INTRODUCTION
Chapter I

INTRODUCTION

Healthcare is one of the most basic needs and an inviolable right of every human being. The right to health has been recognised in a number of international legal instruments. The health care sector has been known for practices thwarting the spirit of competition and regulation. Hence the role of Competition Act is very crucial in placing appropriate restraints. Healthy and fair competition has proven to be an effective mechanism which enhances economic efficiency. This led to the need of a strong legislation to dispense justice in health care sector and the Competition Act, 2002 was passed.

Competition laws involve in formulating a set of policies which promote competition in the local and national market. These are aimed at preventing unfair trade practices and curbing abuse of monopoly in the market by the dominant company. Besides, it prevents artificial entry barriers and aims to remove monopolization of the production processes by encouraging entrance into industries by new players. The objectives of Competition Act, 2002 include the maximization of consumer and producer welfare, as well as maximizing efficiency in production. The well designed and effective competition laws promote the creation of an enabling business environment, which improves static and dynamic efficiencies and leads to efficient resource allocation and in which the abuse of market power is prevented mainly through competition. In the above context, the researcher has made an attempt to identify the anti-competition issues in the pharmaceutical industry and the health care sector. These range from being cross-border in nature to those that exist from the local level to international level.

At present, India currently represents just U.S. $6 billion of the $550 billion global pharmaceutical industry but its share is increasing at 10 percent a year,

4. ibid
compared to 7 percent annual growth for the world market overall. Also, while the Indian sector represents just 8 percent of the global industry total by volume, putting it in fourth place worldwide, it accounts for 13 percent by value, and its drug exports have been growing 30 percent annually. This is because pharmaceutical products are non-homogenous in nature, and there are a large number of “relevant markets” within the pharmaceutical industry.

It is in the absence of effective competition that efficiency of markets is hampered. Different government policies may encourage or adversely affect competition, and hence consumer welfare, particularly in the context of the present globalizing environment. Manufacturers of medical equipment of supplies have a clear responsibility towards patients that the equipment is fit for use and medical supplies, drugs and treatments will be as effective as possible whilst giving the least side effects possible. If these responsibilities have been neglected, it can cause serious consequences to patients and families of those concerned. The procedures for testing medical products are extremely rigorous and it can take years for products to ever reach a human patient. Unfortunately, even with extraordinarily stringent checks, some faulty medical products do slip through the net – with distressing results for both patients and their loved ones.

There is a paradigm shift in business law jurisprudence from ‘caveat emptor’ (let the buyer beware of) to ‘caveat venditor’ (let the seller beware of). Consumers are said to be sovereign. Rights of the consumers have been emerging as a movement since every individual human being ought to be a consumer. Consequent to United Nations Conference on Trade and Development (UNCTAD) guidelines on consumer protection, India enacted the Consumer Protection Act, 1986. The Preamble of this Act provides that “protection of interest of the consumers and for that purpose to make provision for the establishment of consumer council and other authorities for settlement of consumer disputes’ and for matters connected therewith.” The Act empowered the consumers with various powers to realize their rights when they are violated by approaching the appropriate consumer forums.

---

5 IMS Health: IMS Intelligence. 360 Global Pharmaceutical Perspectives, (2004.)
7 Indian Government National Pharmaceuticals Policy, (January 2006).
8 Towards a Functional Competition Policy for India: An Overview” Pradeep Mehta, (CUTS International)
In this research patients are taken as consumers. They buy goods in the form of medicines and drugs and avail services of doctors whenever they are afflicted with diseases or otherwise. A three judges bench of the Supreme Court of India in *Consumer Education and Research Centre v. Union of India* held that “right to health, medical aid to protect the health and vigour of a worker while in service or post- retirement is a fundamental right under Article 21 read with Article 39 (e), 41, 43, 48 A and all related Articles and fundamental human rights to make the life of workman useful and purposeful.” From this judgment onwards and in consonance with the Human Rights Protection Act, 1993, right to health has evolved as not only a human right but also a fundamental right, besides bringing the provisions relating to consumer rights. In *State of Punjab v. Mohinder Singh Chawla*, right to life was declared to include right to health where it was further held that right to health is an integral part of right to life.

Another three judges bench of the Supreme Court in *Air India Statutory Corporation v. United Labour Union*, in 1997, held that right to health and medical care to protect health is a fundamental right under Article 21 read with 39 (e), 41, 43, and 48A.

A five judges Constitution Bench of the Supreme Court in *Confederation of Ex-Servicemen Association v. Union of India* held that right to health of a workman is covered by Article 21 of the Constitution “facilities of health and medical care generate devotion and dedication to give the workers best.”

In 2012, in *Society for Un-aided Private School of Rajasthan v. Union of India*, a bench consisting of three judges of the Supreme Court held that right to receive the

---

9 *Consumer Education and Research Centre v. Union of India* AIR 1995 SC 922; constitution of India under Article 39 (e) The state shall, in particular, directly its policy towards securing that the health and strength of workers, men and women, and the tender age of children are not abuse and that citizen are not forced by economic necessity to enter avocation to their age or strength.

Article 41 The state shall, within limits of its economic capacity and development, make effective provision for securing the right to work, to education and to public assistance in cases of unemployment, old age, sickness and disablement, and in other cases of undeserved want.

Article 43 The state shall endeavor to secure, by suitable legislation or economic organization or in any other way, to all workers, agricultural, industrial or otherwise, work, a living wage, conditions of work ensuring a decent standard of life and full enjoyment of promote cottage industries on an individual or co-operative basis in rural areas.

Article 48A The state shall endeavor to protect and improve the environment and to safeguard the forests and wild life of country.

10 *State of Punjab v. Mohinder Singh Chawla* AIR 1997 SC1225

11 *Air India Statutory Corporation v. United Labour Union* AIR 1997 SC 645

12 *Confederation of Ex-Servicemen Association v. Union of India* AIR 2006 SC 2945
necessary medicines without charges and identifying a positive duty of prevention is at
the core of the right to health.13

Article 21 of the Constitution, provides that, “No person shall be deprived of his
life or personal liberty except according to the procedure established by law.” This
Article mandates that the right available under this Article is not only aimed against the
State, it is also against persons. When right to life includes right to health, it does not
imply that as per this Article the State under Article 12, nor would persons who involve
in health care affect the right to life including right to health. As per the Supreme Court
verdict, both the hospitals and doctors under the control of the State are to follow the
mandates laid down by the Article as well as the judgment. It also implies that doctors
who enroll themselves as medical practitioners in the Medical Council of India come
under the ambit and power of the State. Therefore, it is implied that doctors have an
obligation to take care of the interest of patients irrespective of whether they are in the
government hospital or private hospital. Recently amendments have been made in the
Criminal Procedure Code which makes it the doctors’ duty in the private sector to
accord private treatment under certain circumstance.

The Fundamental Rights, Human Rights Protection Act and the judgments of
the courts attempt to provide and protect the patients, who are not merely consumers,
but also are persons including citizens. While the consumers undergo treatment as
patients, they avail the services of doctors and buy goods in the form of medicines and
drugs from the pharmacists manufactured by the pharmaceutical manufacturers with
the aid and advice of Pharmacists. The consumers’ rights may be violated while they
undergo treatment on two accounts namely when the goods are defective and there is
deficiency in services. Section 2 (f)14 and 2 (g)15 define these words for the effective
implementation of the Act. There are other stakeholders like manufacturers who
involve in manufacturing medicines and drugs which are supplied in the market and
thereby they allow the consumer patients to buy such medicines and drugs.

13 Society for Un-aided Private school of Rajasthan v. Union of India AIR 2012 SC 3445
14 Section 2 (f) of Consumer Protection Act defines “defect” means any fault, imperfection or
shortcoming in the quality, quantity, potency, purity or standard which is required to be maintained
by or under any law for the time being in force under any contract, express or implied or as is
claimed by the trader in any manner whatsoever in relation to any goods.
15 Section 2 (f) of Consumer Protection Act defines “deficiency” means any fault, imperfection,
shortcoming or inadequacy in the quality, nature and manner of performance which is required to be
maintained by or under any law for the time being in force or has been undertaken to be performed
by a person in pursuance of a contract or otherwise in relation to any service
**e- CONSUMER IN HEALTH CARE SECTOR:**

Millions of peoples are access the Internet for health information, which is changing the way patients seek information about, and often treat, certain medical conditions. It is estimated that there may be as many as 100,000 health-related Web sites. The availability of so much health information permits e-consumers to assume more responsibility for their own health care. At the same time, it raises a number of issues that need to be addressed. The health information available to Internet users may be inaccurate or out-of-date. Potential conflicts of interest result from the blurring of the distinction between advertising and professional health information. Also, potential threats to privacy may result from data mining. Health care consumers need to be able to evaluate the quality of the information provided on the Internet. Various evaluative mechanisms such as codes of ethics, rating systems, and seals of approval have been developed to aid in this process. The effectiveness of these solutions is evaluated in this research. The research addresses the importance of including patients in developing standardized quality assurance systems for online health information.

