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Competition Issues in the Pharmaceutical Sector and Right to Access to Medicine

Dissertation submitted in partial fulfilment of the requirements for the degree of LL.M.
Under the guidance of

Dr. Sairam Bhatt

Submitted By-Priya Vijay

LL.M Second Year (Business Laws)

ID No. 438

certificate

This is to certify that, this dissertation on the topic titled as "Competition Issues in Pharmaceutical Sector and right to access to medicine" submitted by Priya Vijay I.D. No. 438 in partial fulfillment of the degree of Master of Laws (LL.M.) for the academic year 2011-12, of the National Law School of India University, Bangalore is the product of the bona fide research carried out by her under my guidance and supervision.

Dr. Sairam Bhat

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Declaration

I, Priya Vijay, do hereby declare that this dissertation titled "Competition Issues in Pharmaceutical Sector and Right to Access to medicine" is the result of bona fide research undertaken by me in partial fulfilment of the LL.M. programme at the National Law School of India University (NLSIU), Bangalore, India under the guidance and supervision of Dr. Sairam Bhatt. I also declare that I have tried to use proper citation in my work.

Date: May 28, 2012

Place-NLSIU, Bangalore

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NLSIU, Bangalore

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Place: NLSIU, Bangalore

List of Cases

1. *Bharat Biotech Ltd. V. A.P. Health and Medical Housing and Infrastructure Development Cooperation.(2003 (1) ALD 463)*
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3. *Carter v. Wallace.*
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8. *N. D. Jayal v. Union of India (2004)9 SCC 362)*
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10. *US Vitamines v. Santuka Associates Pvt. Ltd*
11. *Vincent Panikurlangara v. Union of India, AIR 1987 SC 990*

List of Abbreviations-

AIOCD All India Organization of Chemists and Druggists

COPRA Consumer Protection Act

DCGI Drug Controller General of India

DOJ Department of Justice

DPCO Drug price Control Order

EC European Communities

ECC European Competition Commission

ECJ European Court of Justice

FERA Foreign Exchange Regulation Act

IPI Indian Pharmaceutical Industry

MCI Medical council of India

NPPA National Pharmaceutical Pricing Authority

NRHM National Rural Health Mission

UHC Universal Health Coverage

RESEARCH METHODOLOGY

OBJECT OF THE STUDY-

This research has been with the object of making a deep insight into interaction between Pharmaceutical sector and completion laws and policies and how and why such policies are affecting the Right to access to medicine of Indian Consumer. What is the impact of law governing the Indian Pharma sector and what does the Indian Competition law regime seeks to achieve.

In the light of the above objective various issues that has been identified by the researcher such as merger and Acquisition of Pharma companies and its impact upon right to access to medicine how does the existing competition promoting set up seeks to tackle the issue of ensuring free and fair competition in the sector. to reflect upon these issues this research work is dedicated. Further the issue of abuse of dominant position by big MNCs and excessive pricing has also been addressed.

RESEARCH QUESTIONS

1. What is the rationale behind regulation of Pharmaceutical sector in India from the perspective of Competition?
2. What is the current regulatory regime that influences competition in Pharmaceutical sector?
3. What are the competition issues in Pharmaceutical sector?
4. What does the Competition impact assessment of laws governing Pharma sector reflects?
5. How does competition in Pharma sector impacting consumer?

6. Whether there has been harmonisation between conflicting interests of compulsory licencing and right of patentee?
7. What has been implication of NATCO case and its impact on India?
8. The relation between drug price control regime and right to access to medicine?
9. What has been the impact of recent merger deals in Pharmaceutical sector?

HYPOTHESIS-

The researcher has started with the supposition that the current competition scenario in pharmaceutical sector in India is not competitive enough to ensure fair access to medicines vital to life. Further the law governing the sector is also not pro competition.

METHOD OF STUDY-

The researcher has relied upon descriptive and analytical method of study throughout her thesis.

RESEARCH MATERIALS-

The researcher has used primary sources such as books, statutes, reports, treaties, and secondary sources like articles, reviews, Internet blogs, and other internet resources.

MODE OF CITATION-

The researcher has done proper acknowledgement and used uniform method of citation.

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BACKDROP OF THE STUDY-

"Competition is a situation in the market in which firms or sellers independently strive for the buyer's patronage in order to achieve a particular objective for example, profit, sales or market share.[1]"

India accounts for 8 % of global pharmaceutical production. It is the third largest in terms of volume and fourteenth in terms of value. Indian firms produce about 60000 generic brands across 60 therapeutic categories and 500 active pharmaceutical ingredients (APIs) approximately. India boasts an export of generic drugs worth US $11 billion and the generic drug market is predicted to grow at a CAGR[2] of 17 per cent between 2010-11 and 2012-13[3].

According to data published by the Department of Pharmaceuticals, the total turnover of India's pharmaceutical industry between September 2008-09 was US $21.04 billion and the domestic market was worth US $12.26 billion. As per market studies, India's pharmaceutical industry is expected to reach US $55 billion in 2020[4].

[1] High powered committee on Competition policy and law available at: www.competition- commission-india.nic .advocacy/speech_speech_member.pdf.

[2] Compounded Annual Growth rate

[3] ***CCI Survey Report, 2011***

[4] http://www.ugpsindia.com/pharmaceuticals.html

The main object of antitrust laws[5] in US is to promote efficiency but in European Communities the approach is rigid and even excessive prices of patented products may be considered as anticompetitive.

The primary objective of Competition policy is to promote efficiency and maximize welfare. This definition is of paramount importance and it is sum total of consumers surplus and producer surplus. In the competitive environment welfare is maximized which is synonymous with allocative efficiency. Thus the ultimate goal of competition is interest of consumers. This becomes all the more important because when it comes to consumer of medicinal product because here it is meant for saving life.

The aim of pharmaceutical policy has been promoting accelerated growth of the pharmaceutical industry and towards making it more internationally competitive[6] whereas the Competition policy is intended to promote efficiency and to maximize consumer/social welfare. It also promotes creation of a business environment, which improves static and dynamic efficiencies, leads to efficient resource allocation and consumer welfare, and in

[5] In U.S. around 1800 there were steel and other trusts regulating the whole business. Small players could not enter in the market. These trust abused their dominant positions and people demanded law regulating such behavior. Therefore, Sherman Act, 1890 came into force.

[6] Pharmaceutical Policy 2002 http://www.whoindia.org/LinkFiles/Traditional_Medicine_Pharmaceutical_Policy_2002.pdf, visited on 10/04/2012

which abuse of market power is prevented/curbed. It also promotes good governance by restricting rent seeking practices of economic actors...[7].

Competition policy is inherently deregulatory in character. it promotes the removal of excessive governmental regulation from all sectors of economy so as to promote free markets and greater competition[8].

The subject here becomes of prime relevance because India is a country with largest population (649 million) without access to essential medicine.[9] 50% of health care costs pertain to expenditure in buying medicines. Therefore considering the above situation the problem here is examined from the perspective of Competition law and pharmaceutical sector. Because affordability and availability of essential medicine has been a grave concern in India.

In India, although the fundamental right to health has not been recognised explicitly it is considered part of Right to life under Art 21 of the Indian Constitution which is recognised as spirit of Indian Democratic life. In ***N D Jayal v. Union of India***[10] this right came to be specifically recognized as part of right to life under the Constitution of India. Right to access to quality and affordable medicines is an important component of right to health. At

times, the right to access to medicines gets violated in the midst of many anticompetitive practices.

[7] Draft National competition Policy, 2011, http://www.mca.gov.in/Ministry/pdf/Draft_National_Competition_Policy.pdf

[8] Martyn Taylor, International Competition law: A new Dimension for the WTO?,pp.29, Cambridge University Press,2006

[9] World Medicine Report (2004) of World Health Organization

The scenario in Indian pharmaceutical industry is currently divided into three tier structure. Large MNCs operate as originator drug companies and generic companies along with large Indian generic companies. Medium and small scale industries are also engaged in production of branded generics and contract manufacturing related activities. Much of the small scale is engaged in production of generic medicines. Though, there are public sector undertakings in the pharmaceutical sector, their presence has become marginal[11].

In Indian drug market lack of information leads to erratic working of competitive forces in the Pharmaceutical sector, in the Industry that is based on strong ethical base the physician prescribes the drug and consumer only pays, the marketing policy targeting the consumer leads to exploitative situation. Here the very idea of consumer making rational choice is missing leading to absence of price competition. Even the availability of suitable substitute the highly priced brand may be most relied upon, further low level of knowledge as to effectiveness of one drug over another causes the chain of profitability between different players such as manufacturer, whole seller, retailer and physician is an area of grave concern which is the root of all unethical drug promotion. All this is done at the cost of effective competition in pharmaceutical market.

Issue of regulating Pharma industry is core issue, patents are a major source of market power in the absence of appropriate competition in product market. Patents is behind price competition issues among branded and generics, entry of generics has caused major fall in price after expiry of patent term. As the Indian Patent Act did not provided for product patent leading to grave monopoly by MNCs charging highest prices. the TRIPS agreement

[11] Report by Centre For Trade and Development (CENTAD) on Competition law and Pharmaceutical Industry, available at http://www.cci.gov.in/images/media/completed/PharmInd230611.pdf. accessed on 13/04/2012

was a milestone which laid down basic policy standard to be followed by all members and mandated that both product and process patent to be permitted as a result India also discharged its obligation by bringing amendment to Patents Act 1970 in 2005 and legalised product patents for pharmaceuticals.

In this paper attempt has been made to identify anti competitive practices prevalent in pharmaceutical sector and identify areas and practices which fall in the domain of Competition Commission. What can be tools that can be used by Competition law to improve access to medicine and secure competitive environment in the sector.

In pursuit of a move to improve access to Cancer drug in a landmark case, the Indian Patent Office has issued the first-ever compulsory license in India to a generic drug manufacturer. This effectively ends German pharmaceutical company Bayer's monopoly in India on the drug *sorafenib tosylate*, used to treat kidney and liver cancer. This on the face of it appears to be very much done in the interest of consumers but it has also raised many question such as why only one compulsory licence till date

Another segment of this work deals with impact of the recent activity of major merger & acquisitions of major Pharma companies.

Another section of the thesis deals with Competition assessment of the laws and regulations governing the sector. It is the process of evaluating government policies, regulations, rules and laws for identification of those which unnecessarily impede competition and suggest measures to redesign the identified ones so that competition is not unduly inhibited. Policies framed by governments have diverse social and economic objectives; competition assessment of these policies mandatorily requires balanced cost-benefit analysis of all their socio-economic goals. The competition assessments of such

policies, rules and regulations ensure that the potential harm they may cause to competition should not be more than necessary to achieve these social goals.

CHAPTER ONE

PHARMACEUTICAL SECTOR AND COMPETITION: DIFFERENT ASPECTS

This chapter deals with following-

1. A brief history of Pharma sector in India.
2. Statistics about Indian Pharma sector.
3. What is the role of Competition in Pharmaceutical sector
4. What is the need of regulating Pharma sector from the perspective of competition?

HISTORY OF PHARMACEUTICAL SECTOR IN INDIA-

In India, modem system of medicine is a 20th century phenomena, though the traditional system of medicine has been in practice for many centuries. Therefore, in discussing the evolution of the Indian pharmaceutical industry, three points of time are very relevant. These are: 1900-1970, 1970-1990 and the decade of 1990s. The period 1900-1970 signifies the dominance of the multinationals in this field that were basically importing bulk drugs and formulations from abroad. Most domestic manufacturers were engaged in repacking the formulations produced by the multinationals and production was concentrated in the hands of the multinationals.

The policy instruments of independent India emphasised on creating a strong public sector. In the pharmaceutical front, specific areas of production were defined for the public, private and the domestic sector though the performance of the multinationals permitted them some leeway in the production of drugs reserved for other sectors also.

The second period of 1970-1990 is very significant for the Indian Pharma industry since, a few important changes that had implications on the growth of the IPI took place during this time. The Patent Act of 1911 was amended in 1970, which came into force in 1972. Under this Act only one process that was used in the actual manufacturing could be patented. This change brought a renaissance to the pharmaceutical industry of India. More units larger in size and capacity set up in the 1970s and 1980s started producing drugs, which were primarily imported till then[12].

[12] N Latitha , Indian Pharmaceutical Industry in WTO Regime: A SWOT analysis: Economic and Political Weekly, Vol. 37, No. 34 (Aug. 24-30, 2002), pp. 3545

In the early 1970s, the government introduced the Monopolies and Restrictive Trade Practices Act and the Foreign Exchange Regulation Act, which aimed at reducing the concentration of economic power with few units and controlling the flight of foreign exchange from the country.

As a tool to protect the indigenous industry from competition, the FERA companies were prohibited from producing certain drugs which were delicenced during 1980s.The 1990s brought trade liberalisation with delicensing it raised production many fold and reduced drug prices by increasing competition in the market. In 1994 Indian government signed the TRIPS agreement but with contribution of public sector declining, Research and development also suffered[13].

