units votes that the Indian pharmaceutical companies would not lose the market.

♦15 companies replied that the prices of Generics will go in a downward trend, 10 companies replied that it will go in an upward trend and 25 companies replied that they have no idea.

♦35 units reported that the restrictions on Reserve Engineered patented products will impact both the top line and bottom line of the levels of production and 15 units reported that they have no idea.

♦20 out of 50 respondent units responded that the number of companies will increase in the product patent regime and 30 units responded that the number of companies will decrease in the product patent regime.

♦It is surprising to note that all the 50 respondent units have not yet created "intellectual property rights Department" in their organization.

♦20 units replied that the EMR would assure the innovator company, a market free of copies of its products, 5 units replied that there may be copies of its products and 25 units replied that they have no idea.

♦30 respondent units reported that the process of granting product patent will not be a transparent one, 20 units reported that they have no idea and to be noted that, no company said it will be a transparent process

♦30 out of 50 respondent units responded that the redressal mechanism for the EMR holder will be elaborate, 15 units responded that it will be a reasonable one and 5 other units responded that they have no idea.

♦10 companies reported that the network between DCGI and the patent office will be a balanced one, 30 units reported that it will be an imbalanced one and 10 companies reported that they have no idea about their net work.

♦15 units replied that the Government may have the role in the grant of exclusive marketing rights and 25 units replied that the Government shall have no role in the grant of exclusive marketing rights and 10 units replied that they have no idea.

♦25 units reported that there is a need for changes in the strategy for entering US market, 10 units reported that no change is needed in the strategy to enter US market and 15 units reported that they have no idea.

♦20 units responded that there will be monopoly of products in the product patent regime,15 units responded that there will be increase in the products prices and 15 units are in the position to wait and see the impact of product patent regime.

♦25 units responded that only very few Indian Drugs are copies of patented products, 15 units responded that they may be many drugs which are copies of patented products and 10 units responded that they have no idea.

♦A hall mark of the study is that if there is no product patent, the products could be barred to enter US market as reported by 20 units; there is no such position like the above, as reported by 20 units and 10 units reported that they have no idea.

♦15 units responded that the pharmaceutical companies stopped the investment in R &D till 2005 and 35 units responded that they have not stopped the investment in R & D.

♦5 units replied that the prices of drugs under product patent regime will be affordable to the people to buy it, 30 units replied that they will not be affordable and 15 units reported that they have no idea.

5.4 suggestions

♦It is suggested that the pharmaceutical companies considerably raise their investments in R &D due to the introduction of product patents.

♦Pharmaceutical companies should create a sound infrastructure for undertaking or enhancing the research activities owing to the introduction of product patents.

♦It is suggested that small and medium pharmaceutical companies ensure good quality research, make sizeable investment in research, exports and up- gradation.

♦It is duty of the Government and the pharmaceutical companies to allay the fears of the common man regarding hike in drug prices.

♦It is suggested that the Government protects the interest of not only the common man but also the pharmaceutical companies in regard to product patents.

♦An important suggestion is that the Indian pharmaceutical companies take all out efforts possible to capture the drug market through good quality drugs at affordable prices through quality research work.

♦Product patent procedures and practices should be simplified and transparent to attract more companies to produce quality drugs at reasonable prices.

♦Separate intellectual property right cells should be created in all the pharmaceutical companies to deal with product patent related issues.

♦Network between the drugs controller General of India (DCGI) and the patent office must be a balanced one so that the position regarding issue, renewal and registration of patent can be known earlier.

This study was initiated with an intention to understand the pharmaceutical companies' long term orientation for survival and growth in the wake of WTO accord and the research & development initiatives. With the product patent being introduced from 2005, companies with clear vision and undertaking of the domestic and global markets will only be successful.

Hence the overall Indian has to transform its drug industry into a world class manufacture of quality products on a sustainable scale of operation. The essence of future growth lies in its ability to innovate and introduce new products. If the Indian pharmaceutical industry has to emerge as a global competitor, the manufacturing and marketing innovation is the focus. Cost –reduction opportunities in manufacturing and marketing innovation through quality novel drugs and promotion will have to be concentrated. Companies that prepare for the future keeping the present in perspective will emerge as the survivors in the long-term.

The domestic market will be attractive due to the growing awareness of medical care, changing profile of diseases, rising per capita income and improving health infrastructure. Hence it is clear that the competition will only rise and the profit margins will be thin but the growth is guaranteed.