The rise of e-commerce in India has led to the emergence of niche healthcare portals in the country. Gone are the days when one had to go to the neighborhood chemists for buying medicines, a handful of healthcare start-ups are now willing to deliver them right at your doorstep. The rising acceptance of e-commerce among consumers in India has led to the emergence of niche healthcare portals in the country along with many other categories.

**1.1 SCOPE OF THE STUDY:**

The current study focus on issues governing Competition in the health care sector in India, with special emphasis on practices regulated or prohibited by the Competition Act 2002 and its amended Act 2007. The overarching of the present study is to “understand the nature of the Pharmaceutical firms and health care sectors on market and explore its implications for industrial capacity access and, consumer access and public health with reference to the Competition Act 2002. The study has made an attempt to cover all important aspect pertaining to the terms of reference and has made in depth analysis of some issues that are of crucial importance for enforcement of Competition Act in the health care sector.

The study examines all possible issues that underline the objectives framed. The Pharmaceutical products/ process can be divided in to therapeutics (drugs),
diagnostics, vaccines and prophylactics preventive technologies-products /methods). Since the scope of examining all such products/process categories is prohibitively outsized, the study has examined only therapeutics. This is also because the medicines are directly consumed by the people and the large amount of consumers and Competition Act which is emerge in this product range primarily in relation how drugs are innovated and patented, generic availability, pricing practices and nature of interactions in the Pharmaceutical distribution markets.

However, it is not to suggest that the markets for vaccines, diagnostics and prophylactics do not carry any competition concerns-which can definitely be a distinct stand alone study. There is an increasing tendency to get more drugs out of the prescription ambit. There are both advantages and disadvantages to this issue .It is not to suggest that Over the Counter Drugs market present no Competition concerns in an increasingly drug advertising driven market where information asymmetries and lack of effective consumer drug information forms the perverse genesis of this market. Even while the study refers to OTC drugs in Pharmaceutical market overview, the major focus of this study in relation to prescription drugs or what is generally called as “ethical drugs”. It is a known fact that the prescription drugs are chosen by the doctors who are generally price insensitive due to variety of reasons including perverse incentives – but purchased by patients (Consumers). Hence, consumers and competition concerns are more in ethical drug market which the study rightly focuses in it’s entirely. While the study examines the Pharmaceutical sector and market positions of companies their strategies and practices have been identified. Even with reference to pricing, the pricing practices of companies have been highlighted. The Competition Act replaced the MRTP Act, 1969, and there was a shift in the focus from curbing monopolies to promoting competition. The Competition Act 2002 aims to prevent practices having an adverse affect on competition and abuse of dominance of enterprises either by entering into anti competitive agreements, or combinations.

It is therefore important to ensure effective competition in the health care sector where competition is also directly linked with the public health objectives. It is essential for the health care sector in India to operate under a law that curbs anti-competitive activities. The new Competition Act, 2002 has all the required provisions. It would, anyhow, depend on how it is implemented. Competition is not an end in itself – it is a means to the objective of economic efficiency. It benefits consumers by
restraining prices and encouraging companies to innovate. The significant issues of health care sector through the lens of Competition Act 2002 which broadly includes: - anti-competitive practices along the pharmaceutical value chain and competition distortive provisions in the health sector to compete fairly.

These issues and challenges cannot be studied in isolation without looking at the predominant issue of ensuring availability, affordability and accessibility of medicines to the public which is part of the fundamental right to life under Article 21 of the Indian Constitution and a consideration that motivates the pricing decisions of life saving medicines under the National List of Essential Medicines in accordance with the Essential Commodities Act and the Drug Price Control Order, administered by the National Pharmaceutical Pricing Authority. Balancing the entrepreneurial interests with the objective of consumer welfare is a critical challenge unique to the pharmaceutical industry and therefore the study cannot be complete without getting a closer look at anti competitive measures and how they impact market competition. The study in fact attempts to guide the policy makers towards achieving this equilibrium through some of its findings in impact of Competition Act in Health Care Sector and prevention of anti competitive measures prevailing in Pharmaceutical firms and suitable legislations and amendments in preventing the same.

Whereas the study tries to address most of the anti competitive issues which were brought by Doctors, Pharmacists and Pharmaceutical industries against the Patients were considered. The significant purpose of this study, there is a likelihood of some of the health care sector with reference to the Consumer welfare having been missed out in various researches. In most cases it could be because of inter-se prioritization leaving out the lesser of the issues to save on space and maintain the focus on the main study. The need for the study is

- to identify anti-competitive activities prevalent in the health care sector
- Identify areas and practices which fall within the Competition Commission’s regulatory ambit.
- Explore ways and means to use Competition Act to enhance consumer access to medicines and secure a competitive environment in the industry.
In India around 80% of the population incurs expenditure on health care which is very high compared to certain developed countries. The Competition Act seeks to ensure fair competition in India by prohibiting trade practices which cause appreciable adverse effect on Competition in markets and for this purpose provides for establishment as a quasi judicial body to be called the Competition Commission of India which shall also undertake the Competition advocacy for creating awareness and imparting anti-Competition issues.

The Competition Act 2002 plays a vital role in improving the Health Care System. The Act further substantially improve the functioning of health care markets through greater breadth and intensity of competition prevailed in Pharmaceutical firms and the delivery of health care services from medical professionals such as Doctors, Pharmacists and Pharmaceutical firms against the Patients. The innovative pharmaceutical industry in health care sector driven by, and drives medical progress. Already, the health care sector has contributed to significant improvements in patient well-being. Some major steps have been taken in present research to resolve the anti competitive measures and its impact of competition Act 2002 on health care sector especially to the Patients. For instance HIV/AIDS-related causes and a number of cancers, yet major hurdles remain, including cancers and orphan diseases. There is an urged need to study the anti competitive measures that prevailed in health care sector and to prevent the same by the Competition Act 2002.

1.2 RESEARCH PROBLEM

The research questions that are analysed and answered in the present study are the following:

1) What are the laws relating to the Health care Sector?
2) How the Competition laws deals with protection of health care sector?
3) What are the nexus exists between the Competition Act and Consumer Protection Act?
4) What are the views of the doctor about the Competition law and its impact on health care sector?
5) What are the views of the Pharmacists about the Competition law and its impact on health care sector?
6) What are the views of the Patients about the Competition law and its impact on health care sector?
7) What are the views of the Pharmaceutical Manufacturer about the Competition law and its impact on health care sector?

8) What are the views of the e-consumers about the Competition law and its impact on health care sector?

9) What is the level of satisfaction of the e-consumers (Patients) about efficacy of Competition Policy on health care sector?

10) How far the Competition Act Beneficial to the stakeholders?

1.3 OBJECTIVES OF THE STUDY

From the analysis of the above study the following objectives are deduced under:

i) To formulate the approach adopted by the Competition law and policy in order to find out its impact on health care sector.

ii) To explain the general framework of the existing statutory laws to prevent the anti – competitive measures.

iii) To analyse the Competition Act 2002 and Consumer Protection Act on health care sector in India.

iv) To find out the impact of the Competition Act 2002 by the Doctors.

v) To find out the impact of the Competition Act 2002 by the pharmacists.

vi) To find out the impact of the Competition Act 2002 by the Patients.

vii) To find out the impact of the Competition Act 2002 by the Pharmaceutical Manufacturer.

viii) To evaluate the effectiveness of the Competition Act on health care sector in India.

ix) To critically evaluate and compare the views of Pharmacists, Consumers (Patients) including e-consumers, Pharmaceutical Manufacture and Doctors with reference to the impact of Competition law with respect of health care sector.

x) To find out the inadequacy of law relating to health care sector.

1.4 HYPOTHESES:

From the above research questions and objectives of the study the below listed hypotheses are formulated for the purpose of testing them in the light of data collected for the purpose.
The major hypotheses and sub-hypotheses are:

1. The application of Competition Act to ensure to prevent anti-competitive and collusive practices in the health care sector and to protect the rights of the Patients.
2. Anti-Competition issues in the health care sector can be looked upon by segregating them into issues at domestic level and those at international level.
3. The key factors of success application of Competition Act on health care sector based on the perception of the Patients, Doctors, Manufacturers and Pharmacists and Patients.
4. The existing Competition Act and Consumer Protection Act are an obvious legal remedy to deal with the anti-competitive practices in the health care sector.
5. The Redressal Authority CCI, its role and functions in curbing the anti-Competitive practices.

1.4.1 Major hypothesis for Consumers

The Consumers’ attitude on Competition Act and their socio-economic, religious background are associated

Sub- Hypotheses

1. There is a significant correlation between the age group of consumers and their level of attitude.
2. There is a significant correlation between sex of consumers and their level of attitude.
3. There is a significant correlation between residence of consumers and their level of attitude.
4. There is a significant correlation between religion of consumers and their level of attitude.
5. There is a significant correlation between educational qualification of consumers and their level of attitude.
6. There is a significant correlation between marital status of consumers and their level of attitude.
7. There is a significant correlation between occupation of consumers and their level of attitude.

8. There is a significant correlation between number of members of family of consumers and their level of attitude.

1.4.2 Major hypothesis for Doctors

The Doctors attitude on Competition Act and their Age, Sex, Education, Experience (ASEEP) are associated.