Right to live a healthy life free from all fatal disease requires protection and cure whenever there is threat of a life threatening disease. The role that medicines play these days which is though not equal to God but is not lesser than that also, therefore the Pharmaceutical sector in any country is of the most strategic importance for the government of the day.

II) WHY TO BE REGULATED-

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being."

- Preamble to the WHO Constitution

[13] Jha Ravindra Options for Indian Pharmaceutical Industry in the changing Environment, Source: Economic and Political Weekly, Vol. 42, No. 39 (Sep. 29 - Oct. 5, 2007), pp. 3958

According to 2011 census India's population is 121 crores out of which around 45-48% people living below poverty line. 90% of total work force is in unorganised sector. According to 11th Five Year Plan (2007-2011) India spent only 1.2% of GDP on health care. According 12th Five Year Plan (2012-2017), Indian will spend 2.6% of its GDP. Even if India spends around 3% of its GDP, access to medicine and better health care to all people (including BPL also) may be not satisfactory unless PDS regarding public health is restructured. Planning Commission has recently tried to define poverty line and in fact I say its the mockery of BPL. Access to medicines and healthcare has five aspects: availability of supply, price, quality, ability to pay and access to proper and affordable consultations. All these aspects are vitiated in our country by a number of factors[14]

II. COMPETITION IN PHARMA SECTOR , POVERTY AND ROLE OF GOVERNMENT

Competition is laudable for consumers but what about the 40% people who are living below the poverty line? Hardly can they manage for one time food, how they are supposed to access better public health care facilities and medicines. If we only beat about the competition in Pharma sector and govt's effort in isolation, it would be the failure on the part of the biggest democratic nation in the world i.e. India now Pvt. Sector and Govt should play a good partnership to deal with this issue as we have seen the PPP in road

[14] Options For Using Competition Law/Policy Tools In Dealing With Anti-Competitive Practices In The Pharmaceutical Industry And The Health Delivery System, Report Prepared For World Health Organization Office Of The Who Representative To India & Ministry Of Health And Family Welfare Government Of India By Cuts Centre For Competition, Investment & Economic Regulation (Cuts C-Cier) Cuts International Jaipur, India 2006

infrastructure, Delhi Metro, petroleum, minerals then why not public health care? By discharging its constitutional obligations, state's effort is appreciable but now with the pace of time, govt should go hand in hand with private sector so that poor people particularly and other people generally can be beneficiary of better public health care and medicines.

Govt should take help from NGOs and public health care schemes should be reachable to BPL through these NGOs.

In Canada there is Universal Health Coverage (UHC) whereas in India the High Level Expert Group has submitted its report on UHC to Planning Commission .the National Advisory council discussed the prospects of providing UHC. Chairman of the High Level Expert Group (HLEG) constituted by the Planning Commission on Universal Health Coverage recommended for doubling of expenditure on health to 2.5 per cent of the gross domestic product by 2017 and to three per cent by 2022.another more significant recommendation was to eensure availability of free essential medicines by increasing public spending on drug procurement[15].in the light of this Public Procurement Bill 2012 is important.

Competition law is important for proper functioning of markets in a open free market economy in the absence of effective regulatory mechanism there may many such practices hindering competition or lack of conducive mechanism promoting competition[16].The pharmaceutical sector having hospitals, medical instruments diagnostics and pathological

[15] High Level Expert Group Report on Universal Health Coverage for India http://planningcommission.nic.in/reports/genrep/UHC_ExecSummary.pdf

laboratories has a complex market distinct from other sectors because of asymmetries of information of the consumers of this sector. It is the industry where mandate of physician and pharmacist is taken as most reliable due to medical illiteracy in Indian drug market consumers.

ADVANTAGES OF COMPETITION REGIME-

Coming on what are the advantages that competition bring with it are[17]-Firstly, allocating resources in the direction preferred by consumers generally described as 'allocative efficiency' this has the benefit of reducing the risk that goods or services produced will not be wanted or not wanted at price at which they are offered. Secondly, the continual pressure on all producers and sellers in the market to use raw materials and human capital in a way that keeps down costs, and therefore, prices, for fear of losing custom to other sellers who find ways to attract business either by general price cuts or by discounts to favoured buyers referred to as productive efficiency. Thirdly, the constant process of dynamic adjustment to continual changes in consumer preference is an incentive for producers to invest in research and development and to innovate, leading to the survival and growth of those companies which make the necessary changes in good time, whilst those that fail to do so inevitably fall behind called dynamic efficiency".

The main goal of developed competition law is that of social welfare which takes into account both the economic welfare of final consumers and the profits of producing companies. but at times a merger may allow considerable cost saving to the merging parties but reduce competition and so lead to price rises.

[17] D.G Goyder & Joanna Goyder,Goyder's EC Competition law, fifth edition, 2009,Oxford University Press pp.9

As one of the leading industries in India, the Indian Pharmaceutical Industry represents 8% of the global total industry by volume and 13% by value. The "organized" sector of India's pharmaceutical industry consists of 250 to 300 companies, which account for 70% of products on the market, with the top 10 firms representing 30 %[18]. Such structure itself suggests that this sector needs to be highly monitored considering the strategic importance from the perspective of necessity as well as economic point of view.

OBJECT OF REGULATORY CONTROL-

All the important actors in the pharmaceutical industry – the manufacturers, wholesalers, retailers and prescribing physicians are also subject to regulatory controls. These regulatory controls pursue three primary objectives[19]:

(a) Preserving the incentives for research and development and the flow of new innovative drugs.

(b) Ensuring the safety of drugs consumed by the public; and

(c) Controlling the quantity and quality of drug expenditures.

Competition, therefore, empowers the poor, creates opportunities for new firms, including Small businesses, to enter markets and grow, puts pressure on existing firms to innovate, ensures lowest possible prices for consumers and better quality products.

[18] http://www.kpmg.com/IN/en/WhatWeDo/Industries/Documents/IM/Indian%20Pharma%20Outlook.pdf

[19] OECD Policy Rountables on **Competition and Regulation Issues in the Pharmaceutical Industry 2000 available at http://www.oecd.org/dataoecd/35/35/1920540.pdf, accessed on 13/4/2012**

DRUG PRICING & COMPETITION-

In most developed countries, the regulation of drug prices is considered necessary to contain public expenditure due to the government's role in funding social health. a substantial portion of the population in India is market-dependent and has to meet all their expenses on this account out of their own pocket, making price regulation of pharmaceutical products unavoidable. Competition is the key driving force behind the development of new innovative drugs, and a significant factor in keeping down the prices and production costs of off-patent drugs It is essential for the pharmaceutical sector in India, to operate under a law that curbs anti-competitive activities to ensure fair access and availability of medicines. The previous antitrust regime MRTP Act, 1969, did not have adequate provisions to deal with a large number of anti-competitive practices, like collusion or cartelisation, mergers and acquisitions, and abuse of intellectual property rights, which is a very common practice in the pharmaceutical industry, if viewed globally. The new Competition Act, 2002, is a much improved law, and has the required provisions, including extra territorial jurisdiction to deal with the anti competitive activities in today's era.

Lastly, one of the objectives of competition is that distribution of gains should accrue to the common people. But what about the consumers who are not the part of the market system i.e. the very poor. It is true that with the introduction of competition in the markets access to goods and services is certainly enhanced but this enhancement in access is skewed and unevenly distributed. It is tilted in favor of urban and semi-urban areas as well as rich and upper middle class, and the common people could not benefit much during the competition regime. The growth stimulating processes sometimes tend to neglect the poor

and lead to wider disparities within the society. To regulate this situation, there is need to empower and enable the common people to derive the benefit of competition. That is the challenge before us[20].addressing these concerns the various issues has been discussed in the following modules of this thesis.

[20] *www.cuts-ccier.org/icrr/doc/**ICRRReport_ExecutiveSummary**.doc*

CHAPTER TWO

REGULATORY FRAMEWORK OF THE PHARMACEUTICAL SECTOR

This chapter contains the following-

1. *The laws& policies governing the sector*
2. *The impact of laws on competition*
3. *The Competition Act, patents Act & TRIPS agreement.*
4. *The authorities governing the sector.*

Legal and regulatory Framework presents comprehensive information about the existing legal framework that regulates the Pharma and Life science industry in India. The strategic importance of the Pharma sector has already been discussed elaborately in the previous chapter, Therefore law being the mechanism to ensure orderly state of affair in society it is necessary that a structured system of law exists in society that ensures proper competitive functioning of the sector which secures interest of the patients. further it is also to be seen that whether the laws governing the sector are pro competition or not?

The inventories of the laws are as follows:

RELEVANT LEGISLATIONS

- Drugs and Cosmetics Act, 1940.
- Drugs and Cosmetics Rules, 1945.
- Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.
- The Indian Medical Council Act, 1956.
- Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002.
- Drug Price Control Order, 1995.
- Essential Commodities Act (Section 3)

SOME RELEVANT POLICIES

- Draft National Pharmaceutical Policy, 2006
- Drug Policy 1986.

REGULATORY AGENCIES

- Central Drug Standard Control Organization (CDSCO).
- Drug Controller General of India (DCGI)
- Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers
- National Pharmaceutical Pricing Authority (NPPA)
- State level: State Drug Controllers and Inspectors.

Other key laws and policies that affect pharmaceutical sector include:

- Competition Act of 2002
- Indian Patent Act, 1970
- TRIPS Agreement
- Policies relating to Trade, FDI, Procurement, others.

Though the list stated above seeks to laid down an extensive system tries to fix responsibilities and liabilities of all the players of the sector, still there are various provisions in the regulatory framework which is impeding competition in the pharmaceutical market.

Pharmaceutical Sector Laws, Regulations and Policies

Drugs and Cosmetics Act and Rules

Drugs and Cosmetics Act, 1940 is the law which regulates the import, manufacture, distribution and sale of drugs and cosmetics in this country. The main object of the Act, as it is observed by the ***Supreme Court in Chimanlal Jagjivindas Sheth v. State of***

Maharashtra[21] is to prevent sub-standards in drugs presumably for maintaining high standards of medical treatment. The abovementioned act is to be read together with the Rules (Drug and Cosmetic Rules, 1945). Some of the rules have also have the potential of being abused or implemented arbitrarily having detrimental effects on competition.

Select laws, rules and practices are given below as illustrations-

Sections 10A[22], 26A

Section 10A: ...If the Central Government is satisfied that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or any drug does not have the therapeutic value claimed for it ...and that in the public interest it is necessary or expedient so to do then, that Government may, by notification, prohibit the import of such drug or cosmetic. The Central Government on the basis of the expert advice can indeed adopt an approved national policy and prescribe an adequate number of formulations which would on the whole meet the requirement of the people at large. While laying the guidelines on this score, injurious drugs should be totally eliminated from the market[23]. **Section 26A**[24] If the Central Government is satisfied that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or any drug does not have the

[21] **1963 AIR 665,)**

[22] Drug and Cosmetics Act 1945, available at: http://cdsco.nic.in/html/copy%20of%201.%20d&cact121.pdf

[23] Vincent Panikurlangara v. Union of India, AIR 1987 SC 990

[24] Drug and Cosmetics Act 1945, available at http://cdsco.nic.in/html/copy%20of%201.%20d&cact121.pdf

therapeutic value claimed for it ...and that in the public interest it is necessary or expedient so to do then, that Government may, by notification regulate, restrict or prohibit the manufacture, sale or distribution of such drug or cosmetic.

The provisions vest control in the government to make decisions to eliminate certain drugs from the market on grounds of public interest but have to be monitored carefully due to their potential to promote anti-competitive behaviour

Section 16[25] and Schedule M to the Rules on Good Manufacturing Practices[26]:

Standards of quality-

(1) for the purposes of this Chapter, the expression" standard quality" means--

(a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and

(b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.

(2) The Central government after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend the Second Schedule for the

[25] Drug and Cosmetics Act 1945, available at: http://cdsco.nic.in/html/copy%20of%201.%20d&cact121.pdf

[26]GOOD MANUFACTURING PRACTICES AND REQUIREMENTS OF PREMISES,PLANT AND EQUIPEMNT FOR PHARMACEUTICAL PRODUCTS http://rajswasthya.nic.in/Drug%20Website%2021.01.11/Revised%20Schedule%20%20M%204.pdf

purposes of this Chapter, and thereupon the Second Schedule shall be deemed to be amended accordingly.

Implications- Provisions regarding standards of quality have often been abused to create artificial barriers to entry for others while creating favourable conditions for some. As discussed in ***Bharat Biotech Ltd. V. A.P. Health and Medical Housing and Infrastructure Development Cooperation***[27].