Conclusion

While the discussion in this study is confined to the above three issues that the Indian pharmaceutical companies face in the anvil of the new TRIPS compliant regime, the transition from a limited term process patent regime to the product patent regime can have several other far reaching implications. The impact of this transition will become evident in the years to come. In the meantime, the Indian pharmaceutical industry must gear up to face the challenges. Creation of a level playing ground is possible the moment the domain knowledge of patents is even among all the players in the Indian market place. To begin with, the efforts to achieve parity in knowing the rules of the game can be confined to India . But sooner or later the Indian pharmaceutical companies will have to transform into knowledge-based organizations capable of producing research-based medicine at prices affordable to the Indian people.

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- Intellectual property law in India – by Gogia law Agency
- Intellectual property rights – by prabuddha Ganguli.

APPENDIX

INTELLECTUAL PROPERTY RIGHT AND THE IMPACT OF TRIPS AGREEMENT

A STUDY WITH REFERENCE TO INDIA PATENT LAW

INTERVIEWSCHEDULE TO PHARMA COMPANIES /DISTRIBUTERS

Name of the company :

Position of the Respondent :

Product Manufactured /dealed with :

Annual Turnover : Rs.

Capital Invested : Rs.

Are you a member of any Association of Pharma Companies / Distributors?

YES / NO

If yes, Name it ……. :

Does such Association conduct any meeting on the impact of WTO on Pharma Companies ?

Decision taken in that meeting :

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1. Do you think that the absence of product patents in pharmaceutical industry made copying or piracy extremely lucrative in India?

2. Do you favour the view that the investment on R & D will jump to twice the level before , when product patents are introduced?

3. Is it true that the profitability will be much higher from the original discovery research than copying?

4. Do you think that the product patent regime will benefit the industry, country and patients?

5. Do you accept the fact that the following factors affect the Companies in respect of product patents ?

    a) Poor Quality

    b) No Investment in Research

    c) No Exports

    d) No desire to upgrade and globalize

6. Is it true that the prices of pharmaceutical will rise in the product Patent regime?

7. Do the Small the pharma companies have the wherewithal to undertake patent challenges?

8. Do you think that if Indian patent laws are made stronger , more Foreign companies would be interested in coming here and working on diseases that are specific to the region?

9. What is Patent Extension Technique?

10. Is Polymorphism (where the same compound has different structures) patentable?

11. Are optical isomers (compounds that have the same chemical formula, but are structurally different in three dimensional forms) patentable ?

12. Are analogy processes patentable?

13. If the composition includes additives that generate a truly new and Inventive product is it patentable?

14. Does the patent cover the pro-drugs & what is the extent to which Claims relating to compounds should be allowed to improve the product patent?

15. Are the new drug delivery systems, new dosage forms, new Strengths and new indications for any prior heart- drug patentable?

16. Do you think that the large pharmaceutical companies began Preparing for 2005, a decade ago itself?

17. Do you think that though the patens Act has existed since 1970, the Government has deliberately kept pharmaceutical companies out of the ambit of product patents?

18. What will be the immediate impact of the new product patent regime on the Indian pharma industry?

19. Is it true that less than 5% of the drugs available in the Indian Market are copies of patented products and hence Indian pharmaceutical companies need not agonize over it?

20. Since all developing nation are also switching to product patent Regime by 2005, will the Indian pharmaceutical companies lose the markets, where many of them have been exporting bulk drugs
Of formulations of patented products?

21. Do you think that the main driver of competition in the generic Industry will be the price even more than the quality?

22. Will it exert a downward pressure on the prices of generics in the Market leading to an unviable category in the medium to long- term?

23. will the restrictions on Reverse Engineered patented products impact both top line and bottom line?

24. Do You think the number of pharmaceutical companies in India Will come down drastically from over 20,000 today, as in the case Of chine, where the pharmaceutical firms have come down from over 6000 to just about 600 today?

25. Have you set up exclusive intellectual property Rights Department to nurture creativity and innovation your R & d team?

26. Would the Exclusive Marketing Rights (EMR) assure the Innovator company of a market free of copies of its product?

27. Would the Exclusive Marketing Rights (EMR) assure the Innovator company of a market free of copies of its product?

28. Is there more transparency in the grant process, including full Disclosure of pending EMR requests?

29. Does the EMR regulation elaborate a rederessal mechanism for the EMR holder if generic continues to self in the markets?

30. Has the amendment to the patent Act, 1970 created an imbalance in the regulatory framework between two Govt. bodies DGGI (Drugs Controller General of India and patent office?

31. If an EMR is granted, is there no Government authority to ensure That right respected?

32. Will domestic pharmaceutical companies that take the aggressive patent challenge route into the US market be forced to rethink the strategies following the recent high profile set back of DRL (Dr. Reddy's Lab) with Pfizer/

33. Do you know the fact that if an Indian pharma company has not Undertaken the exercise of patenting its product or process, it could be barred entry into US market?