Sub-Hypotheses

1. There is a significant correlation between the age group in year of the Doctors and their level of attitude.

2. There is a significant correlation between the sex of the Doctors and their level of attitude.

3. There is a significant correlation between the educational qualification of Doctors and their level of attitude.

4. There is a significant correlation between the number of years of practice of the Doctors and their level of attitude.

5. There is a significant correlation between the number of patients given consultation per day by the Doctors and their level of attitude.

6. There is a significant correlation between the number of medical representatives met in a day by the Doctors and their level of attitude.

1.4.3 Major hypothesis for Pharmacists

The Pharmacists’ attitude on Competition Act and Health care and their Socio-Economic, Religious, Educational and Employment factors (SEREEP) are associated.

Sub-Hypotheses

1) There is a significant correlation between the age of the scientists and their level of attitude.

2) There is a significant correlation between the religion of the scientists and their level of attitude.

3) There is a significant correlation between the educational qualification of the scientists and their level of attitude.
4) There is a significant correlation between the experience in years of the scientists and their level of attitude.

1.4.4 Major hypothesis for Pharmaceutical Manufacturers

The Pharmaceutical Manufacturers attitude on Competition Act and Health care and their socio-economic background are associated.

Sub-Hypotheses

1. There is a significant correlation between the age of the manufacturers and their level of attitude.

2) There is a significant correlation between the educational qualification of the manufacturers and their level of attitude.

3) There is a significant correlation between the size of the Company of the manufacturers and their level of attitude.

4) There is a significant correlation between the length of experience of the manufacturers and their level of attitude.

5) There is a significant correlation between the nature of the Product of the manufacturers and their level of attitude.

6) There is a significant correlation between the position with reference to R & D of the manufacturers and their level of attitude.

In this research, the above are the Sub-Hypotheses which are tested based on the data collected, measured, quantified and tabulated and shown in table in the sixth chapter.

1.5 CONCEPTUAL DEFINITIONS

In this research the stakeholders are consumers, doctors, manufacturers and pharmacists. For a systematic analysis they are required to be defined in a clear cut fashion. Further there are concepts Anti-competitive practices, Unfair trade practices and attitude which are also to be defined.

"predatory price"\textsuperscript{16} means the sale of goods or provision of services, at a. price which is below the cost, as may be determined by regulations, of production of the goods or provision of services, with a view to reduce competition or eliminate the competitors.

\textsuperscript{16} Section 4 explanation (b) of Competition Act, 2002
"Unfair trade practice" means a trade practice which, for the purpose of promoting the sale, use or supply of any goods or for the provision of any service, adopts any unfair method or unfair or deceptive practice including any of the following practices, namely;—

(1) the practice of making any statement, whether orally or in writing or by visible representation which,—

i. falsely represents that the goods are of a particular standard, quality, quantity, grade, composition, style or model;

ii. falsely represents that the services are of a particular standard, quality or grade;

iii. falsely represents any re-built, second-hand, renovated, reconditioned or old goods as new goods;

iv. represents that the goods or services have sponsorship, approval, performance, characteristics, accessories, uses or benefits which such goods or services do not have;

v. represents that the seller or the supplier has a sponsorship or approval or affiliation which such seller or supplier does not have;

vi. makes a false or misleading representation concerning the need for, or the usefulness of, any goods or services;

vii. gives to the public any warranty or guarantee of the performance, efficacy or length of life of a product or of any goods that is not based on an adequate or proper test thereof; Provided that where a defence is raised to the effect that such warranty or guarantee is based on adequate or proper test, the burden of proof of such defence shall lie on the person raising such defence;

viii. makes to the public a representation in a form that purports to be—

   (i) a warranty or guarantee of a product or of any goods or services; or

   (ii) a promise to replace, maintain or repair an article or any part thereof or to repeat or continue a service until it has achieved a specified result, if such purported warranty or guarantee or promise is materially misleading or if there is no reasonable prospect that such warranty, guarantee or promise will be carried out;

ix. materially misleads the public concerning the price at which a product or like products or goods or services, have been or are, ordinarily sold or provided,

---

17 Section 2(1)(r) of Consumer Protection Act, 1986
and, for this purpose, a representation as to price shall be deemed to refer to the
price at which the product or goods or services has or have been sold by sellers
or provided by suppliers generally in the relevant market unless it is clearly
specified to be the price at which the product has been sold or services have
been provided by the person by whom or on whose behalf the representation is
made;
x. gives false or misleading facts disparaging the goods, services or trade of
another person.18

“Restrictive trade practice” means a trade practice which tends to bring about
manipulation of price or conditions of delivery or to affect flow of supplies in the
market relating to goods or services in such a manner as to impose on the consumers
unjustified costs or restrictions and shall include19—
(a) delay beyond the period agreed to by a trader in supply of such goods or in
providing the services which has led or is likely to lead to rise in the price;

18 Explanation. - For the purposes of clause (1), a statement that is— (a) expressed on an article
offered or displayed for sale, or on its wrapper or container; or (b) expressed on anything attached
to, inserted in, or accompanying, an article offered or displayed for sale, or on anything on which the
article is mounted for display or sale; or (c) contained in or on anything that is sold, sent, delivered,
transmitted or in any other manner whatsoever made available to a member of the public, shall be
deemed to be a statement made to the public by, and only by, the person who had caused the
statement to be so expressed, made or contained;

(2) permits the publication of any advertisement whether in any newspaper or otherwise, for the sale or
supply at a bargain price, of goods or services that are not intended to be offered for sale or supply at
the bargain price, or for a period that is, and in quantities that are, reasonable, having regard to the
nature of the market in which the business is carried on, the nature and size of business, and the
nature of the advertisement.
Explanation.—For the purpose of clause (2), "bargaining price" means—
(a) a price that is stated in any advertisement to be a bargain price, by reference to an ordinary price or
otherwise, or
(b) a price that a person who reads, hears or sees the advertisement, would reasonably understand to be
a bargain price having regard to the prices at which the product advertised or like products are
ordinarily sold;
(3) permits—
(a) the offering of gifts, prizes or other items with the intention of not providing them as offered or
creating impression that something is being given or offered free of charge when it is fully or partly
covered by the amount charged in the transaction as a whole;
(b) the conduct of any contest, lottery, game of chance or skill, for the purpose of promoting, directly or
indirectly, the sale, use or supply of any product or any business interest;
(3A) withholding from the participants of any scheme offering gifts, prizes or other items free of charge,
on its closure the information about final results of the scheme.
19 Section 2(1) (nn) of the Consumer Protection Act, 1986,
(b) any trade practice which requires a consumer to buy, hire or avail of any goods or, as the case may be, services as condition precedent to buying, hiring or availing of other goods or services;

On analysis of the above definition, it can be understood that where sale or purchase of a product or service is made conditional on the sale or purchase of one or more other products and services, it amounts to restrictive trade practice. Technically, this type of arrangement is called tie-up sales or ‘tying arrangement’\(^{20}\). The effect of such an arrangement is that a purchaser is forced to buy some goods or services which he may not require along with the goods or services which he wants to buy.

For example: A is a furniture dealer. He is selling Sofa at Rs. 20,000 and Bed at Rs. 15,000. He has an offer that whoever will buy Sofa and Bed both, he will charge Rs. 30,000 only. Here the choice is open to the customer to buy the products single or composite. This is not a restrictive trade practice.

**Consumer Courts**

The Consumer Protection Act, 1986 provides for a three tier approach in resolving consumer disputes. There are 3 levels of consumer courts\(^{21}\) namely:

a) National Consumer Dispute Redressal Commission or National Commission: Value of claims above Rs.1 crore

b) State Consumer Dispute Redressal Commission or State Commission: Value of claims from Rs.20 lakhs to Rs.1 crore

c) District Consumer Disputes Redressal Forum or District Forum: Value of claims upto Rs.20 Lakhs

District Forum and State Commission are formed by States with the permission of the Central Government while the National Commission is formed by the Central Government. Presently there are 34 State Consumer Disputes Redressal Commissions in India.

---

\(^{20}\) An agreement in which a vendor conditions the sale of a particular product on a vendee's promise to purchase an additional, unrelated product. In a tying arrangement, the product that the vendee actually wants to purchase is known as the "tying product," while the additional product that the vendee must purchase to consummate the sale is known as the "tied product." Typically, the tying product is a desirable good that is in considerable demand by vendees in a given market. The tied product is normally less desirable, of poorer quality, or otherwise difficult to sell. For example, motion picture distributors frequently tie the sale of popular video cassettes to the purchase of second-rate films that are piling up in their warehouses for lack of demand.

\(^{21}\) Consumer Court is the special purpose court, mainly in India, that deals with cases regarding consumer disputes and grievances. These are judiciary set ups by the government to protect the consumer rights. Its main function is to maintain the fair practices by the sellers towards consumers.
Attitude

Attitude is defined by several scholars differently. According to Egaly and Chaiken, an ‘attitude is a psychological tendency that is expressed by evaluating a particular entity with some degree of favor or disfavor’.\textsuperscript{22} According to Jung, ‘attitude is a readiness of psyche to act or react in certain way.’\textsuperscript{23} There are several theories and models related to attitude. These theories and models elaborately rely on the tripartite concepts of cognitive, conative and affective, correspondingly meaning knowledge, involvement and assessment. These concepts have been taken for the present analysis.