Schedule M to the Rules deal with standardization related to pharmaceuticals. The argument here is not that schedule M should comply with safety standards. However it has to be ensured that it has to be scientific and not arbitrary in prescribing standards

Rule 64: Conditions to be satisfied before a license in Form 20, 20-B, 20-F,20-G, 21 or 21-B is granted or renewed[28]**.** *(1)*A license in Form 20, 20-B, 20-F, 20-G, 21 or 21-B to sell, stock, exhibit or offer for sale or distribute drugs shall not be granted or renewed to any person unless the authority empowered to grant the license is satisfied that the premises in respect of which the license is to be granted or renewed are adequate, equipped with proper storage accommodation for preserving the properties of the drugs to which the license applies and are in charge of a person competent in the opinion of the licensing authority to supervise and control the sale, distribution and preservation of drugs.

[27] **2003 (1) ALD 463**

[28] Drug and Cosmetics Rules 1945, amended upto 2005 available at http://cdsco.nic.in/Drugs&CosmeticAct.pdf, visited at 17/04/2012

(2) In granting or renewing a license under sub-rule *(1)* the authority empowered to grant it shall have regard-

(i) to the average number of licenses granted during the period of 3 years immediately preceding, and

(ii) to the occupation, trade or business ordinarily carried on by such applicant during the period aforesaid

Provided that the licensing authority may refuse to grant or renew a licence to any applicant or licensee in respect of whom it is satisfied that by reason of his conviction of an offence under the Act or these rules, or the previous cancellation or suspension of any licence granted or renewed thereunder, he is not a fit person to whom licence should be granted or renewed under this rule. Every such order shall be communicated to the licensee as soon as possible.

Provided further that in respect of an application for the grant of a licence in Form 20-B or Form 21-B or both, the licensing authority shall satisfy himself that the premises in respect of which a wholesale licence is to be granted or renewed are--

(i) of an area of not less than ten square meters; and

(ii) in the charge of a competent person, who-

(a) is a Registered Pharmacist, or;

(b) has passed the matriculation examination or is s equivalent examination from a recognized Board with four years' experience in dealing with sale of drugs, or

(c) holds a degree of a recognized university with one year's experience in dealing with drugs:

Provided also that--

(i) in respect of an application for the grant of a licence in Form 20 or Form 21 or both, the licensing authority shall satisfy itself that the premises are on an area of not less than 10 square meters; and

(ii) in respect of an application for the grant of a licence--

(a) in Form 20 or Form 21 or both, and

(b) in Form 20-B or Form 21-B or both, the licensing authority shall satisfy is self that the premises are of an area not less than 15 square meters;

Provided also that the provisions of the preceding proviso shall not apply to the premises for which licences have been issued by the licensing authority before the commencement of the Drugs and Cosmetics (1st Amendment) Rules, 1977,

(3) Any person who is aggrieved by the order passed by the licensing authority in Sub-rule (1) may, within 30 days from the date of such order, appeal to the State Government and the State Government may, after such enquiry into the matter as is considers necessary and after giving the appellant and opportunity for representing his view in the matter, make such order in relation thereto as it thinks fit.

Implications-The Rules nowhere confer on the licensing authority the power to refuse or renew the licences, on the ground other than what has been provided therein. However there have been instances in practice where the power to grant or renew licences has been used arbitrarily by the government thereby creating the need for regulating such powers.

Rule 85[29]**:** The Central Licensing Approving Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons thereof, cancel a license issued under this part, or suspend it for such period as he thinks fit either wholly or in respect of any of the drugs to which it relates (or direct the licensee to stop manufacture, sale or distribution of the said drugs and (thereupon order the destruction of drugs and) the stock thereof in the presence of an Inspector) if in his opinion, the licensee has failed to comply with any of the conditions of the licensee or with any provisions of the Act or rules made there under.

Implications -This rule has been abused in a recent instance where the Ministry of Health and Family Welfare suspended the manufacturing licenses of three vaccine manufacturing PSUs in 2008 and thereafter the government has only been purchasing vaccines from private players. The Parliamentary Standing Committee has demanded that this closure be revisited.

Rule 122B[30] **of the Drugs and Cosmetics Rules, 1945**

The proviso in Sub-rule (3) empower the Drug Regulator to modify or relax generation of certain test data in case of new drugs approved and marketed for *several years* in other countries, if he is satisfied that there is adequate published evidence regarding the safety of the drug, subject to the other provisions of these rules.

[29] *ibid*

[30] *ibid*

The term 'several years' needs to be clearly defined in the Rules. Thereafter, Drug Regulator should grant relaxation in the generation of test data only after the expiry of the specified time period[31].This is needed in order to not create undue delays in the entry of new drugs into the market.

1. Drugs and Magic Remedies (Objectionable Advertisements) Act 1954

The purpose of the Act is to control advertisements of drugs in certain cases and to prohibit advertisements of remedies that claim to possess magic qualities. According to this Act, advertisement includes any notice, circular, label, wrapper or other document and any announcement made orally or by means of producing or transmitting light, sound or smoke.

The objectionable advertisements tend to cause the ignorant and unwary consumer to resort to self-medication or to resort to quacks who indulge in such advertisements for treatments, which cause great harm. It was therefore found necessary in the public interest to put a stop to such undesirable advertisements[32].

Drugs and Magic Remedies Act does not have a full proof mechanism to require that promotional materials are submitted for pre-approval. Except for the Advertising standards

[31] Reddy and Sandhu, "Report on Steps to be taken by the Government of India in the context of Data Protection provisions of Article 39.3 of the TRIPS," Ministry of Chemicals and Fertilizers, 2007.available at http://chemicals.nic.in/DPBooklet.pdf,visited on 17/04/2012

[32] http://www.fda-mah.com/MagicDrug.aspx

council of India code, no other statutory provision can be pointed out that sets out specific standards in relation to information available on the internet i.e. to prevent consumers from gaining inappropriate access to information[33].

No person can advertise anything that directly or indirectly gives a false impression of the drug, makes a false claim or is false and misleading in any material particular. This issue was addressed by Court in the case ***Colgate- Palmolive (India) ltd v. Anchor Health and Beauty Care Private ltd***[34]. The case was filed by Colgate against Anchor for telecasting advertisements that disparage or slander Colgate toothpastes. Colgate raises its objection on two main issues, namely, that Anchor claims that it is the 'only' toothpaste containing triclosan, fluoride and calcium. Also it claims that it is the 'first' toothpaste to provide all round protection. Colgate objected to the words 'only' and 'first' pointing out that they also had the three ingredients in their toothpaste and they had been in the market for much longer and hence the two claims of Anchor were false statements. Anchor claimed that 'only' is used with reference to a range of their own products and 'first' is not with reference to the product but with reference to the slogan 'all round protection'. The Court in this case held that since even Anchor had admitted that the words 'only' and 'first' is not intended to convey the meaning it does, Colgate has a prima facie case. The court pointed out that it is in public interest not to allow Anchor to make such a misleading claim and that the balance of convenience went against Anchor.

[33] Competition law and Indian Pharmaceutical Industry ,By Centre for trade and development, 2012,pp121,available at http://www.cci.gov.in/images/media/completed/PharmInd230611.pdf, visited on 17/04/2012

[34] (2008) 7MLJ 1119

Indian Medical Council Act 1956 -this act constitutes the Indian Medical council which is the body governing the medical professionals as well as medical education.

Indian Medical Council (Professional Conduct, and Ethics) Regulations related to the professional conduct, etiquette and ethics were notified in 2002.

The Act lays various duties of medical practitioner towards the patient as well towards the profession.

The Medical Council of India (MCI) via amendment to the "Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation 2002" has brought out the code of conduct for doctors and professional association of doctors in their relationship with pharmaceutical and allied health sector industry which prohibit them from accepting any gifts, travel facility or hospitality, from any pharmaceutical company or the health care industry.

Even though the intention behind framing the code of conduct appears good, the greater issue is the enforcement of these guidelines which seems an uphill task. Who would be the 'competent authority' and 'institutional body' supposed to act as a watch-dog of public interests? MCI has a very dismal record as far as enforcement of its own guidelines is concerned. Laws have no meaning when enforcement lacks[35].

In exercise of the powers conferred under section 20A read with section 33(m) of the Indian Medical Council Act, 1956 the Medical Council of India, with the previous approval of the Central Government, provides for regulations relating to the Professional Conduct, Etiquette and Ethics for registered medical practitioners as under these

[35] http://www.indianpediatrics.net/apr2010/apr-329-330.htm

Regulations. But unfortunately, despite the serious medical malpractices that go on, there is little regulation on the actions of health care providers.

Regulation 1.5: Use of Generic names of drugs: Every physician should, as far as possible, prescribe drugs with generic names and he / she shall ensure that there is a rational prescription and use of drugs[36].

Implication on Competition- Generic drugs are essential for effective competition and making medicines available at low prices to consumers. However, due to the various collusive arrangements, doctors often end up prescribing branded and expensive drugs instead of the cheaper generics.

This provision tries to guard against that but is weak and lacks teeth as it does not prescribe any punishment for failure to comply. One way, often suggested, of checking the rent-seeking behaviour of the doctors, as has been successfully experimented, even in neighbouring Bangladesh, is to *mandate* doctors to prescribe drugs with generic names. However, given the enormous clout of the pharmacists in India, this mandate has not worked. What is, thus, desperately required in India, is an effective mechanism to contain the rent-seeking behaviour of the doctors and pharmacists so as to check the anti-competitive practices in this market.

[36] Reg. 1.1, THE INDIAN MEDICAL COUNCIL (PROFESSIONAL CONDUCT, ETIQUETTE & ETHICS) REGULATIONS, 2002, available At http://www.punjabmedicalcouncil.com/Code%20of%20Ethics.pdf

Regulation 8.2 which provides[37]:

Any complaint with regard to professional misconduct can be brought before the appropriate Medical Council for Disciplinary action. Upon receipt of any complaint of professional misconduct, the appropriate Medical Council would hold an enquiry and give opportunity to the registered medical practitioner to be heard in person or by pleader. If the medical practitioner is found to be guilty of committing professional misconduct, the appropriate Medical Council may award such punishment as deemed necessary or may direct the removal altogether or for a specified period, from the register of the name of the delinquent registered practitioner. Deletion from the Register shall be widely publicized in local press as well as in the publications of different Medical Associations/ Societies/Bodies.

Implication on Competition-

The above provision also has proved to be ineffective as it does not prescribe specific punishment for medical misconducts even against very serious grievances. Given the failure of these institutions, the Consumer Protection Act (COPRA) often becomes the only way for affected consumers to protect their interests. COPRA, promulgated in 1986 to protect the rights and interests of consumers, recognizes medical misconduct as an offense. are district, state, and national quasi-judicial bodies to redress such cases. However, even this instrument remains grossly ineffective against medical negligence, since (1) the redress process often becomes too lengthy for the common consumer; (2) the responsibility of proving negligence lies with the consumer; and (3) the services provided through the

[37] Reg.8.2

informal market and government providers remain in a gray area, because the "purchase" of services is hard to prove.

Drug Price Control Order, 1995

The drug prices in India are controlled through the Drugs (Prices Control) Order (DPCO). The DPCO is an order issued by the government under Section 3 of the Essential Commodities Act, 19551[38] empowering it to fix and regulate the prices of essential bulk drugs[39] and their formulations[40]. The order incorporates a list of bulk drugs whose prices are to be controlled, further provides for the procedure for fixation and revision of prices, the procedure for implementation, the procedure for recovery of dues, the penalties for contravention and various other guidelines and directions. The order is subject to the guidelines of Drug Policy and supposedly aims to ensure equitable distribution, increased

[38] The Essential Commodities Act, 1955 was enacted for the control of production, supply, distribution, trade and commerce in certain commodities that were declared essential by the Central Government. The Act defines 'Essential Commodities' to include drugs since they are considered essential for the health of society. Section 3 of the Act authorizes the Central Government to regulate or prohibit the production, supply, distribution, trade and commerce in any of the 'essential commodities' if the same is necessary for maintaining or increasing supplies of these commodities for securing their equitable distribution and availability at fair prices.

[39] A bulk drug is any pharmaceutical, chemical or biological product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeia or other standards and which is used as such or as an ingredient in a formulation. (Source: The Drugs Prices Control Order, 1995)

[40] A formulation is a medicine processed out of bulk drug/s for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals, but shall not include any medicine included in the Ayurvedic, Homeopathic or Unani system of medicines. Hence, the DPCO is applicable only to allopathic drugs. (Source: The Drugs Prices Control Order, 1995)

supply and cheap availability of bulk drugs. Drugs and formulations have been subjected to price control for more than three decades now[41].

Currently 37 drugs out of the National List of Essential Medicines of 348 are under price control pursuant to the Drug Price Control Order (DPCO), 1995.

The National Pharmaceuticals Pricing Policy 2011 presently seeks to limit itself to the central objective of promulgating the principles for pricing of Essential Drugs as laid down in the "National List of Essential Medicines 2011" as declared by the Ministry of Health and Family Welfare, Government of India[42].further The draft National Pharmaceuticals Pricing Policy 2011 plans to cap prices of all 348 essential drugs and their combinations at the average price of the top three brands in the respective segments[43].