34. If product patents are expected only in 2005, would the Investment into R & D be put on hold till such time?

35. Would the economic domination in health care mean that the Affordability factor, so crucial to the Indian population will be given a good-bye?

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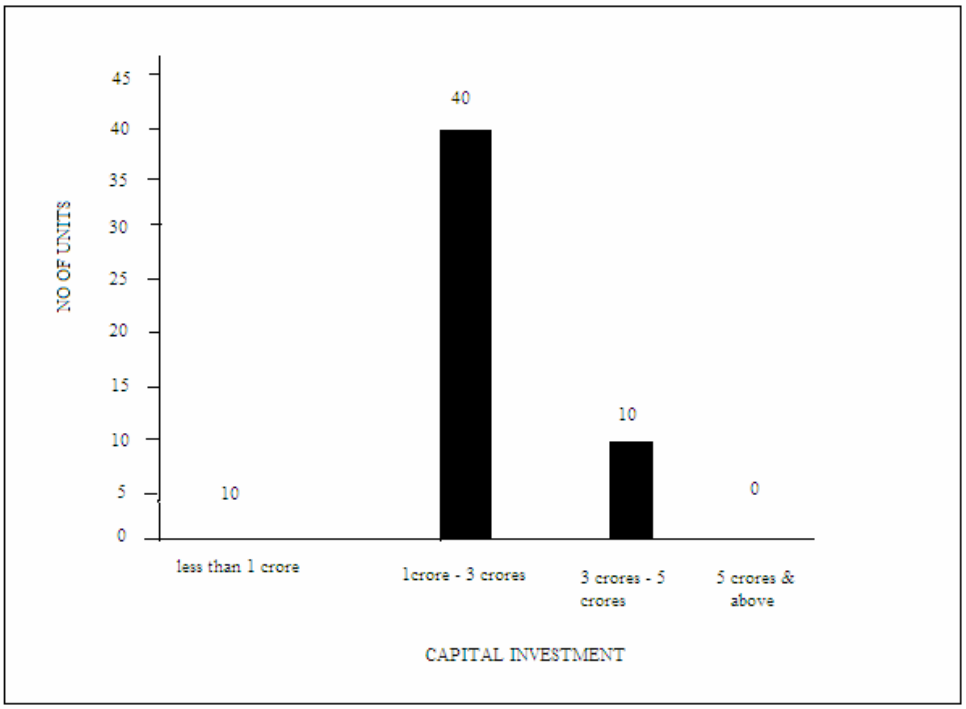