For the present purpose, the concept attitude means and includes persons’ knowledge, involvement and assessment. With reference to attitude of the stakeholders consumers, scientists, manufacturers and doctors, it refers to the following; Attitude of the consumers means knowledge of consumers about Competition Act and Health Care. It also includes their involvement and ability to assess the utility and relevance of Consumer Protection Act, Competition Act and Health Care. Attitude of the scientists means knowledge, involvement and assessment of the scientists in relation to Patents Act, Pharmaceutical Patents. Attitude of the manufacturers means knowledge, involvement and assessment on the relevance and utility of Pharmacy Act, Consumer Protection Act, Patents Act, Drugs and Cosmetics Act etc. Doctors are the ultimate service providers to the patient consumers. Attitude of doctors means knowledge, involvement and assessment of doctors in relation to Consumer Protection Act, Patents Act, and Pharmaceutical Patents.


Pharmacists

Pharmacists, also known as chemists (Commonwealth English) or druggists (North American and, archaically, Commonwealth English), are healthcare professionals who practice in pharmacy, the field of health sciences focusing on safe and effective medication use. A pharmacist is a member of the health care team directly involved with patient care. Pharmacists undergo university-level education to understand the biochemical mechanisms and actions of drugs, drug uses, therapeutic roles, side effects, potential drug interactions, and monitoring parameters. This is mated to anatomy, physiology, and pathophysiology. Pharmacists interpret and communicate this specialized knowledge to patients, physicians, and other health care providers. Among other licensing requirements, different countries require pharmacists to hold either a, Master of Pharmacy, or Doctor of Pharmacy degree.

The most common pharmacist positions are that of a community pharmacist (also referred to as a retail pharmacist, first-line pharmacist or dispensing chemist), or a hospital pharmacist, where they instruct and counsel on the proper use and adverse effects of medically prescribed drugs and medicines. In most countries, the profession is subject to professional regulation. Depending on the legal scope of practice, pharmacists may contribute to prescribing (also referred to as "pharmacist prescriber") and administering certain medications (e.g., immunizations) in some jurisdictions. Pharmacists may also practice in a variety of other settings, including industry, wholesaling, research, academia, military, and government.

In this research, the scientists are not taken in the ordinary sense as prescribed above. Since this research is about the Competition Act and Health care, the Pharmacists are the important stakeholders. Normally the pharmaceutical products are invented by the Pharmacists. The above definition clearly reveals that the people who are experts in their field either in practical or theoretical aspects are considered as scientists. In this research, the person who acquires Master’s Degree in Pharmacy or acquired Ph.D after their master’s degree is considered as Pharmacists. These scientists are involved in the inventive process of inventing Pharmaceutical products. Therefore the ‘scientists’ in this research refers to the “Pharmacists”. Wherever the term ‘Scientist’ is used in this research it means and refers to the term Pharmacists and hence they are taken as a stakeholder in this research.
Pharmaceutical Manufacturers

The expression Manufacturer is defined in S. 2(1)(j) of the Consumer Protection Act, 1986

"manufacturer"²⁴ means a person who—

(i) makes or manufactures any goods or parts thereof; or

(ii) does not make or manufacture any goods but assembles parts thereof made or manufactured by others; or

(iii) puts or causes to be put his own mark on any goods made or manufactured by any other manufacturer."²⁵

Further the term "manufacturer" means any person who manufactures a drug under Drugs (Price control) Order, 1995²⁶ and the Order also defines the term ‘manufacture,’²⁷ “in these words, in relation to any drug, includes any process or part of a process for making, altering, finishing, packing, labeling, breaking or otherwise treating or adapting any drug with a view to its sale and distribution, but does not include the compounding or dispensing of any drug or the packing of any drug in the ordinary course of retail business, and "to manufacture" shall be construed accordingly.”²⁸

The expression ‘manufacturing process’ is defined in S. 2(k) of the Factories Act, 1948.²⁹ For the purpose of the present research the term manufacturers of

---

²⁴ Subs. by Act 62 of 2002, S. 2 (w.e.f. 15-3-2003). Prior to substitution it read: "(j) 'manufacturer' means a person who—

i) makes or manufactures any goods or parts thereof; or

(ii) does not make or manufacture any goods but assembles parts thereof made or manufactured by others and claims the end product to be goods manufactured by himself; or

(iii) puts or causes to be put his own mark on any goods made or manufactured by any other manufacturer and claims such goods to be goods made or manufactured by himself"

²⁵ Explanation-Where a manufacturer despatches any goods or part thereof to any branch office maintained by him, such branch office shall not be deemed to be the manufacturer even though the parts so despatched to it are assembled at such branch office and are sold or distributed from such branch office;

²⁶ Section 2 (m) of Drugs (Price control ) Order, 1995

²⁷ Section 2 (l) of Drugs (Price control ) Order, 1995


²⁹ ‘Manufacturing process’ means any process for

(i) Making… altering, repairing, ornamenting, finishing, packing, filling, washing, cleaning, breaking up, demolishing or otherwise treating or adopting any article or substance with a view to its use, sale, transport, delivering or disposal or

(ii) pumping oil, water, sewage, or any other substance or
medicines and drugs is defined to mean and include any person who involves, owns or controls the process of making, finishing, packing, filling medicinal substances for the purpose of curing diseases or to improve the health of human beings. In the definition of manufacturing process of the Factories Act, clause viii also includes processing of medicines and drugs.

But in this research, the Manufacturers are not taken in the ordinary sense as prescribed in the Consumer Protection Act, 1986. Since this research is about the Pharmaceutical Patents, the Manufactures are the important stakeholders. Normally the Pharmaceutical products are manufactured by the Pharmaceutical manufacturers to the patients or those who used to get consultation from doctors for their ailments. Therefore the ‘manufacturer’ in this research refers to the “Pharmaceutical manufacturers”. Wherever the term ‘manufacturers’ are used in this research it means and refers to the term Pharmaceutical manufacturer and hence they are taken as a stakeholder in this research.

**Medical Practitioners**

According to section 2(f) of the Pharmacy Act, 1948 "medical practitioner" means a person ---

(i) holding a qualification granted by an authority specified or notified under section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916), or specified in the Schedules to the Indian Medical Council Act. 1956 (102 of 1956); or

(ii) registered or eligible for registration in a medical register of a State meant for the registration of persons practicing the modern scientific system of medicine; or

(iii) registered in a medical register of a State, who, although not falling within sub-clause (i) or sub-clause

(ii) is declared by a general or special order made by the State Government in this behalf as a person practicing the modern scientific system of medicine for the purposes of this Act; or

---

30 Subs. by Pharmacy (Amendment) Act 1959 (24 of 1959), sec. 3, for clause (f) (w.e.f 1-5-1960).
(iv) registered or eligible for registration in the register of dentists for a State under the Dentists Act, 1948 (16 of 1948); or

(v) who is engaged in the practice of veterinary medicine and who possesses qualifications approved by the State Government. ³¹ For this research the medical practitioners are otherwise called as “Doctors”. Therefore wherever the term ‘Doctor’ is used in this research it represents and means the term Medical Practitioners’. This definition does not include doctors who are dentists and doctors who are veterinary medicine Practitioners

Drugs and medicines

The definition of 'drugs' is an inclusive one. In Langamurti v. State of Orissa, drugs are defined to include all medicines for external or internal use of human beings or animals or any substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases in human beings or animals. ³² This definition is based on the definition of section 3(b) of Drugs and Cosmetics Act,1940. Accordingly “Drugs”³³ means and includes—

(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;³⁴

(ii) such substances (other than food) intended to affect the structure or any function of human body or intended to be used for the destruction of (vermin) or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette³⁵

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human

³¹ http://www.ipapharma.org/pdf/Pharmacy_act_1948.pdf visited on 17.06 2014
³³ Subs. by Act 11 of 1955, s. 2, for clause. (b).
³⁵ Amended as per Act 68 of 1982 (w.e.f. 01-02-1983)
beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.\(^{36}\)

**Consumer**

The primary purpose of the definition is to restrict the availability of consumer remedies to consumers only. The method adopted is to confine the Act to non-business buyers from business sellers. The definition is as follows:

“Consumer”\(^{37}\) means any person who,—

(i) buys any goods for a consideration which has been paid or promised or partly paid and partly promised, or under any system of deferred payment and includes any user of such goods other than the person who buys such goods for consideration paid or promised or partly paid or partly promised, or under any system of deferred payment when such use is made with the approval of such person, but does not include a person who obtains such goods for resale or for any commercial purpose; or

(ii) hires or avails of any services for a consideration which has been paid or promised or partly paid and partly promised, or under any system of deferred payment and includes any beneficiary of such services other than the person who hires or avails of the services for consideration paid or promised, or partly paid and partly promised, or under any system of deferred payment, when such services are availed of with the approval of the first mentioned person but does not include a person who avails of such services for any commercial purpose.”\(^{38}\)

But in this research the consumers are not taken in the ordinary sense as prescribed in the Consumer Protection Act, 1986. Since this research is about the health care, the consumers are the end users. Normally the Pharmaceutical products are consumed by the patients or those who get consultation from doctors for their ailments. Therefore the ‘consumers’ in this research refers to the “patients”. Wherever the term ‘consumers’ are used in this research, it means and refers to the term patients and hence the patients who are taken as stakeholders in this research are consumers in this study.