"*When India passed its Patent Act in 1970, it also instituted a Drug Price Control Order (DPCO) under the Essential Commodities Act of 1955 to control the price of drugs and ensure access to the general pubic. Under this order, prices of bulk drugs and their formulations were fixed by the government as per a specified formula that allowed a 100% margin on ex factory cost. Price changes of the remaining drugs were also to be monitored. However, over a period of time, as a result of sustained lobbying by the Indian*

[41] http://www.pharmaceutical-drug-manufacturers.com/pharmaceutical-policies/drugs-price-control-order.html

[42] Draft NATIONAL PHARMACEUTICALS PRICING POLICY, 2011 (NPPP-2011) available at: http://pharmaceuticals.gov.in/draftnppp.pdf

[43] *Id*

pharmaceutical industry, the number of drugs listed in the DPCO fell from 347 in 1979 to 76 in 1995[44].

Recently government is considering strengthening the price control regime to increase competition and ensure affordable medicines to the general public. To this end, a new Drug Pricing (Regulation & Management) Act is being considered. The proposed Act would, while retaining the DPCO within its ambit, have additional provisions such as end-to-end price monitoring and negotiated settlement of prices of new/patented drugs. It would also lay emphasis on cutting promotional expenses that contribute substantially to the price of the drug[45]."

Implication upon Competition

Section 8[46]: Power to fix retail prices of scheduled formulations- There is scope for informal collusion of the pharmacists at the local level. For example consider this, the Maximum Retail Price (MRP) that is set by the manufacturers under the guidelines of the National Pharmaceutical Pricing Authority (NPPA) , is the ceiling on the retail price and need not be the actual selling price. However retailers do not compete and the MRP becomes the reference price for them to collude informally.

[44] http://spicyipindia.blogspot.in/2007/08/resurgence-of-price-controls-in-india.html

[45] *Id.*

[46] Drug price Control Order 1995 available at: http://nppaindia.nic.in/drug_price95/txt5.html

Section 8(2)[47]**:** Where the Government fixes or revises the price of any bulk drug under the provisions of this Order and a manufacturer utilises such bulk drug in his Scheduled formulations he shall, within thirty days of such fixation or revision, make an application to the Government, in Form-III for price revision of all such formulations and the Government may, if it considers necessary, fix or revise the price of such formulation.

However, in the case of downward revision in bulk drug prices, manufacturers seldom apply for price revision. ***The Report (Seventh) of the Standing Committee on Chemicals and Fertilizers on Availability and Price Management of Drugs and Pharmaceuticals (2005***[48]***)*** observes that "drug companies fail to furnish information as prescribed under DPCO '95, but no specific provision for punitive actions are there in DPCO'95 to take action against errant companies/units".As a result the manufacturers lack sufficient incentive to lower the drug prices.

Sections 3, 8 and 9 DPCO 1995 on fixing prices of Scheduled drugs.- because there are no provisions of fixing prices of substitutes of scheduled drugs as a result, companies continue to charge high prices through creating substitutes thereby hurting consumers who could otherwise gain through lower prices. An example of such a practice is the substitution of Pseudoephedrine with Phenylpropanolamine (PPA). Actifed, an international brand of Glaxo for cough and cold, contains psuedoephedrine. However, in

[47] *id*

[48] Seventh Report standing committee on chemicals & fertilizers (2005-06) ministry of chemicals & fertilizers (department of chemicals & petrochemicals) availability and price management of drugs and pharmaceuticals, available at http://164.100.24.208/ls/CommitteeR/chemicals/7rep.pdf

India it contains PPA. In high doses, PPA has been found to enhance the risk of cerebrovascular accidents. Glaxo preferred to use PPA in India because while psuedoephedrine is under price control, PPA is not it observes "*in some cases, it has been noticed that whenever Government/NPPA fixes/revises ceiling or non-ceiling price of medicines/formulations some drug companies change the composition of the medicines/formulations and obtain new licenses from respective State Drug Controller/Licensing Authority. The State Drug Controller/Licensing Authority should not allow change in composition without any valid ground and without consulting Drug Controller General of India (DCGI and NPPA)*[49]

Essential Commodities Act (Section 3)

Drugs are essential for health of the society. therefore has been declared an essential and accordingly put under the Essential Commodities Act. In the year 1970, the Drug Prices Control Order issued under the Essential Commodities Act, 1955. Subsequently DPCO was revised in 1979, 1987 and 1995. Not all drugs available in the country are under price control. Only 74 out of about 500 commonly used bulk drugs are kept under statutory price control. All formulations containing these bulk drugs either in a single or combination form fall under price controlled category. However, the prices of other drugs can be regulated, if warranted in public interest[50]. Rest of the drugs are under the category of essential and life saving drugs, and as directed by the Hon'ble Supreme Court in the K.S.

[49] ***(Gulathi, 2004). The Report (Seventh) of the Standing Committee on Chemicals and Fertilizers on Availability and Price Management of Drugs and Pharmaceuticals 2005***

[50] See Economic constraints for access to medicines in India, WHO publication available at: www.centad.org

Gopinath case[51] that government is duty bound to ensure that "... essential and life-saving drugs do not fall out of price control". However, the dwindling numbers from the list of scheduled drugs under price control conveys a different story. The bulk drugs are regulated under the DPCO[52].

FDI POLICY -100 percent foreign direct investment is allowed under the automatic route in the drug and pharmaceuticals sector including those involving use of recombinant technology.

The government is to come out with a US $ 639.56 million venture capital(VC) fund to give a boost to drug innovation and to build Pharma infrastructure in the country. The Pharma healthcare and biotech sector witnessed five merger and acquisition transactions worth US $ 250 million[53].

Draft National Pharmaceutical Policy, 2006

The draft National Pharmaceutical Policy, 2006 seeks to strengthen the Drug Regulatory System and the patent office. It focuses on research and drug development with clinical trials. The policy aims at providing a better access to anti-cancer and anti-HIV/AIDS drugs to the patients[54].

[51] March 10, 2003, WHO India Report whoindia.org/.../Trade_Agreement_Chapter06_Final_Report_IND_G...

[52] *Supra note 18.*

[53] A brief report Pharmaceutical industry in India, http://www.cci.in/pdf/surveys_reports/indian-pharmaceuticals-industry.pdf

[54] http://arhamconsultants.com/nationalpharmaceuticalpolicy2006.htm

It gives purchase Preference to Pharma Public Sector Undertakings. For strategic reasons, it proposes that it is essential that PSUs continue to play an important role in future. Their continued survival can be ensured in case some kind of purchase preference based on the NPPA approved prices is accorded to them. It therefore recommends that a list of drugs manufactured by the PSUs along with prices (to be certified by NPPA) should be prepared for supply to Government. All departments/hospitals of Central Government purchasing these drugs from the market would be required to first procure these from the PSUs at prices approved by NPPA.

Implication upon Competition- This purchase procurement policy recommendation restricts competition by the private sector. The concept of competitive neutrality means that government sponsored business activities should not enjoy net competitive advantages over their private sector competitors. For example, a purchase preference policy in favour of central PSUs which was extended for three more years in 2005 had the effect of discriminating against private sector players. Under the policy, central PSUs could enjoy purchase preference if the price quoted by it fell within 10% of the lowest bidder's quote. Fortunately it was terminated by the government in 2008 and not extended further as before in a bid in order to create a level-playing field between private and state-run companies. A policy recommendation of the nature proposed in the NPP, 2006 would take us back to square one.

Competition Act 2002

The competition law is applicable to healthcare players if they can be considered as undertakings. Since hospitals, health professionals, health insurers, pharmaceutical firms, pharmacists, etc. perform economic activities thus they can be considered to be undertakings and hence are subject to competition rules. even in countries where there is

little competition among the health care players due to excessive regulation, a hospital entering into an agreement with another hospital or pharmaceutical firm would have to comply with the competition law.

The reason behind why the Competition Act comes into picture while dealing with Pharmaceutical sector is threefold-

- Identify anti-competitive activities prevalent in the pharmaceutical market.
- Identify areas and practices which fall within the Commission's regulatory ambit.
- Explore ways and means to use Competition law and policy to enhance consumer access to medicines and secure a competitive environment in the industry.

The Competition Act applies to the sector in the following means-

- Regulation of Combination
- Anti Competitive agreements
- Abuse of Dominance

The Act prohibits any person or enterprise form entering into a combination which could cause or is likely to cause an appreciable adverse effect on competition in India. *(Sec.6 (1) of the Competition Act, 2002) The Commission is empowered to declare such combinations as void. The commission can look into the merger or amalgamation upon receiving a notice from the parties or a statutory authority.

The Patent Act

Patents are a major source of market power in the absence of effective product market competition. It must be noted that patent system is at the core of price competition related issued among branded and generics. Generic entry after the expiry of the patent is a major reason for drastic fall in prices. The Patent Act, 1970 since its inception did not provide for product patents. This was in the light of experience prior to 1970 when product patents led

to aggressive monopolies by pharmaceutical MNCs. It was noted that the prices were one of the highest in the world. Hence two expert studies conducted by the government resolved in favour of withdrawal of product patent regime for pharmaceuticals. The TRIPS Agreement (1995) as a cornerstone Agreement in setting common binding standards has mandated that both products and process patents in all fields of technology shall be available. Hence the 2005 Amendment to the Patents Act, 1970 reintroduced product patents for pharmaceuticals[55].

TRIPS Agreement

The TRIPS Agreement (1995) as a cornerstone Agreement in setting common binding standards has mandated that both products and process patents in all fields of technology shall be available. Hence the 2005 Amendment to the Patents Act, 1970 reintroduced product patents for pharmaceuticals. TRIPS Agreement] mandates all WTO member countries (except Least developed countries (LDCs) currently under transition period) to provide for effective patent protection, for products and process without discrimination as to the field of technology, generic price competition in pharmaceuticals has turned out to be a major issue[56]though there are flexibilities in the TRIPS agreement, including limitation and exceptions and non-voluntary uses, it remains to be seen how the patent law

[55]Refer Competition Law and Indian Pharmaceutical Industry A Report by CENTAD, 2010

[56] It is noted that "TRIPS Agreement standards amounted to a veritable revolution in international intellectual property law from which research based pharmaceutical industry emerged as one of the biggest winners. Faced with take it or leave it decision, all developing country members of the WTO including those with growing pharmaceutical production capabilities, such as India, Brazil, and eventually China, agreed to respect relatively stringent world-wide norms of patent protection no later than 2005". See, (Reichman, 2009).

and jurisprudence evolve and interact with larger policy concerns of access to medicines at affordable prices to Indian consumers[57].

AUTHORITIES REGULATING THE SECTOR

The following table show the list of authorities regulating the sector and their function

Regulating Agency	***Functions***
National Pharmaceuticals Pricing Authority (NPPA)	Monitoring and regulating prices of select medicines
MRTP Commission	Anti-competitive and unfair trade practices
Competition Commission of India	Will deal with anti-competitive practices and MRTPC would be disbanded
Controller General of Patents, Designs and Trade Marks	Empowered to take action against the patent-holders in case of abuse of patent rights
Medical Council of India	Regulates medical education standards and the behaviours of doctors under the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002
Pharmacy Council of India	Regulation of pharmacy education and pharmacy profession
Central Drugs Standard Control Organisation and State Drugs Standard Control Organisations.	Regulates medical education standards and the behaviours of dectors under the Indian Medical Council (professional

[57] *Supra* note 34.pp 78

	conduct, etiquette and Ethics) regulations, 2002

Though the Indian Pharma sector has well laid down legal framework and regulatory agencies are well in place to ensure the fair functioning of the sector and securing interest of the patients but their functioning has shown till now that the foul players have evolved the mechanism of their own to defeat the goal of the regulatory agencies.

CHAPTER THREE

COMPETITION ISSUES IN PHARMACEUTICAL SECTOR

This chapter contains the following-

1. The various competition issues in the sector
2. The key players in the Pharma market with their share.
3. Issues affecting competition-
4. Anti competitive agreements & Instances of Collusive practices
5. Abuse of dominant positions-statutory provisions and practices
6. Regulation of Combination-statutory provisions and cases.

Introduction-

Competitive markets facilitate wider choice of goods and services for consumers at lowest possible prices and best quality. Competition creates environment for firms to minimise their costs and pass on the cost reductions to consumers. In this way, consumers, especially the poor, can get value for money. Competition, therefore, empowers the poor, creates opportunities for new firms, including small businesses, to enter markets and grow, puts pressure on existing firms to innovate, ensures lowest possible prices for consumers and better quality products[58].

Since hospitals, health professionals, health insurers, pharmaceutical firms, pharmacists, etc. perform economic activities thus they can be considered to be undertakings and hence are subject to competition rules.