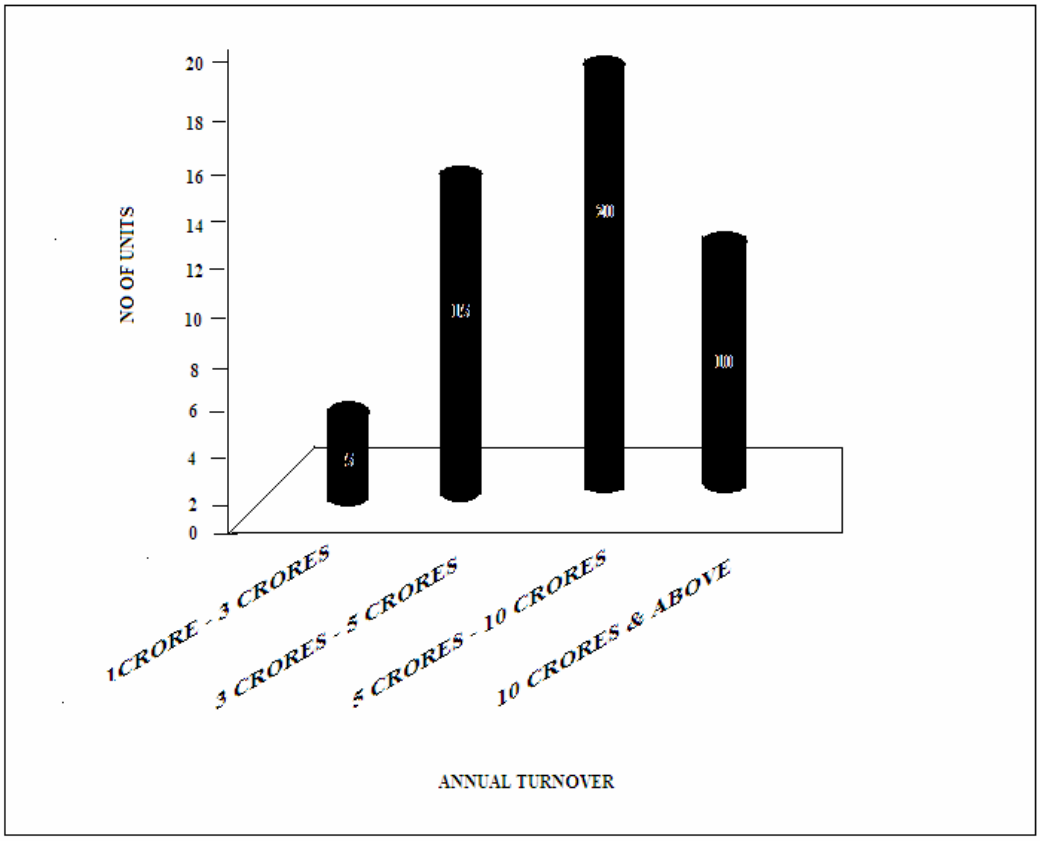
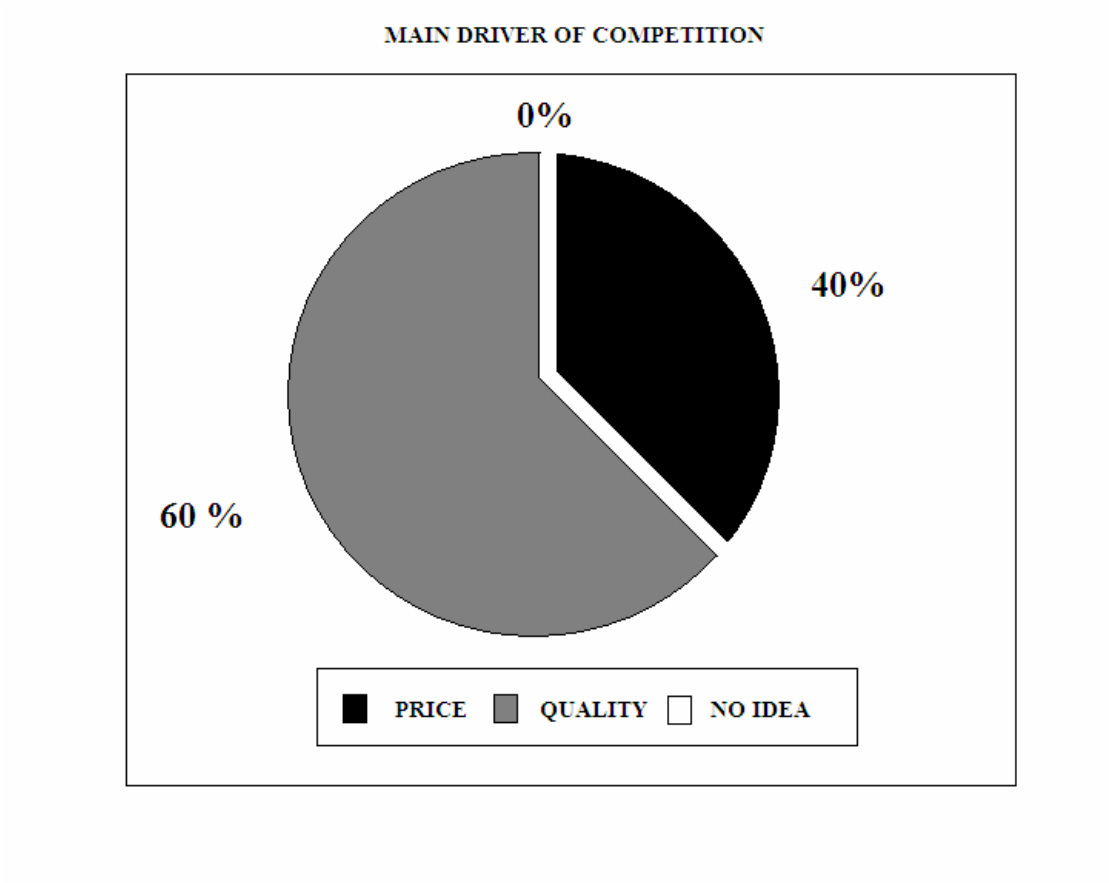
DIAGRAM - 4.3

CAPITAL INVESTMENT IN RESPONDENT UNITS



ANNUAL TURNOVER OF THE RESPONDENT UNITS




MAIN DRIVER OF COMPETITION
0%
40%
60 %
PRICE
QUALITY
NO IDEA

NATURE OF RESPONDED UNITS