---

\(^{36}\) [http://cdsco.nic.in/html/copy%20of%201.%20d&cact121.pdf](http://cdsco.nic.in/html/copy%20of%201.%20d&cact121.pdf) visited on 18.06.2014

\(^{37}\) Section 2 (f) of Competition Act, 2002 & Section 2(1)(d) of Consumer Protection Act, 1986

\(^{38}\) Explanation.—For the purposes of this clause, “commercial purpose” does not include use by a person of goods bought and used by him and services availed by him exclusively for the purposes of earning his livelihood by means of self-employment;
1.6 REVIEW OF LITERATURE

The review of the literature for this study focuses on procedures used to identify anti-competitive and collusive practices in the health care sector and to protect the rights of the Patients/Consumers and what effect a inter relationship existing between the Competition Act 2002 and Consumer Protection Act 1986. The review focuses to identify anti-competitive practices in Health care sector. The chapter begins with a definition of Competition Act 2002, followed by the findings of researchers using questionnaire. The research outcomes the impact of Competition Act and Consumer Protection Act to ensure to prevent anti-competitive and collusive practices in the health care sector and to protect the rights of the Patients/Consumers are discussed.

The sources of law pertinent to the field of Competition Act 2002 in the form of juristic works are, by no account, rich in India. In this part books, articles, journals, dissertation, notes and reviews made by jurists, authors, and scholars are analyzed to find out the gap in the existing literature on the topic ‘Competition Act on Health care Sector Doctor, Consumer/Patients, Manufacturer and Pharmacists perspectives.

Literature was reviewed using books and book reviews from the electronic search engines Google scholars are as follows:

**Competition Act, 2002 - Principles & Practices**, this book presents a systematic, up-to-date, exhaustive commentary on the competition Act, 2002. the provisions of the Act have been subjected to intensive and comprehensive analysis. This book never analysis about the Competition Act on health care sector.39

**Competition Law of India** this book contains Competition Commission of India (Selection of Chairperson & Other Members of the Commission) Rules, 2003 Competition Commission of India (Salary, Allowances and other Terms and Conditions of Service of Chairperson and other Members) Rules, 2003 Competition Commission of India (Return of Measures for Promotion of Competition Advocacy, Awareness & Training on Competition Issue) Rules, 2003 Competition Commission of India (Form and Time of Preparation of Annual Report) Rules, 2003 Competition Commission of India (Form of Annual Statement of Accounts) Rules, 2009 Competition Commission of India (General) Regulations, 2009 Competition Commission of India (Lesser Penalty) Regulations, 2009 Competition Commission of India (Determination of Cost


**A guide to Competition Law in India (Competition Act 2002)** this book being a comprehensive guide on the new Competition Act, 2002, which seeks to check anti-competitive practices and abuse of dominance by corporate houses and companies. It studies in detail the law of monopolies and competition in India, Report of the High Level Committee, Competition Policy, Competition Act of UK, conclusions of law in Microsoft Case, etc but never emphasis the impact of the Competition Act on health care sector regime.

Taxman’s **A guide to Competition Law** this book is a Chart Showing Enforcement Of Provisions Of Competition Act, 2002 From Different Dates Competition Act, 2002, As Amended By Competition (AMDT) Act, 2007 (Enforced From Various Dates) Notifications Issued Under Competition Act, 2002 Competition Commission Of India (General) Regulations, 2000 Competition Commission Of India (Meeting For Transaction Of Business) Regulations, 2009 Competition Commission Of India (Procedure For Engagement Of Experts And Professionals) Regulations, 2009 Other Relevant Rules Covering Competition Commission Of India/Competition Appellate Tribunal. This book has emphasised various components incorporating the Practical Commentary Of Competition Act, 2002 never emphasis the health care perspectives or Medicine.

The sources of law pertaining Competition Act 2002 and its impact on health care sector. A good piece of literature on the research subject is available in Competition Law by Dr. Avatar Sing’s authored and comprehensive new work which analyses the Competition Act 2002 and its impact on Competition consumer and society.

After the enactment of the Competition Act 2002, a number of books and research articles were published mainly focusing on the evolution of law and its scope. Among them following are worth mentioning. The book authored by T. Ramappa entitled “Competition law in India” Policy, issues and developments makes a detailed

---

study of key issues include anti-Competitive agreements abuse of dominant position and combinations undertakes only a comparative study of Competition law in the US and UK and not concerned the functioning of health care sector.

Suresh T. Viswanathan’s 2003 book “Law and Practices of Compensation Act 2002” was reviewed which discuss only the international thought on Competition with special relevance to Competition Act 2002, in which no attempt has been made to focus on Pharmaceutical and Health care sector.

The book Competition law in India authored by Abir Roy and Jayantkumar, Eastern law house 2008 was reviewed which analyses the roles of Competition Commission of India in enforcing the provisions of the Act but not the Act concerning the health care sector.

Diego Fornaciari in International Journal of Environmental Research and Public health 2010 in his paper “quality health care in the European Union thanks to Competition law” emphasis the health care in reference to competition law in European Union, a comparative study has been made with India.

The article “ Five reasons why health care quality research hasn’t affected Competition law and Policy by David A. Hyman has highlighted only five specific barriers and overcome these translation barriers on which anti-Competitive and unfair trade practices has no analysed.

The article “Competition law and Anti Competition Professional behavior affecting health care” by Frances Miller pointed out only the existing Competition law could be extremely useful in deterring anti competitive activity detrimental to the health sector in UK. The present study has attempted to study anti-competitive practices in India.

The article Competition law in Medical Services and the quality of care, Concepts and history by Mark V. Pauley has reviews the concept of optional quality in medical care from an economic view point and no attempt has made how far the Competition law on health care sector

---

The article titled “A Consumer perspectives on the Pro’s and Con’s of anti-trust enforcement in health care by John D. Blurm has focused on health care anti-trust and medical consumerism generally and no attempt has made to anti competitive practices in health care sector and Pharmaceutical firms.

India: Revisiting The Competition Act, 2002- Introduction Of The New Competition (Amendment) Bill, 2012 this article concludes that, the Bill is a step in right direction by the Central Government to bring the competition law regime in our country at par with that of other jurisdictions. However, the Bill still fails to address certain key issues under the Act and has primarily looked into the procedural aspects. This article has analysed lot of concepts such as treatment of joint ventures, leniency policy etc. under the Act still remain unclear and require more clarity. This article never analysis the health care perspectives.

India: Indian Competition Act: An Overview, this article, This article explains that evolution of the Competition Act 2002 and a comparison exists between the MRTP Act 1969. Further this article highlights more on the Competition Act 2002 rather concentrating the Anti-Competitive Practises and Collusive Practises in the health care sector.

Application of the Competition Act 1998 in the healthcare sector: guidance for providers, this article emphasis the Choice and competition are governed by specific rules in Competition Act 1998 and Competition Law in England. The researcher has identified the gap exists between the Competition and choices in India.

The Law of Intellectual property (2009) by DR.S.R.Myneni is an excellent book. The author in his book focused on national and international aspects of Intellectual property. The approach followed by the author is to discuss international law on the area first and then deal with the corresponding national law. This helps the

---

43 Article entitled 12-Loyala Consumer Law Review Volume 8 /Issue 2 John D. Blurm, Associate Dean for Health law Loyala University ,Chicago.
44 Article by Payel Chatterjee, Shashank Gautam and Simone Reis Nishith Desai Associates ast Updated: 28 February 2013
45 Article entitled India: Indian Competition Act: An Overview by Rajkumar Dubey Last Updated: 27 July 2005
46 Monitor, Making health care work for Patients,Monitor, Wellington House, 133-155 Waterloo Road, London, SE1 8UG
researcher to understand the implication of each provision in a global background and also to identify areas of harmony and divergence at the national level.

**Medicine, Patients and the Law** (2007)\(^{48}\) by Margaret Brazier and Emma Cave The authors in this book highlight the relationship between the doctors and the patients both the frame work of that relationship and how the law deals with conflicts when a patient is dissatisfied with the care that he received. It also looks at a pertinent question in medical law, where it is argued that it is not only what an individual patient may be entitled but also what a society should also need. The author also focused on medical negligence aspect and it is not strongly focused on liability of a medical practitioner.