The Competition issues in the pharmaceutical sector involves addressing basically three issues-

- Regulation of Combinations
- Anti-competitive Agreements
- Abuse of Dominance

[58] Pradeep S Mehta and Manish Agarwall CUTS International Time for a Functional Competition Policy and Law in India *Mainstreaming competition principles into policy and legal framework is pro-development, Jan 2006, p.4 available at* www.cuts-international.org/pdf/compol.pdf

The goal of competition law is economic efficiency. It aims at welfare of consumer by controlling prices and motivating companies to innovate and come out with better quality product with least price. However at times a monopoly or coordinated network of companies may be a efficient arrangement able to produce economies of scale. Competition law permits weighing the trade off between the cost and harm to consumers for allowing monopoly as against potential benefits.

The competition Act 2000 defines **relevant geographic market**[59] which here means national market in India. It is vital to the assessment of relevant market to know the geographical boundaries where the market power is alleged to have been exercised in an anticompetitive manner. The definition of relevant markets has had impact on the outcome of many cases.

GlaxoSmithKline Services Unlimited v. Commission of the European Communities[60] as regards to the relevant geographic market, the Court of first Instance endorsed that Commission's view that for defining relevant geographic market it must be considered to be the national market, owing, in particular, to the existence in the Member States of the Community of different price and reimbursement regulations, different brand and packing strategies, different distribution systems and different prescribing habits.

[59] Section 2 (s) of the Competition Act of 2002 (the Act) means "a market comprising the area in which the conditions of competition for supply of goods or provision of services or demand of goods or services are distinctly homogenous and can be distinguished from the conditions prevailing in the neighbouring area"

[60] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62006J0501:EN:HTML

The main anticompetitive practices that occur in the pharmaceutical sector may be primarily categorised as breaches of intellectual property rights, anticompetitive mergers and takeovers and anti-competitive agreements.

Current market players with their market share in the pharmaceutical industry in India-

Company Name	Sales in US $ Million	Year end
Cipla	6.368.06	March 2011
Ranbaxy Labs	5,687.33	December 2010
Dr.Reddy's Lab	5,285.80	March 2011
Sun Pharma	1,985.78	March 2011
Lupin Ltd.	4,527.12	March 2011
Aurobindo Pharma	4,229.99	March 2011
Piramal health	1,619.74	March 2011
Cadila health	2,213.70	March 2011
Matrix Labs	1,894.30	March 2011
Wockhardt	651.72	December 2011

Source-A brief Report Pharmaceutical Industry in India March,2012[61]

The pharmaceutical industry is undergoing a process of consolidation whereby there is concentration at the top due to mergers and acquisitions to tap the opportunities emerging

[61] Survey Report released by Competition Commission of India, available at-http://www.cci.in/pdf/surveys_reports/indian-pharmaceuticals-industry.pdf

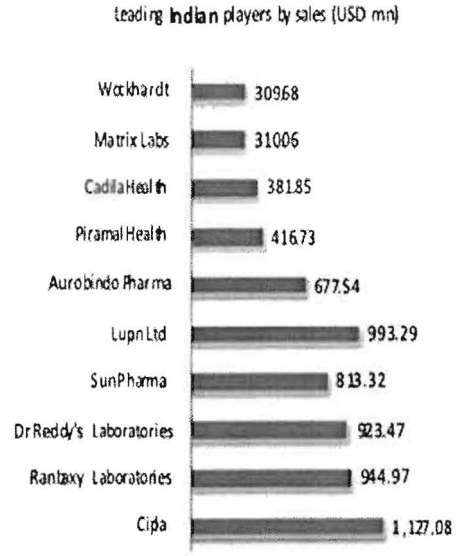
in the domestic as well as the global market in the various stages of the value chain such as R&D, manufacturing and marketing. Given the structural bottlenecks and the risk and time involved, big domestic firms do not and cannot spend the required amounts on R&D. Cost, in effect, is the crux of the issue[62].

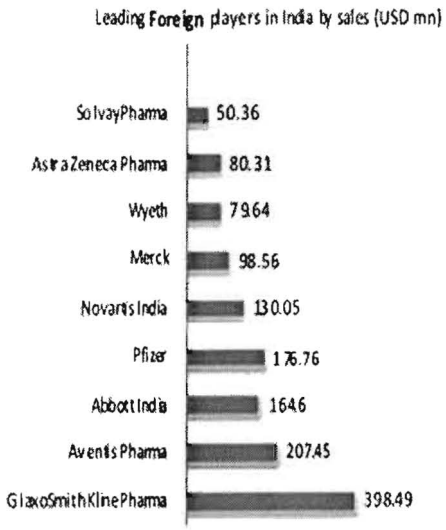
The MNCs are obviously in favour of developing drugs which are more suitable for the developed world. Thus barring a few cases, much of the research is undertaken for lifestyle-related diseases. Here the role of the government is of utmost importance. Even most developed countries' pharmaceutical industries rely on the government-funded laboratories and academic research for R&D in this sector. The breakthrough drugs typically come out of government-funded laboratories. Therefore, government- funded research organisations have to expand their role by partnering with the private sector.

[62] Ravinder Jha, Options for Indian Pharmaceutical Industry in the Changing Environment, Economic and Political Weekly, Vol. 42, No. 39 (Sep. 29 - Oct. 5, 2007), pp 3966

Key Players

Local players enjoy a dominant position driven by formulation development capabilities and early investments





Cipla enjoys the largest market share of 5.2%, followed by Ranbaxy (now a subsidiary of Daiichi-Sankyo), with a 4.7% share.

Some of the largest Pharma companies in the world have been in the Indian market since the 1970s, and 5 out of the top 10 domestic Pharma companies are already foreign owned, with a consolidated share of 22 – 23%.

Source- Indian Pharmaceutical Industry, ACE Global Consulting LLP[63]

[63] http://www.slideshare.net/aceglobal1/indian-pharmaceutical-sector-2011

STATUTORY PROVISIONS:

Anti- competitive agreements[64] and collusive practices

Section 3 of the Competition Act 2002 which prohibits anti competitive agreements, defines it as an agreement having appreciable adverse effect on competition. Anti-competitive agreements include both, the horizontal[65] and the vertical agreements[66].

Section 19 which provides for inquiry into anti-competitive agreements.

Section 27 which concerns orders, passed by the Commission after inquiry into agreements or abuse of dominant position.

Pharmaceutical companies often enter into agreements and joint-venture arrangements at each stage of the manufacturing process – at the research and development phase (for example, to pool patented know-how) and/or at the marketing and promotion phase (for example, to exploit complementary marketing strengths). Thus, the pharmaceutical industry is most prone to anti-competitive practices.

[64] Article 81 of the EC Treaty deals with the treatment of anticompetitive Agreements. The US law on anticompetitive agreements is contained in section 1 of the Sherman Act.

[65] *Horizontal agreements*: - these are between and among competitors who are at the same stage of production, supply, distribution etc. Examples- cartels, collusive bidding, bid rigging, sharing of markets etc.

[66] *Vertical agreements*: - these are between parties at different stages of production, supply, distribution etc. Examples- tie in agreements, exclusive supply/ distribution agreements, refusal to deal.

The specific anti-competitive practices of the pharmaceutical sector are covered under Section 3 of the Act are collusive agreements including cartels, tied selling, exclusive supply agreements, exclusive distribution agreements, refusal to deal and resale price maintenance. The relevant provisions are given as below:

Sec 3[67] (1) No enterprise or association of enterprises or person or association of persons shall enter into any agreement in respect of production, supply, distribution, storage, acquisition or control of goods or provision of services, which causes or is likely to cause an appreciable adverse effect on competition within India.

(2) Any agreement entered into in contravention of the provisions contained in subsection (1) shall be void.

(3) Any agreement entered into between enterprises or associations of enterprises or persons or associations of persons or between any person and enterprise or practice carried on, or decision taken by, any association of enterprises or association of persons, including cartels, engaged in identical or similar trade of goods or provision of services, which—

(a) directly or indirectly determines purchase or sale prices;

(b) Limits or controls production, supply, markets, technical development, investment or provision of services;

[67] Sec.3 of Competition Act 2002

(c) Shares the market or source of production or provision of services by way of allocation of geographical area of market, or type of goods or services, or number of customers in the market or any other similar way;

(d) Directly or indirectly results in bid rigging or collusive bidding, shall be presumed to have an appreciable adverse effect on competition:

Provided that nothing contained in this sub-section shall apply to any agreement entered into by way of joint ventures if such agreement increases efficiency in production, supply, distribution, storage, acquisition or control of goods or provision of services.

Explanation.—For the purposes of this sub-section, "bid rigging" means any agreement, between enterprises or persons referred to in sub-section (3) engaged in identical or similar production or trading of goods or provision of services, which has the effect of eliminating or reducing competition for bids or adversely affecting or manipulating the process for bidding

(4) Any agreement amongst enterprises or persons at different stages or levels of the production chain in different markets, in respect of production, supply, distribution, storage, sale or price of, or trade in goods or provision of services, including—

(a) tie-in arrangement;

(b) exclusive supply agreement;

(c) exclusive distribution agreement;

(d) refusal to deal;

(e) resale price maintenance,

shall be an agreement in contravention of sub-section (1) if such agreement causes or is likely to cause an appreciable adverse effect on competition in India.

Explanation.—For the purposes of this sub-section,—

(a)"tie-in arrangement" includes any agreement requiring a purchaser of goods, as a condition of such purchase, to purchase some other goods;

(b)"exclusive supply agreement" includes any agreement restricting in any manner the purchaser in the course of his trade from acquiring or otherwise dealing in any goods other than those of the seller or any other person;

(c) "exclusive distribution agreement" includes any agreement to limit, restrict or withhold the output or supply of any goods or allocate any area or market for the disposal or sale of the goods;

there are innumerable instances of anticompetitive agreements and collusive practices in the pharmaceutical sector.

Evidences of tie-in arrangements in the pharmaceutical (and healthcare sector) are many. Several surveys have revealed that consumers visiting private doctors or private hospitals witnessed tied selling of medicine as well as diagnostic tests. Doctors would instruct patients to buy prescribed medicines from particular shops or go to specific diagnostic centres. Sometimes doctors suggest several unnecessary tests which may not be relevant as part of their arrangements. These practices are anti-competitive in nature and impose heavy costs on consumers. In a survey conducted by ***CUTS International***, only 15% of the

respondents claimed that they had been asked to purchase medicine from a particular shop. On an average, those visiting private doctors or private hospitals, reported a higher incidence of tied selling of medicines. When healthcare service providers were asked about tied selling of medicines, only 11% admitted that they had ever resorted to such practices while 35% of them believed that other doctors resorted to tied selling practices with a profit or commission consideration.

Competition may also be impeded when two independent undertakings in way other than direct price fixing enter into agreements that apportion particular markets between themselves. While is it argued sometimes that market sharing agreements have a pro-competitive element since it reduces distribution costs and benefits consumers by lower prices. But it is not necessary that such effect on the market comes out through the agreement. Even in the absence of an agreement, based on cost benefit analysis parties would chose to distribute in particular geographic markets[68].

Instances of Collusive Arrangements between doctors and pharmaceutical firms-

- Piramal Healthcare in Mumbai took some 200 diabetologists in late January and then a batch of oncologists in mid-March to Turkey. Some of these travellers were investigated by MCI.
- Dr. Reddy's Lab in Hyderabad paid for about 200 doctors to visit Hyderabad in January.

[68] CENTAD Report 2010, pp.133

- Navi Mumbai-based Wan bury dispatched some 100 doctors to Dubai in mid-February and put them up at the luxurious Dhow Palace Hotel. Cox and Kings handled the package tour at a cost of about Rs.40, 000 per person.
- MIMS editor found that Ahmedabad based Troikka, despite the MCI ban on doctors accepting gifts, had distributed some LCDs. He said that the case is already being investigated by the MCI and that the health ministry has already been approached to empower the Drugs Controller General, India, to take actions against companies that induce doctors to violate the law.[69]

The Competition Commission of India (CCI) recently initiated complains of anti-competitive practices by All India Organization of Chemists and Druggists (AIOCD). In the case of ***US Vitamines v. Santuka Associates Pvt. Ltd***[70]., the CCI on July 1 this year made 'absolute' the interim order it passed on 16.05.2011 under section 33 of the Competition Act 2002 directing the Mumbai-based manufacturing company US Vitamins Ltd not to terminate its C&F agency with Santuka Associates Pvt. Ltd based at Cuttack in Orissa. After close examinations of the arguments advanced by both the parties, the Commission found that the contentions raised by the opposite parties have no substance and cannot be accepted. It also found that the information (petition) filed by Santuka Associates was highlighting the anti-competitive conduct of AIOCD. The informant had also filed material to show that the termination of its agency is direct fallout of anti-competitive behaviour of the AIOCD. By observing all aspects of the case, the

[69] Source- *Collusion among Health Service Providers in India: Need for Effective Regulation, CUTS, 2010* http://www.cuts-ccier.org/COHED/

[70] http://www.expresspharmaonline.com/20110815/management01.shtml

Commission found that several allegations made by the informant against AIOCD were correct, and felt that that it was not the only case where the anti-competitive behavior of AIOCD was called in question. Further, the Commission had wanted the national trade body, not to issue any direction or threat to USV Ltd for terminating its C&F agency with Santuka Associates, the informant (petitioner).