**Law of Torts and Consumers**, (2008)\(^{49}\) by S.R. Myneni. This book predominantly concentrates on law of torts. The author in this book highlights the civil wrongs from the consumers perspective. As a consumer every one faces many problems due to wrongs done to them. It is the duty of the State to provide protection to the consumer. In this book the liability of the manufacturers are discussed but not about the Pharmaceutical manufacturers. This book also covers torts relating to intellectual property i.e. Trade Mark, Patents and Copy rights. It highlights the remedies for the infringement of Intellectual Properties more particularly Trademark, Patents, Copy rights and has not touched Pharmaceutical Patents.


---

\(^{48}\) Margaret Brazier and Emma Cave, *Medicine, Patients and the Law*, 4\(^{th}\) edition, Lexis Nexis, Butterworths, New Delhi, India (2007)


\(^{50}\) Feroz Ali Khader, *The Law of Patents – with Special Focus on Pharmaceuticals in India*, Lexis Nexis Butterworths, New Delhi, India (2007)

Law of Consumer Protection (2005)\textsuperscript{52} is by DR.G.B. Reddy. The author in this book has discussed and analysed the Consumer Protection Act, 1986. In this book the author has made an earnest attempt to trace the origin, evolution and growth of consumer movement with special reference to India. It contains relevant extracts from a number of legislations having a bearing on consumer protection but not relevant to the attitude of the consumers towards Patents in general and Pharmaceutical Patents in particular.

Law Relating to Intellectual Property Rights (2007)\textsuperscript{53} by V.K. Ahuja. This book enlightens the readers about the I.P.R. with relevance to the TRIPS agreement. The TRIPS agreement opened a new era in the field of IPR. It evolved minimum standard for Copyrights, Patent, Trademarks etc. This book highlighted and analysed the existing law of I.P.R. in India and also discussed the knowhow and licences to give an overall picture of the law on I.P.R.

The article “Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector” by A.M.Y Kapczynski, December, 2009 California Law Review, is an empirical case study relating to the Indian pharmaceutical sector in pursuance of product patent regime arising out of TRIPS agreement. The author hails the development of generic drug industry in the country. He appreciates the crafting of the Indian Patent Act in general and provisions relating to the efficacy, traditional knowledge and disclosure of the geographical origin of biological material in the patent application in material. He advises the patent

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{53} V.K. Ahuja, \textit{Law Relating to Intellectual Property Rights}, Lexis Nexis Butterworths, New Delhi, India (2007)
\end{itemize}
\end{footnotesize}
examiners in India not to blindly follow U.S and E.U decisions relating to PCT applications.

The Modern Law of Patents (2005)\textsuperscript{54} by Fysh, is an edited volume and it is an important book to guide in the law of Patents. This book identified the gap in existing texts and then attempting to fill the gap. This book discusses recent series of cases emerging from the House of Lords. It explains and points out the infringement of patents at the international level. The author in this book restrained from expressing any view about exception to patentability. Seventh chapter in this book titled Pharmaceutical: first and second medical use ‘claims’, it discussed about pharmaceutical claims on patents aspect, but has not focused on Patents with reference to consumer aspect of Pharmaceutical Patents.

Intellectual Property Law in India (2010)\textsuperscript{55} by Justice.P.S.Narayana is about the enactments dealing with Patents Law, Trademark, Copyrights and Designs Act. This book discusses the recent changes in the field of Intellectual Property with reference to Indian scenario. The author in this book has taken care to discuss the recent case laws of different High Courts and Supreme Court in India. Further relevant discussion is also incorporated relating to the amendment of the enactment and the rules framed by the government of India. The author has highlighted only on general aspects and does not deal with Pharmaceutical Patents or on the aspect of consumers.

Medicinal Product Liability and Regulations (2013)\textsuperscript{56} authored by Richard Goldberg in the recent time the world is very much concerned about the health care. The author in his book traced the liability over the medicinal product as well as the regulations. The author emphasize the multitude of a new drugs continue to emerge as new technologies such as genomics become more significant in drug discovery, fresh drug safety problems arise. Medicinal products, more than any other type of product, continue to exemplify the scientific uncertainty. The author at the same time highlights the importance of the development of the drug industry at worldwide. This book is partly relevant to this research.

\textsuperscript{54} Fysh, The Modern Law of Patents, Lexis Nexis, Butterworths, New Delhi, India (2005)
\textsuperscript{55} P.S.Narayana, Intellectual Property Law in India, 3\textsuperscript{rd} edition, K.C.Gogia publications, Hyderabad, India (2010)
\textsuperscript{56} Richard Goldberg, Medicinal Product Liability and Regulation, Hart Publication, Oxford and Portland,Oregon (2013)
All the above mentioned jurists works taken as a whole archaic for the purpose of meeting the objectives of Competition policy and lose relevance in the light of Competition Act its impact on health care sector, because the spirit of law behind these rulings has drastically changed and witness a service of new judgments in times to come. The review of the existing literature on Competition Act reveals that no effective study has been made so far to trace out the link between the Impact of Competition Act on health care sector. In the sphere of health care its need for the Country has to be focused to prevent the anti-Competitive practices exists in Pharmaceutical industry. But no attempt is made to study whether a Competition Act 2002 can bring the desired preventive measures in the Health care in India. It is obvious that there exists direct nexus between the Competition Act and Health care sector and the present research is directed towards that end. The above review of literature reveals that the majority of the works are confined to general principles and procedural aspects of Competition Act and relating to Health Care sector. Majority of the authors in their books, articles and journals are confined with the legal aspect of IPR at the national and international level. No book or research work appears to have been carried out on the topic chosen by the researcher. Though a few authors and researchers have carried out research on the legislative frame work and legal system requirements on Competition Law jurisprudence, they are related to general perspective and the area need further study with reference to the latest trend and development of Competition Act and health Care sector. Hence the research has taken up this unique topic to fill the lacuna.

1.7 RESEARCH METHODOLOGY

The researcher has adopted both doctrinal and non-doctrinal approach. Field work has been undertaken. Historical method is employed to trace out the object for the enactment of Competition Act instead of MRTP Act. Analytical method is used to analyze the nature of competition in the medical field and anti-competitive practices prevailing in this sector. The researcher has also applied Comparative method to compare the various competition/anti-trust legislation prevailed at the international level (U.K, U.S.A and EU).

The researcher has undertaken an empirical approach for otherwise without a field study anything suggested or observed in this particular topic will only provide a bird’s eye view and not a full-fledged view of the legal issues that are involved.
It analyses the attitude of Scientists, Manufacturers, Doctors and Consumers. To obtain the views of Scientists, Manufacturers, Doctors and Consumers regarding their views, survey was conducted for the four different stakeholders. Coimbatore is taken for the study. There are different phases in the research. First phase was related to selection of samples of various stakeholders. Second phase was related to framing of questionnaires. These questionnaires' nature, content and number of questions varied from stakeholder to stakeholder. Third phase was related to administering of questionnaires to various stakeholders. The researcher himself individually approached, administered and collected the questionnaires. The fourth phase codification of the collected questionnaire on the basis of 3 point scale and the classification of various independent variables of stakeholders were undertaken. Quantification and tabulation were done in the fifth phase. Finally in the sixth phase application of appropriate data analyzing techniques to the data collected, classified and tabulated was made. Findings are represented in the form of tables and diagrams including Pie Diagram and Bar Diagram.

Selection of Samples of the Stakeholders

The samples are selected from various stakeholders namely Pharmacists, Manufacturers, Doctors and Consumers. Consumer patients have been selected randomly throughout District of Coimbatore. 550 consumers have been selected and questionnaires were administered to them personally. From among 550 questionnaires, 50 questionnaires were rejected due to various reasons and 500 eligible questionnaires have been taken for this study. It consists of close ended questions which deal with dependent variables, whereas the socio economic and other related variables of respondents are independent variables which are structured at the beginning of the questions. The number of questions, nature of questions, content of questions and the socio-economic background of the respondents are different. Hence distinct and separate Questionnaires were framed for the stakeholder.

Doctors have been selected randomly throughout District of Coimbatore. The researcher has limited the survey within the urban and semi-urban area of District of Coimbatore. The researcher has circulated the questionnaire to 126 respondents throughout District of Coimbatore. 126 doctors have been selected and questionnaires were administered to them personally. From the received 126 questionnaires, 26 questionnaires were rejected due to various reasons and 100 eligible questionnaires
have been taken for this study. It consists of close ended questions which deal with dependent variables, whereas the socio economic and other related variables of respondents are independent variables which are structured at the beginning of the questionnaire.

Pharmacists should have enrolled themselves with Pharmacy Council. Pharmacists have been selected randomly throughout District of Coimbatore. From across the District of Coimbatore 50 Pharmacists were selected and questionnaires were administered to them personally. The questionnaire consists of close ended questions which deal with dependent variables, whereas the socio economic and other related variables of respondents are independent variables which are structured at the beginning of the questions.

The list of pharmaceutical manufacturers in Coimbatore has been collected from The Tamil Nadu Pharmaceutical Manufacturers’ Association, Chennai. Questionnaires were administered by post and by courier service to all the 24 companies. After several difficulties only 22 companies were responded by returning the filled in questions. Of which 2 questionnaires were incomplete and so were eliminated. The remaining 20 respondents have been taken in to consideration. The remaining companies did not respond and they also avoided the researcher from approaching them. The questionnaire administered to the pharmaceutical manufacturers consists of close ended questions which deal with dependent variables, whereas the socio economic and other related variables of respondents are independent variables which are structured at the beginning of the questionnaire.

**Framing of Questionnaires**

The Questionnaires were framed so as to apply scaling technique for the purpose of quantifying the dependent variables. Likewise various independent variables were listed out and such independent variables were quantitative in nature and hence they were classified based on certain objectives and justifiable norms of classification. However the number of independent variables and the classification of each independent variables varies from stakeholder to stakeholder. Some of the independent variables are the same in all the stakeholders but the classification varied based on the requirement of the study.

The dependent variable is common for all the stakeholders. It consist of three components i.e. knowledge, involvement and assessment. But the number of questions
for the measurement of dependent variable ‘attitude’ varies from stakeholder to stakeholder. Since attitude is the common dependent variable and knowledge, involvement and assessment are the common components of attitude, the legal provision on which the attitude of stakeholders is measured and quantified varies. In the case of scientists, attitude is analysed predominantly on Competition Act. With reference to manufacturers, it is related to Pharmacy Act, Drugs and Cosmetics Act, Drugs (Price control) Order besides Competition Act. In the case of doctors, their attitude is measured in terms of their attitude towards Competition Act, Consumer Protection Act, Indian Medical Council Act, Medical Practitioners (Code of ethics) Rule and Medical Product Liability.

**Classification of Independent Variables**

**Independent and Dependent variables of Consumers**

The independent variables are listed in the Questionnaire which is framed, administered and collected from consumers/Patients.

1. **Age** : Below 35 years, 35-45 years, above 45 years.
2. **Sex** : Male / Female.
6. **Marital Status** : Married, Unmarried.
8. **Family Members** : 2 members, members, 3 members, 4 & 5 members.

**Independent variables of Doctors**

The independent variables are listed as below in the Questionnaire which is framed, administered and collected from doctors.

1. **Age group in year** : Below 35 years, 36-45 years, 46-55 years, Above 55 years.
2. **Sex** : Male / Female.
3. **Educational Qualification** : M.B.B.S, MD / MS.
4. Residence : Urban & Semi-urban
5. Number of years of Practice : Below 5 yrs, 6 – 10 yrs, 11 – 15 yrs, 16 and above.
6. Number of patients given : below 25, 25 to 50.
   Consultation per day
7. Number of medical representatives met in a day : below 3, 4 to 6, 7 & above.

**Independent variables of Pharmaceutical Manufacturers**

The independent variables are listed as below in the Questionnaire which is framed, administered and collected from Pharmaceutical Manufacturers

1. Age : Below 35 yrs, 36 & Above.
2. Educational Qualification : UG & PG.
3. Length of Experience in the field : Below 5 years, 6-10 years and 11 & Above
5. Size of the Pharmaceutical company : Small, Medium & Large
6. Position with reference to R & D : R & D available, R & D not available.

**Independent Variables of Pharmacists**

The independent variables are listed as below in the Questionnaire which is framed, administered and collected from scientists

1. Age : below 35 years, 35- 45 years, above 46 Years.
2. Religion : Hindu / Muslim / Christian.
3. Educational Qualification : M.Pharm and M.Pharm with Ph.D.
4. Experience in field of Pharmaceutical Industry : Below 5, 6 -10, 11 – 20, Above 20

**Codification and Quantification**

Different attitudinal components necessitated the researcher to frame questionnaire differently taking into consideration different components and questions
of independent and dependent variables. The following are the structure and component of independent and dependent variables of different stakeholders.

Attitude is the dependent variable which is measured, quantified and classified. Attitude of the scientists consist of 3 components namely knowledge, involvement and assessment. Totally 20 questions were framed, administered, collected and quantified. For the purpose of quantification 3 point scaling technique was applied and values are given as 0, 1 and 2. This scaling technique is uniform for all the stakeholders to quantify their attitude. This scaling was also applied to the following answers respectively not known, partly known and well known, of which knowledge and involvement have 28 questions and assessment has 06 questions. After quantification, attitude was measured and the means and standard deviation of attitude of variants categorized and analysed for the respondents who scored 0 to 2 in each question. The quantified data was summed up and the means and standard deviation of the classified independent variables were found out and analysed. For instance in the case of scientists age has 3 classifications like ‘below 35 years’, ‘35- 50 years’ and ‘above 50 years’. Their respective means and standard deviation have been computed for the analysis.

Attitude is the dependent variable which is measured, quantified and classified. Attitude of the manufacturer consists of 3 components namely knowledge, involvement and assessment. Totally 24 questions were framed, administered, collected and quantified. For the purpose of quantification, 3 point scaling technique was applied and values are given as 0, 1 and 2. This scaling technique was uniform for all the stakeholders to quantify their attitude. This scaling was applied to the following answers respectively ‘not known’, ‘partly known’ and ‘well known’, of which knowledge has 11 questions, involvement has 07 questions and assessment has 06 questions. After quantification, attitude was measured and the means and standard deviation of attitude of variants categorized and analysed for the respondents who scored 0 to 2 in each question. The quantified data was summed up and the means and standard deviation of the classified independent variables have been found out and analysed. For instance in the case of manufacturers number of years in the field has 3 classifications like ‘below 5 years’, ‘05- 15 years’ and ‘above 15 years’. Their respective means and standard deviation were computed for the analysis.
Attitude is the dependent variable which was measured, quantified and classified. Attitude of the doctors consists of 3 components namely knowledge, involvement and assessment. Totally 31 questions were framed, administered, collected and quantified. For the purpose of quantification, 3 point scaling technique was applied and values were given as 0, 1 and 2. This scaling technique was uniform for all the stakeholders to quantify their attitude. This scaling was applied to the following answers respectively ‘not known’, ‘partly known’ and ‘well known’, of which knowledge has 15 questions, involvement has 06 questions and assessment has 10 questions. After quantification, attitude was measured and the means and standard deviation of attitude of variants categorized and analysed for the respondents who scored 0 to 2 in each question. The quantified data was summed up and the means and standard deviation of the classified independent variables have been found out and analysed. For instance in the case of doctors, Age group in years has 4 classifications like ‘below 35 years’, ‘36-45 years’, ‘46-55 years’ and ‘above 55 years’. Their respective means and standard deviation have been computed for the analysis.

Attitude is the dependent variable which is measured, quantified and classified. Attitude of the consumers consists of 3 components namely knowledge, involvement and assessment. Totally 30 questions were framed, administered, collected and quantified. For the purpose of quantification 3 point scaling technique was applied and values were given as 0, 1 and 2. This scaling technique is uniform for all the stakeholders to quantify their attitude. This scaling is applied to the following answers respectively ‘not known’, ‘partly known’ and ‘well known’, of which knowledge has 24 questions, involvement has 09 questions and assessment has 07 questions. After quantification, attitude was measured and the means and standard deviation of attitude of variants categorized and analysed for the respondents who scored 0 to 2 in each question. The quantified data was summed up and the means and standard deviation of the classified independent variables are found out and analysed. For instance in the case of doctors Age group in years has 3 classifications like ‘below 35 years’, ‘35-45 years’, and ‘above 45 years’. Their respective means and standard deviation are computed for the analysis.

**Tabulation**

Collection of Data is an important one in the empirical research. It consists of classification, tabulation, quantification, analysis and interpretation. Four different
questionnaires have been structured and prepared for four different stakeholders in this research and due care has been taken in collection of data for reaching to a valid and statistically authentic result. For scientists, doctors and consumers, they have been selected and questionnaires were administered to them personally. As far as manufacturers were concerned the researcher adopted the mailed questionnaire method. The researcher sent the questionnaires to the manufacturers by post and by courier services with return covers.

Data Analyzing Techniques

In order to analyse the data, SPSS 17.0 version (Statistical Package for Social Studies) has been used. It is the popular data analyzing package in India for years together. By using this software the collected data was classified categorically and analysed, measured, quantified and calculated. Based on the data collected and classified the hypotheses have been tested. In order to arrive at calculated values, the following data analyzing tools have been used. They are as follows:

Means and Standard Deviation (SD)

Throughout the quantitative analysis, in this research, statistical means and standard deviation have been calculated. These are useful to find the central tendency or the average scored by various independent variables with reference to the level of attitude. These means indicate the level of attitude of various stakeholders based on their independent variables. Statistically standard deviation indicates the level of homogeneity or heterogeneity of the group. These statistical means and standard deviation are of immense use in testing the hypotheses.

$t$-test

In a statistical examination of two population means, a two-sample $t$-test examines whether two samples are different and is commonly used when the variances of two normal distributions are unknown and when an experiment uses a small sample size. This data analyzing technique is used to test the significant difference between population mean and sample mean when sample size is small and population variance is not known. This technique was used in this research. Totally 26 sub-hypotheses have been tested by using this technique in this research.