This is a welcome order and even though in the past cases were dealt with under the MRTP Commission, that was primarily a reformatory law while the current act and the CCI deals with behavioural aspects of economic activities and have deterrent powers. Therefore the CCI is expected to play much more active role in the futures to come.

Cartel[71]-

"A cartel is said to exist when two or more enterprises enter into an explicit or implicit agreement to fix prices, to limit production and supply, to allocate market share or sales quotas, or to engage in collusive bidding or bid-rigging in one or more markets. An important dimension in the definition of a cartel is that it requires an agreement between competing enterprises not to compete or to restrict competition[72].

The Competition Act mandates that cartels would be presumed to be anti-competitive, but also provides for an efficiency defence, namely that nothing in the relevant subsection shall apply to any agreement, if such agreement increases efficiency in production, supply, distribution, storage, acquisition or control of goods or provision of service.

[71] Cartel is defined in section 2, sub section (c) of the competition act, 2002

[72] http://www.taxmann.com/taxmannflashes/flashart22-3-10_4.htm

The Vitamins case (2003[73]) is one of the most severe cartels that occupied considerable attention of competition authorities' world over. The EC Competition Commission fined eight undertakings totalling to Euro 855.23 million (reduced to Euro 790.50 million) for running the vitamins cartel. Foreign MNCs like Roche, BASF, Aventis were found to be involved in cartels. However, Aventis paid substantially less as it turned out to be the whistle blower. It must be noted that price fixing in any form is caught. Article 81 (1) of the EC Treaty[74] and its application in any cases have led to the emergence of a set of jurisprudence that it is not just blatant price fixing that is caught, but also any agreement that might directly or indirectly suppress price competition. In total, fourteen chemical companies were convicted by the US for price fixing in the vitamins market. Criminal

[73] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:l:2003:006:0001:0089:en:PDF

[74] Article 81 comprises three paragraphs. Article 81(1) sets out a prohibition in the following terms:*(1) The following shall be prohibited as incompatible with the common market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market, and in particular those which:*
(a) directly or indirectly fix purchase or selling prices or any other trading conditions;
(b) limit or control production, markets, technical development, or investment;
(c) share markets or sources of supply;
(d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitivedisadvantage;
(e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

prosecutions against sixteen senior executives of the vitamin manufacturers show that comparative jurisdictions have stricter criminal measures in dealing with cartels effectively since fifteen of them received personal sentences.

Another case relates to a Brazilian Case sturdy[75] collusive conduct in the pharmaceutical industry and is significant, because most of the companies involved in this case have a foothold in the Indian industry as well. Twenty pharmaceutical laboratories were recently fined by competition authorities in Brazil, for participating in a cartel, which allegedly attempted to boycott the entry of new generic medicines. The laboratories involved include large multinational groups such as Roche, Aventis, Bayer, GlaxoWellcome and AstraZeneca. The intention of the cartel was to establish a joint action- involving general practitioners-to develop an information campaign against generics, thereby spreading what was regarded as, "distorted information". This case reveals collusion between pharmaceutical companies and doctors on the matter of barring generics, an issue of grave concern since patients usually implicitly rely on the advice meted out by their physicians and in such a case may be deprived of quality products at less expensive prices.

Another case relates to the kind of price fixing practices companies engage in. In the United States, Mylan, a maker of generic drugs was accused of price fixing with its suppliers pushing up the cost of medicines 3000 percent.

[75]Report by CUTS International,available At http://whoindia.org/LinkFiles/Trade_Agreement_Chapter03_Final_Report_IND_GPE_002-3rd.pdf accessed on 26/04/2012

The problem of tied selling was also found to be a major problem where the consumers were asked to buy from a particular shop. . On an average, those visiting private doctors or private hospitals reported a higher incidence of tied-selling of medicine[76].obviously the reason behind has been profit and commission consideration.

The anti-competitive practices most prominently engaged in by pharmacists are reflective of collusive behaviour. Pharmacy-owners may be considered to have banded together to form a huge cartel in the guise of a trade association, All India Organisation of Chemists and Druggists (AIOCD).

Abuse of dominance

It refers to economic dominance. In ***United States v. Aluminium Co. of America***[77]it was observed prohibition of abuse of dominant position is not by way of punishment because such a position may have been acquired by effective management practices and achieved by 'superior foresight' skill and industry. it has to be understood that dominant position of an enterprise has an influence on the structure of market and thus reduces opportunities for others to compete in the market thus distorting competition[78].

Since pharmaceuticals is a knowledge driven sector. IPRs play a crucial role, which mandate monopoly rights to companies which is often used against the interest of

[76] Ibid.

[77] 148 F.2d 416 (2nd Cir 1945)

[78] Banerjee Gautam ,Guide to Competition Law , Commercial law Publication, New Delhi,2011.pp32

consumer. Till the time product patent was not allowed the situation did not required much attention but after commitment to TRIPS, the abuse of dominant position by monopolist can not be ruled out.

Dominance refers to a position of strength which enables an enterprise to operate independently of competitive forces or to affect its competitors or consumers or the market in its favour. Abuse of dominant position includes imposing unfair conditions or price, predatory pricing, limiting production/market or technical development , creating barriers to entry, applying dissimilar conditions to similar transactions, denying market access, and using dominant position in one market to gain advantages in another market..

Section 4 of the Competition Act of 2002 prohibits abuse of dominance. It is to be noted here that it is not dominance per se that is prohibited but its abuse.

The relevant provisions are:

i) No enterprise shall abuse its dominant position.

There shall be an abuse of dominant position under sub-section (1), if an enterprise.—

(a) Directly or indirectly, imposes unfair or discriminatory—

(i) Condition in purchase or sale of goods or service; or

(ii) Price in purchase or sale (including predatory price) of goods or service,

Explanation- For the purposes of this clause, the unfair or discriminatory condition in purchase or sale of goods or service referred to in sub-clause (i) and unfair or discriminatory price in purchase or sale of goods (including predatory price) or service

referred to in sub-clause (ii) shall not include such discriminatory condition or price which may be adopted to meet the competition.

or

(b) Limits or restricts—

(i) Production of goods or provision of services or market therefore; or

(ii) Technical or scientific development relating to goods or services to the prejudice of consumers; or

(c) Indulges in practice or practices resulting in denial of market access; or

(d) Makes conclusion of contracts subject to acceptance by other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts; or

(e) Uses its dominant position in one relevant market to enter into, or protect, other relevant market.

Section 19, which provides for the procedural aspect of inquiry into the dominant position of an enterprise.

Section 27, which mention the orders, which may be passed by the Commission after inquiry into the practice of abuse of dominant position.

Section 28, which concerns division of enterprise enjoying dominant position.

An example of abuse of dominance by patent-holders can be seen in case of excessive or overpricing. An example may be taken from South Africa. In South Africa, the pharmaceutical companies, GSK and Boehringer, patent owners of Antiretroviral (HIV/AIDS) drugs set unjustifiably high prices of these drugs (over and above the WHO generic price) in the domestic market. The SA Competition Act prohibits a dominant firm to charge excessive price to the detriment of the consumers and the Competition Commission ordered issuance of license to market generic versions of the patented Antiretroviral drugs (ARV) drugs in return for the payment of reasonable royalty[79].

Article 82 of the EC Treaty prohibits abuses of a dominant position. As per the case-law Developments, it is not in itself illegal for an undertaking to be in a dominant position and such a dominant undertaking is entitled to "compete" on the merits. However, the undertaking concerned has a special responsibility not to allow its conduct to "impair genuine undistorted competition" on the common market. In the US, section 2 of the Sherman Act makes it unlawful for any person to "monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations.

Dominance has been defined under EC law as a position of economic strength enjoyed by an undertaking, which enables it to prevent effective competition being maintained on a

[79] ***(CUTS International, 2006).***

relevant market, by affording it the power to behave to an appreciable extent independently of its Competitors, its customers and ultimately of consumers[80].

The US courts have defined that the relevant product market "is composed of products that have reasonable interchange ability for the purposes for which they are produced- price, use and qualities considered[81]. Thus, the market is defined with regard to demand substitution, which focuses on buyers' views of which products are acceptable substitutes or alternatives.or"directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions". Thus in the case of General Motors[82] the ECJ concluded that there was enough evidence to support allegations of excessive pricing. In United Brands the ECJ negated the Commission's decision on excessive pricing as the commission did not make a clear case, but it said that "charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied... is an abuse[83].

Predatory Pricing: The EU Commission will generally intervene where there is evidence showing that a dominant undertaking engages in predatory conduct by deliberately incurring losses or foregoing profits in the short term, generally termed as "sacrifice", so as

[80] Case 27/76 United Brands Company and United Brands Continentaal v Commission [1978] ECR 207;

[81] United States v. E. I. du Pont de Nemours & Co. (Cellophane), 351 U.S. 377, 404 (1956);

[82] ***General Motors Continental NV v Commission*** **[1975] ECR 1367**

[83] ***Id***

to foreclose or be likely to foreclose one or more of its actual or potential competitors with a view to strengthening or maintaining its market power, thereby causing consumer harm.

Patents confer a monopoly status on patent owners and there might be abuse of such monopoly status. Such abuse of dominance is one of the major competition concerns, which may well beset our pharmaceutical industry with the introduction of our new patent regime.

The Act prohibits abuse of dominance in Section 4. If, therefore, pharmaceutical companies do engage in overpricing patented products or are unreasonable with respect to licensing terms and so on, our competition law may be resorted to for redressal. It is interesting to note that while intellectual property rights are expressly excluded from the purview of anti-competitive agreements in sec 3 (with the qualification that conditions imposed as a result of such rights are to be reasonable) there is no such exclusion provided in sections dealing with abuse of dominant position and combinations[84].

The most common form of abuse of dominance is excessive or over-pricing. To illustrate this, we take the example of Novartis which exercised its exclusive marketing rights granted in India under the product patent regime. Novartis' Glivec is used for treatment of Chronic Myeloid Leukaemia. There was an increase in the price of the drug from $90 to

[84] Options for using competition law/policy tools in dealing with anti-competitive practices in the pharmaceutical industry and the health delivery system, world health organization office of the WHO representative to india & ministry of health and family welfare government of india.

$2610 as a result of the exclusive marketing rights which put the drug out of reach of approximately 24000 patients in India who suffer from this disease[85].

The major way of dealing with abuse of dominance by a patent-holder is through compulsory licensing. this requires elaborate discussion which shall be dealt with in later part of this research.

A big impediment to competition in the pharmaceutical sector is the high barriers to entry raised by market players abusing their monopoly for manufacturers of generic drugs. Often companies with patented products create artificial entry barriers for generic drug manufacturing companies by setting up their own range of generics so as to recover the losses that they would have to bear upon expiry of the patent. Other practices resorted to by patentees include refusal to license, resale price maintenance and patent pooling.

Dominance has been traditionally associated with market share of the enterprise or group of enterprises concerned. However, other factors play a role in determining the influence of an enterprise or a group of enterprises in the market. These include, besides market share, the size and resources of the enterprise; size and importance of competitors; economic power of the enterprise; vertical integration; dependence of consumers on the enterprise; extent of entry and exit barriers in the market; countervailing buying power; market structure and size of the market; source of dominant position viz. whether obtained due to

[85]Competition Concerns pp36

http://whoindia.org/LinkFiles/Trade_Agreement_Chapter03_Final_Report_IND_GPE_002-3rd.pdf

statute etc. social costs and obligations and contribution of enterprise enjoying dominant position to economic development[86].

REGULATION OF COMBINATION-

Combination includes acquisition of control, shares, voting rights or assets, acquisition of control by a person over an enterprise where such person has control over another enterprise engaged in competing businesses, and mergers and amalgamations between or amongst enterprises where these exceed the thresholds specified in the Act in terms of assets or turnover.

STATUTORY PROVISIONS:

1) Section 5, which deals with what is denoted by a combination of enterprises and persons, delineating the specific circumstances as per which the acquisition of one or more enterprises by one or more persons or acquiring of control or merger or amalgamation of enterprise.

2) Section 6, which provides for regulation of combinations.

3) Section 20 which concerns inquiry into combinations.

4) Section 28, which allows for division of enterprises enjoying dominant position.

5) Section 29 and Section 30, which lays down the procedure for investigation of combinations.

6) Section 31, which enumerates the orders of the Commission on certain combinations

Section 5 of the Indian Competition Act prescribes the thresholds under which combinations shall be examined. The financial thresholds are-

[86] Centad Report 2010 available at: www.cci.gov.in/images/media/completed/PharmInd230611.pdf

- If the two firms merge and the combination has combined assets of at least Rs. 1500 cr or turnover of Rs.4500 cr. They must file notice.
- If the group to which the combined firm belongs has assets of more than Rs 6000 cr or turnover of Rs 18,000 cr, they must file notice.
- When the target company has assets of less than Rs 250 cr or turmover of less than Rs 750 cr, the acquisition has a blanket exemption from filing for 5 years.

Section 6 states that "No person or enterprise shall enter into a combination which causes or is likely to cause an appreciable adverse effect on competition within the relevant market in India and such a combination shall be void. These sections were notified and came into effect as of June 1 2011. Besides this, The CCI also has the power to order a demerger under Section 28 of the Competition Act, 2002 if the merged entity is abusing its dominant position. This means that if the merged entity engages in any form of exploitative or exclusionary practice, the CCI can take suitable action including asking the merged firm to break up. So far, no case of a demerger has come up before the CCI.

The main concern of competition authorities the world over is about the harmful effects of horizontal mergers and combinations. There may also be concerns arising out of acquisitions. Horizontal acquisitions and mergers take place between actual and potential competitors in the same product or geographic markets and at the same level of the production or distribution cycles.

There are various motivations for merger, which include, interalia, to achieve economies of scale and scope, access to distribution and other networks, access to specific markets, to become national champions, efficient management and corporate control, existing an industry, to increase market power. Thus in terms of consequences that ensue from

combinations they flow from the concentration in market power and strategically operating against competitive forces.

Under the EC law, merger are governed under the not under the EC treaty Article 81 and 82 as it proved ineffective but under the EC Merger Control Regulation. Article 2 of the 1989 EC Merger Regulation provides that a concentration which creates or strengthens a dominant position as a result of which effective competition would be significantly impeded in the common market or in a substantial part of it shall be declared incompatible with the common market[87].

In U.S the Sherman Act section 1 regulates mergers since mergers themselves are agreements[88]. In the US they are also covered under Section 5 of the Federal Trade Commission (FTC) Act and they may raise dominance related issues under section 2 of the Sherman Act. The most important antitrust statute governing mergers is the Clayton Act which prohibits mergers and acquisitions the effect of which may be substantially to lessen competition in any line of commerce, or any activity affecting commerce[89].

[87] http://europa.eu/legislation_summaries/other/l26046_en.htm

[88] Although mergers allow merging firms to come together and fix prices and engage in other concerted practices leading to anticompetitive agreements, they're not considered as per se unlawful. Hence effects of merging firms on markets are considered under the rule of reason.

[89] Dror Ben-Asher, IN NEED OF TREATMENT? MERGER CONTROL, PHARMACEUTICAL INNOVATION & CONSUMER WELFARE, Discussion Paper No. 270 12/99 available at: http://www.law.harvard.edu/programs/olin_center/papers/pdf/270.pdf

Section 7 of the Clayton Act only condemns mergers the effect of which may be to lessen competition, it means merger itself is not prohibited rather prior notice is required it the proposed merger crosses a sale figure or asset limit[90].

In the US parties planning to get merged must notify under the Hart-Scott-Rodino Act before consummating their merger[91]. It must be noted that the US the parties merging must provide the authorities with an analysis of effects of proposed merger. The Department Of Justice and Federal Trade Commission have divided amongst themselves based on industries. The pharmaceutical industry mergers are revived by the FTC. Unless the agencies make a second request seeking more information, a merger takes effect within 30days[92].

The standards that are applied by the Competition Commission to judge the Combination are-

- Barriers to entry into the market. Section 20.4.b. of the Competition Act, 2002.

Extent to which substitutes are available or are likely to be available in the market.(Section 20.4.g of the Competition Act, 2002)

[90] Ramappa T. Competition law in India, Policy Issues and Developments, 2006, Oxford University Press, New Delhi.pp191

[91] 15 USC Section 18a

[92] Centad Report 2010 www.cci.gov.in/images/media/completed/PharmInd230611.pdf

- Likelihood that the combination would result in the removal of a vigorous and effective competition or competitors in the market. (Section 20.4.i. of the Competition Act, 2002)
- Implications for the nature and extent of innovation. (Section 20.4.l. of the Competition Act, 2002)

The commission has the power to either approve the said combination or reject the same. Or the commission can also suggest modifications.

Large Indian pharmaceutical companies are also expanding their reach overseas through acquisitions abroad. Examples include Ranbaxy's acquisition of RPG Aventis; and Wockhardt's acquisition of CP Pharmaceuticals.

The assessment of the merger upon Research & development has been emphasised upon by EU which is called innovation approach[93]. The proposed merger or acquisition has to be assessed from the point of view of impact upon R&D. It is a concern that acquisitions that involve takeover of generic companies may lead to change in priorities of these companies and adversely impact the competition in generic markets.

Several concerns has been raised regarding the increased merger & acquisitions activities , it is apprehended that may lead to price rise of essential drugs as MNCs may not have Indian market in their priority , cartelisation, and concentration of market share.

[93]Morgan J Eleanor, Innovation and Merger Decisions in the Pharmaceutical Industry Review of Industrial Organization 19: 183, 2001.available at: http://www.springerlink.com/content/m348h7j5r5660358/fulltext.pdf

A high-level committee headed by Planning Commission member Arun Maira recommended[94] giving more teeth to the Competition Commission of India (CCI) in allowing mergers and acquisitions (M&A) in the pharmaceutical sector and not changing the foreign direct investment (FDI) rules. The panel was of the of the view that the present FDI policy governing the Pharma sector should not change, even as the necessary gate keeping should be done by CCI that has the provision to check such activities the view was expressed that "There is no need to follow the government route when we have more updated and more sophisticated policy instruments under the CCI[95].

At present, the government allows 100 per cent FDI in new projects in the Pharmaceutical sector, but all M&As are cleared by the FIPB. The Maira Committee also suggested that all mergers and acquisitions (M&As) in the pharmaceutical sector should be vetted by the Competition Commission of India (CCI) and not by the Foreign Investment Promotion Board (FIPB)[96]. But the concern has been expressed that such high threshold limit may hinder CCI but refused the demand of reducing the threshold limit for Pharma sector which will convey a wrong indication.

[94] Draft National Competition Policy 2011, available at: http://www.mca.gov.in/Ministry/pdf/Draft_National_Competition_Policy.pdf

[95] http://www.business-standard.com/india/news/maira-committee-favours-no-change-in-pharma-fdi-policy/450725/

[96] http://www.business-standard.com/india/news/maira-committee-favours-no-change-in-pharma-fdi-policy/450725/

CAPTER FOUR

MERGER & ACQUISITIONS OF PHARMA COMPANIES

This chapter contains the following-

i) Live cases of recent merger & acquisitions

ii) Their Implications

There have been plenty of merger activities in Pharma sector during previous fifteen years including many by Pfizer and Schering's $14 billion purchase of Organon, A Dutch entity. But the thing is that consolidation has not lead to an upsurge of new drug, and further analyses estimate that R&D productivity today is 2/5 of what it used to be ten years before.

Pfizer alone has spent more than $60 billion on R&D over the past eight years but has not produced one drug from its own labs with annual sales surpassing $1 billion. "These mergers tend to have a negative effect on R&D culture in general," says Ian Wilcox, global director of the pharmaceutical practice for Hay Group Consulting, particularly when scientists are jettisoned along with other staffers in the inevitable wave of layoffs following a takeover[97].

Several of the largest firms are the result of successive large horizontal mergers, and this has contributed significantly to industry concentration. Such mergers are often rationalized on grounds of economies of scale and scope in R and D, marketing, and administration. It was found in a research that for larger firms, mergers are a response to patent expirations and gaps in a company's product pipeline, which lead to excess capacity of the fixed marketing resources. For smaller firms, mergers are primarily an exit strategy in response to financial trouble[98].

Incentives for Mergers and Acquisitions by Indian companies

- Build critical mass in terms of marketing, manufacturing and research infrastructure.

[97] http://www.businessweek.com/technology/content/mar2009/tc2009039_020072.htm

[98] http://www.nber.org/reporter/fall06/danzon.html

- Establish front end presence
- Diversification into new areas: Tap other geographies / therapeutic segments / customers to enhance product life cycle and build synergies for new products
- Enhance product, technology and intellectual property portfolio.
- Catapulting market share

Acquisitions are the quickest way to front end access. What is interesting is the fact that apart from market access – i.e marketing and distribution infrastructure, the acquiring company also gets an established customer base as well as some amount of product integration (the acquired entities generally have a basket of products) without the accompanying regulatory hurdles. Over the last two years, several Indian companies have targeted the developed markets in their pursuit of growth, especially via the inorganic route. Companies such as Ranbaxy, Wockhardt, Cadila, Matrix, and Jubilant have made one or more European acquisitions, while others such as Torrent are also scouting for potential targets[99].

Some of the instances are as follows-

Sun Pharmaceuticals Industries/Taro Pharmaceutical Industries[100]The complaint charged that Sun's acquisition of Taro would result in reduced competition and higher pricesto consumers for three generic formulations of the anticonvulsant drug carbamazepine. The drugs named in the complaint were immediate-release carbamazepine tablets, chewable carbamazepine tablets, and extended release carbamazepine tablets. The

[99] http://www.frost.com/prod/servlet/market-insight-top.pag?docid=88873859

[100] C-4230

complaint alleged that the merger would reduce the number of firms producing the generic chewable tablet from three to two and reduce the number of firms producing the immediate-release form from four to three, leaving Teva as the only remaining significant competitor.

The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act. by eliminating actual, direct, and substantial competition between Sun and Taro in the markets for the manufacture and sale of generic immediate release carbamazepine tablets and chewable carbamazepine tablets,thereby: (1)increasing the likelihood that Sun will be able to unilaterally exercise market power in this market, (2) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors, and (3) increasing the likelihood that customers would be forced to pay higher prices; and

b. by eliminating the expected actual, direct, and substantial competition between Sun and Taro upon their respective approvals in the market for the manufacture and sale of extended-release carbamazepine tablets,thereby: (1) increasing the likelihood that Sun will be able to unilaterally exercise market power in this market, and (2) increasing the likelihood that customers would be forced to pay higher prices[101].

The acquisition was held to be constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45[102].

[101] In the Matter of ,SUN PHARMACEUTICAL INDUSTRIES LTD.,) Docket No. C-4230 a corporationhttp://www.ftc.gov/os/caselist/0710193/080813sunpharmcmpt.pdf

[102] Available at: http://www.law.cornell.edu/uscode/text/15/45

Mylan Laboratories/E. Merck OHG[103] The complaint charged that Mylan's acquisition of a generic subsidiary of Merck would result in reduced competition and higher prices to consumers for five generic drugs produced by both companies to treat hypertension and cardiac problems. The drugs named in the complaint were: acebutolol hydrochloride capsules (a beta blocker used to treat hypertension),flecainide acetate tablets (an anti-arrhythmia drug used to treat heart problems), guanfacine hydrochloride tablets (an alpha blocker used to treat hypertension), nicardipine hydrochloride capsules (a calcium channel blocker used to treat hypertension), and sotalol hydrochloride AF tablets (a beta blocker used to treat hypertension). Mylan and Merck, through an agreement with Par Pharmaceuticals, were the only two suppliers of generic cebutolol hydrochloride capsules, and among a small number of suppliers for the other four drugs. The order requires that Merck divest its assets in the five drugs to Amneal. The order also requires that Mylan and Merck provide transitional services to help Amneal obtain necessary FDA pproval.further the obligation was imposed upon the respondent to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner. and to create an effective and viable and effective competitor who is independent of respondent.

In the near future, we shall rather witness more strategic collaborations between Indian and global pharma companies, especially in the generic space. The number of high profile

[103] In the Matter of Mylan Laboratories and E. Merck OHG available at : http://www.ftc.gov/os/caselist/0710164/070921do0710164.pdf

M&As of Indian pharma companies will significantly increase as and when the valuation of the domestic companies appears quite attractive to the global pharma majors. This could happen, as the local players face more cut-throat competition both in Indian and international markets, squeezing their profit margins.

The period from 2006 to 2010 saw some significant M&A deals that changed the face of Indian pharma industry. Some of them were the acquisition of Matrix Lab by US-based Mylan Inc in August 2006, Japan's Daiichi Sankyo acquired Ranbaxy Laboratories in June 2008, France-based Sanofi Aventis took over Shanta Biotech in July 2009 and last year, in May, US-based Abbot Laboratories acquired Piramal Healthcare.