$t$-test was applied to the test of the significance of mean in the context of standard deviation. Accordingly, this test enables the researcher to find out whether means of two different groups belong to the same population or different populations.
In this research population is same but the independent variables are classified into two or more groups. When the means of two or more groups differ significantly it implies that there are influences on the groups. At times small variation of the means may be due to diversity (heterogeneity) of population. t-test provides mechanism whereby probability of errors due to accidental influence is avoided and thereby after calculation P-value is evolved. P-value means percentile value. Percentile means percentage. Accordingly 1% and 5% may be given for errors. If P-value is significant at 1% it implies that there is a better substantial significant the means. Where as if the P-value is significant it also implies that there is a difference between these groups only at 5% error level. Therefore significant at 1% level is always better than at 5% level with reference to t-test.

**One Way ANOVA test**

Analysis of variance is popularly known as ANOVA. Variance refers to “A measurement of the spread between numbers in a data set. The variance measures how far each number in the set is from the mean. Variance is calculated by taking the differences between each number in the set and the mean, squaring the differences (to make them positive) and dividing the sum of the squares by the number of values in the set.” Variance is used in statistics for probability distribution. Since variance measures the variability (volatility) from an average or mean, and volatility is a measure of risk. Statisticians use variance to see how individual numbers relate to each other within a data set, rather than using broader mathematical techniques such as arranging numbers into quartiles. Sir Ronald Aylmer Fisher used the term variance for the first time and gave this important technique. Analysis of variance is defined by him in these words “the separation of variance ascribed to one group of case from variance ascribed to other group.” The analysis of variance is essentially a procedure for testing the difference between different groups of data for homogeneity. Thus, ANOVA is a kind of statistical data analyzing technique which is used to find out the significance difference between mean of two or more samples in this research.

---

58  *Ibid*
59  *Ibid*
all sub-hypotheses in this research there are 16 sub-hypotheses that have been tested by using ANOVA test.

**Chi-Square test**

It is a non-parametric test. This technique is used to find out the significance of difference between observed and expected values. Karl Pearson developed a non-parametric test otherwise called Chi-Square test of Goodness of fit (for one way classification or for one variance) for testing the significance of the discrepancy between experimental frequencies and the theoretical frequencies obtained under some theory or hypothesis and is used in this research to test the hypotheses in the fifth and sixth chapters. The level of attitude of doctors and consumers have been tested by using Chi-Square technique to find out whether there is any association between two the variables that is the independent and dependent variables. It is known as test of independence.

**Pearson Correlation Co-efficient test**

Product Moment or Co-Variance or Pearson’s method was introduced by Kerl Pearson a noted British Biometrician and Statistician who developed a mathematical method for measuring the intensity or magnitude of linear relationship between two variables which is called as Co-efficient of correlation. Therefore it is named as “Pearson Correlation Coefficient.” The variables are measured based upon the arithmetic mean and standard deviation. According to him “the correlation coefficient of two variables is obtaining by dividing the sum of the products of corresponding deviation of various items of two series from their respective means by the product of their standard deviation and the number of pairs of observation.” In other words, its calculation is based upon the covariance of the concerned variables.

Pearson’s Correlation Co-efficient between two variables X and Y usually denoted by r(X,Y) or simply ‘r’ is a numeral measure of linear relationship and is defined as the relationship of the convenience between X and Y to the product of standard deviation of X and Y. This technique has been used in this research to find out the relationship between different sets of variables. This technique has been used to analyse the attitudinal levels of all stakeholders.

**Regression Analysis**

The literal or dictionary meaning of ‘Regression’ is ‘to avert’ or ‘return back’ or ‘moving backward, or ‘return to the mean value’. The term regression was first used by
British Biometrician Sir Francis Galton in 1887. M.M.Blair defines it in these words, “Regression is the measurement of average relationship between two or more variables in terms of original units of data.” From the above definition, it is clear that regression analysis is a statistical technique, which helps in unknown values of one dependent variable from known values of independent or explanatory variables. In most technical form, the independent variable is also known as regression or predictor or explanatory, while dependent variable is known as regressed or explained variable.

Regression is the determination of statistical relationship between two or more variables. In simple regression two variables are used. One variable (independent) is the cause of the behavior of another one (dependent). When there are more than two independent variables the analysis concerning relationship is known as multiple associations and the equation describing such relationship is called as the multiple regression equation.

Regression analysis is concerned with the derivation of an appropriate mathematical expression for finding values of a dependent variable on the basis of independent variable. It is thus designed to examine the relationship of a variable Y to a set of other variables X₁, X₂, X₃…………Xₙ. The most commonly used linear equation in Y=b₁ X₁ + b₂ X₂ +…….+  bₙ Xₙ + b₀

Here Y is the dependent variable, which is to be found. X₁, X₂,… and Xₙ are the known variables with which predictions are to be made and b₁, b₂ ,…..bₙ are coefficient of the variables. In this research this technique is used to test the hypotheses.

1.8 SOURCES OF DATA

The researcher has used primary and secondary data in the present study in order to interpret the above said problem. Under primary source of data, data from substantial and relevant authority has been availed. Similarly the data collected through Questionnaire form the primary source. Under the secondary source of data, the researcher has collected published data from multiple sources.

The modern electronic sources including internet and the data available in websites, newspapers, periodicals, have been utilized for the present research by the
current researcher. Apart from these the results analyzed from the responses of the respondents has also been incorporated in the relevant areas of this current research.

1.9 DELIMITATIONS

The present study is confined only to District of Coimbatore with reference to the views and opinions of the doctors, Consumers (patients) and Pharmacists. Consumers (Patients) evaluation about Competition issues on health care sector on the basis of their knowledge as to the above said research problem.

1.10 LIMITATION

In the study due to the apathy of manufacturers of very big firms, adequate number of respondents could not be studied in spite of repeated requests and reminders. In a country like India awareness of various stakeholders on Competition Act is very poor even among Pharmacists, pharmaceutical manufacturers and doctors many of them did not properly understand object effect of Competition Act. Similarly scheduled and non-scheduled medicines and drugs are important in pharmaceutical industry and business but due to clarity in classification neither the manufacturers nor the Pharmacists understand the differences. Hence reliable answers could not be obtained from them in these matters. Attitude is analysed in the context of knowledge, involvement and assessment. Knowledge refers to awareness. Whereas involvement refers to their participation and assessment implies their behavioral attitude in deciding their future course of action. However in this study attitude is predominantly relied on the awareness of stakeholders and their personal feeling of involvement and assessment. Involvement and assessment could not exactly reflect their active participation and actual evaluation. They meant only their knowledge of involvement and assessment. These are the limitations of the study.

1.11 PLAN OF THE STUDY:

The researcher has arranged the topic of the thesis in the following manner:

The First chapter is “Introduction”. In this chapter it covers the research problem, objective of the study, limitation of the study, review of literature, hypothesis and sub-hypothesis and various research methodologies adopted along with sources of research.

The Second Chapter is " Regulatory framework of the Competition Act 2002". In this chapter the evolution of Competition Act both at national and
International perspectives are discussed and analyzed. The history of the patent regime in pharmaceutical industry in India has crucially viewed.

The third Chapter is “Evolution of Competition Act on Health Care sector and Pharmaceutical Sector” In this chapter the background of the legislation in the Pharmaceutical Sector Competition Law and Competition Commission in India and its changing dynamics and future challenges has analyzed. The Regulatory web of the Pharmaceutical Sector in India its Implications for Ex-ante Competition in the light of experiences in comparative jurisdictions has also discussed and analyzed.

The fourth Chapter “Competition Act,2002 in comparison with the Anti trust Competition Laws in force in USA and European Union”. In this chapter the background of anti- trust laws in USA and European Countries has compared with the Competition Act 2002. The provisions and judicial pronouncements to prevent anti – competitive practices and measures taken to prevent the same has discussed and analysed.

The fifth Chapter “Significance of Competition Act 2002 and Consumer Protection Act in curbing the Anti – Competitive practice” In this chapter laws relating to Health professionals and their impact of Competition Act 2002 on this aspect is critically analyzed. In this chapter laws relating to consumers, Consumer Protection Act, 1986 and anti- competitive practices in health care sector, the views of consumers on this aspects is critically analysed. In this chapter impact of the e-consumers in respect of Competition Act 2002 and the role Medical transcription in affecting the Health Care Sector is also one of the current challenge is also analysed.

The Sixth Chapter “Assessment of Competition Act, 2002 on Patients, Doctors, Pharmacists and Manufacturers” In this chapter, the researcher has circulated the questionnaire throughout District of Coimbatore. The researcher limited the survey with in the South Indian Manchester town of Coimbatore. The researcher has tested the Patients (500 Samples), Doctor’s (100 Samples), Pharmacists (50 samples) and Pharmaceutical Manufacturer (20) in order to access their knowledge and assessment of the impact of Competition Act 2002 on health care sector. In this chapter the researcher proved the hypothesis that there is an association between the health professionals and Patients about the legal perception on Competition Act 2002 and their knowledge about Consumer Protection Act, 1986 and also tests their involvement to the above said laws.
The Seventh Chapter is "Conclusion". All the findings of the study and further suggestions including the suggestions for further research constitute the conclusion chapter.