Recent Merger activities in Pharmaceutical sector:

No.	YEAR	Acquirer		Target Company
		Company	Country	
1.	June'08	Daiichi Sankhyo Co Ltd	Japan	Ranbaxy Laboratories
2	Aug.08	Fresenius Kabi AG	Germany	Dabur Pharma
3	June,09	Pfizer (Animalhealth Business)	U.S	Vetnex Animal Health Ltd (earlier ICICI

				Venture acquired from Ranbaxy
4.	June ,09	Vetoquinol SA	France	Wockhardt (Animal Care Subsidiary)
5.	Jul,09	Abbott Laboratories	U.S	Wockhardt (Nutrition Business)
6.	Jul,09	Sanofi Aventis	France through Merieux Alliance	Shantha Biotech (Hiked stake from 60% to 80%
7	May,10	Abbott Laboratories	USA	Piramal Healthcare(Sale of Business)

Source-http://www.expresspharmaonline.com/20100715/management01.shtml

Case 2- Daiichi-Ranbaxy Acquisition Deal In November 2008, Daiichi Sankyo of Japan acquired Ranbaxy Laboratories at US $4 billion for a controlling stake of 63.92% of Ranbaxy's equity shares (position as of December, 2008). Daiichi paid Rs737 ($15.42) per share. Pursuant to the change in the ownership of the Company, the Board of Directors of the Company was re-constituted on December 19, 2008 (Annual Report 2009). As per the Company's 2009 annual report "...[t]he coming together of Ranbaxy and Daiichi Sankyo

is a path-breaking confluence that, in one sweep, catapults the new, empowered entity to the status of the world's 15th largest pharmaceutical Company. Individually, the two pharmaceutical giants are formidable - one, India's largest generics Company and the other, among the largest innovator companies in Japan". This possible motive for the acquisition seems strategizing market position, combined with strengths of both generic market networks and skills in innovation[104].

Ranbaxy was possibly was a good target because of its size, investment in R&D and a rich pipeline of products going off patents. While the Ranbaxy deal may have been bigger in size; it was finally an acquisition of a global generic major by a large innovator company looking at enhancing its presence in the generics market.

Acquisitions result in aggressive price increases, diversion of drugs to remunerative global markets, and adverse effects on the availability of drugs in the local market, IPA secretary general D.G. Shah said in a presentation to the Planning Commission[105].

Piramal Bought by Abbot Laboratories

Two years later, US-based Abbott Laboratories bought the healthcare solutions business of Piramal Healthcare Ltd for $3.72 billion, becoming India's largest drug company in the process. The Piramal-Abbott deal will go down in history as a crucial milestone for the Indian pharma industry.The transaction is a global acknowledgement of the power of the domestic pharma Industry. Piramal was the first acquisition of a domestic formulations

[104] CENTAD Report, 2010

[105] http://www.livemint.com/2011/09/04222300/Planning-Commission-in-favour.html?atype=tp

company by an MNC in the last 12 years (Biddle Sawyer – GSK was the last deal in 1998[106].

The deal offers Abbott Lab a combined 7% market share in the Indian generic market and makes Abbott Lab the single largest player in the Indian pharmaceutical sector. Further, the deal provides Abbott Lab, the much required access to other emerging markets. This deal would enable Abbott to capitalize on Piramal Healthcare□s strong commercial presence, including a large sales force in rural area and it is expected that the combined Abbott and Piramal Healthcare sales forces will be the industry's largest in India. The acquisition makes the company a leader by revenue market share in the Indian market with around 7%.

Acquisition of Dabur Pharma by Fresenus Kabi

The acquisition significantly expands Fresenus Kabi's i.v. drug portfolio and secures its supply of high quality APIs for cytostatics. Dabur Pharma, headquartered in New Delhi, is one of the leading suppliers of generic drugs and active pharmaceutical ingredients (API) to treat cancer. The company holds a substantial number of drug registrations in Asia, Europe and the US. Dabur Pharma was acquired for its investment in oncology research and a very rich pipeline of off-patent oncology products.

Shantha Biotech acquired

Shantha Biotech for its research in vaccines and its potential as a major supplier of vaccines to the developing world. it has been claimed that the acquisition of Shantha

[106] http://www.expresspharmaonline.com/20100715/management01.shtml

Biotech by Sanofi-aventis will enable the domestic biotech company to get world class r & d and partnership of international vaccine development company. Further they argued that a price of none of the vaccines of Shantha Biotech has gone up after this acquisition[107].

it is obvious that the Indian patient will be deprived of vaccines and oncology products at prices that these companies would have offered as Indian entities. Moreover, one cannot argue that access to new drugs of original research would not have been possible without these acquisitions. On the contrary, it can be said that in spite of acquisitions, new drug may not be accessible for a variety of reasons, unaffordable pricing being the major reason. Not only new, but even the existing off-patent medicines may also become inaccessible from the new owners for various reasons such as rationalisation of product portfolio, price increases to pay for the premium paid by the acquirers, discontinuation of product for inadequate margin, etc.

But on the other hand it is countered by the argument that he intense competition in the pharma business coupled with authorities like the NPPA and regulations like DPCO firmly in place the prices are unlikely to go up. Most MNCs have now realised that aggressive pricing in emerging markets will not only delay market penetration but will result in loss of market share. Hence there is a trend in adopting India centric pricing[108].

Those having competitive aspect of it say that though these companies were attracted by the potential in the generic drug market rather than the desire to engage in anti-competitive practices, it cannot be ignored that these companies have the potential to engage in such

[107] http://indiatoday.intoday.in/story/the+buyout+bogey/1/125866.html

[108] http://www.expresspharmaonline.com/20100715/management01.shtml

practices if opportunities present themselves. Such opportunities are indeed likely to present themselves in the near future. Data released in various newspaper articles shows that the hold of MNCs on the Indian pharmaceutical market is increasing; the top four firms now include only one local company (Cipla), a complete contrast to the situation in 2008 when GSK (now ranked fourth in terms of market share) was the only MNC in the top 10. Collectively, MNCs have now cornered about 25% of the market share.

A pattern is indeed developing where the market is being slowly transformed from a very competitive one to one dominated by few companies. If such companies were to dominate the market, there is nothing that can stop them from abusing the position if they believe they can get away with it.

A glance at the history of these MNCs regarding adherence to competition law can be a guidance for their future conduct. Sanofi-Aventis, for example, was part of the famous international vitamins cartel, which according to published research, has been convicted of price fixing for more than ten times in its history. GSK has been a subject of investigation under EU and Greece competition laws under allegations of abuse of dominance in the pharmaceutical market. A lawsuit was filed in April 2004 against Abbott Labs after it was accused of abusing its monopoly over an essential anti-retroviral drug to overcharge tens of thousands of AIDS patients. Early this year, Mexico's Federal Competition Commission fined Fresenius Kabi and two other firms for rigging government tenders for insulin[109].

In the light of these there is urgent need for empowering the Competition commission of India to enable it to play a more constructive role in the regulation of merger & acquisition

[109] Pradeep Mehta, **Overseeing pharma mergers through competition lens, available at:** http://www.cuts-ccier.org/ArticlesJune10-Overseeing_pharma_mergers_through_competition_lens.htm

deals in the sector. Because the potential victims of unregulated mergers are the poor consumers, who may end up paying more, while a sound regulatory policy willed by the parliament to protect and promote their welfare is unable to evolve.

CHAPTER FIVE

ISSUES RELATING TO PATENTING AND COMPULSORY LICENCING

Intellectual property (IP) law subjects intellectual assets to the owner's exclusive control. Competition law on the other hand, seeks to avoid market barriers and benefit consumers by ensuring that a multiplicity of suppliers of goods, services and technologies may effectively compete against each other. The relationship between these two areas of law poses uniquely difficult challenges to policymakers, particularly in developing countries where the regime of competition law is yet not grown enough. Patents give monopoly right which is against the concept of antitrust law.[110] This is the reason several scholars state that patent and antitrust laws are against to each other. [111] Indeed on several occasion in United States history, courts and scholars have taken the approach.[112] It is facile to say that

[110] *See* Section 1 and Section 2 of the Sherman Act, 1890.

[111] *See* Herbert Hovenkamp, Mark D. Janis and Mark A. Lemley, IP AND ANTITRUST: An Analysis of Antitrust Principles Applied to Intellectual Property Law, Aspen Publishers, vol. 1, ch. 1, p. 10 (2007).

[112] United States v. Westinghouse Elec. Corp., 648 F.2d 642, 646 (9th Cir. 1981) "One body of law creates and protects monopoly whereas the other body proscribes it." In Henry v. A.B. Dick Co., 224 U.S. 1, 27 (1912) the court sated that pated is true monopoly; William C. Robinson, The Law of Patents for Useful Inventions, at 67 (1890); Hon. Giles S. Rich, Are Letters Patent Grants of Monopoly? 15 W. New Eng. Law. Rev. 239 (1993) (reviewing the history of patents whether patents are "monopolies")

antitrust law forbids monopoly. Courts have seen inherent conflict between patent and antitrust policy.[113]

Patent protect technical embodiments of inventions and are considered to be the strongest form of legally granted monopolies amongst the various categories of intellectual property rights. Since it is the strongest form of market intervention, it is bound to have certain effects on competition.

In cases where IPRs are granted, governments can adopt measures to mitigate the monopolisation of technologies and promote competition. Thus, although Article 31(b) of the TRIPS Agreement only refers to the refusal of a voluntary licence as a condition for the granting of a compulsory licence[114], the unilateral refusal to license a patent generally known as "refusal to deal" can be considered grounds for granting a compulsory licence and has been contemplated in a number of national patent laws. The possibility of allowing third parties to use IPRs in cases of refusal to deal has also been considered in some

[113] E.g., *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1203 (2d Cir. 1981): The conflict between the antitrust and patent laws arises in the methods they embrace that were designed to achieve reciprocal goals. While the antitrust laws proscribe unreasonable restraints of competition, the patent laws reward the inventor with a temporary monopoly that insulates him from competitive exploitation of his patented art.

[114] CL is the authorisation issued by the government permitting a third party to make, use or sell a patented invention without the patent owners consent. Circumstances of national emergency or extreme urgency, unsuccessful negotiations to get licence for the patented product could be some of the reasons for exercising this option, though the user must pay adequate remuneration to the patent holder.

countries under competition law in the context of the "essential facilities" doctrine[115]. The essential facilities doctrine was developed in US to limit property rights and was first applied to physical assets rather than IPRs in circumstances where it was not so difficult to determine compensation for the property owner[116].

In the Pharma sector this doctrine can be used as a ground for using patented knowledge and resort can be had to compulsory licensing.

Undue enforcement of IPRs can also amount to anti-competitive conduct. In particular, preliminary injunctions may be effectively used to prevent legitimate competition. This is why courts in the United States and Europe have generally taken a very cautious approach towards the granting of injunctions in patent cases. Compulsory licences can be used, both in the context of IPRs and of competition laws, to remedy anti-competitive practices. Article 31(k) of the TRIPS Agreement, explicitly provides for the granting of such licences

[115] A company which has a dominant position in the provision of facilities which are essential for the supply of goods or services on another market abuses its dominant position where, without objective justification, it refuses access to those facilities. Thus in certain cases a dominant undertaking must not merely refrain from anti-competitive action but must actively promote competition by allowing potential competitors access to the facilities which it has developed. BRONNER AND BEYOND, ESSENTIAL FACILITIES IN THE EUROPEAN UNION, COLUMBIA JOURNAL OF EUROPEAN LAW,vol.10, http://www.jonesday.com/files/Publication/e2d79ea9-8440-49e6-a879-c834f4b0b557/Presentation/PublicationAttachment/9cf89b02-295b-43cf-8a00-3cbea13a85bf/Article%20essential%20facilities.pdf

[116] Vinod Dhall, Competition law Today, Concepts, Issues, and the Law in Practice, Oxford University Press, 2008 pp 135

in the case of patents. For example, in the US the grounds for granting compulsory licences under competition law have included the use of patents as a basis for price-fixing or entry restricting cartels.[117]

In ***Microsoft's case*** in 1994[118]Marshall stated that developing countries do not have resources to deal with the monopolistic approach of IPRs holders in developed countries and it requires international antitrust standard to help developing countries to deal with the abuses from industrial monopolies. Various provisions of TRIPS permit monopolization and further it has increased the issues of abuse of monopolization by extensive interpretation of TRIPS provisions[119], bilateral agreements[120] , and multilateral treaties[121] sometimes imposed on developing countries because of their economic vulnerabilities.

[117] By Carlos M. Correa, Intellectual Property and Competition law, Exploring Some Issues of Relevance to Developing Countries, available at: http://www.iprsonline.org/resources/docs/corea_Oct07.pdf

[118] Marshall H Richard Patents, *Antirust, and the WTO/GATT Using TRIPS as a Vehicle for Antitrust Harmonization,* 28 Law and Policy in International Business 1167 (1997) ("Monopolized markets also stifle innovation because the concentration of power in the monopolists provides insurmountable obstacle for smaller companies to challenge the monopolist assuming there is no antitrust law to come to their aid). Furthermore, there is no threat from others in the market if the law allows the monopolist to retain the monopoly. The lack of innovation may also minimize consumer's option.")

[119] WTO, Canada-Patent Protection of Pharmaceutical Products, Report of the Panel, WT/DS114/R dated 17th March 2000, *See* generally Daya Shanker, Brazil, *the Pharmaceutical Industry and the WTO,* 5 Journal of World Intellectual Property 51 (2002).

[120] David Vivas-Eugui, *Regional and Bilateral Agreements and a TRIPS-plus world: The Free Trade Area of the Americas (FTAA),* TRIPS Issues Papers 1, Quaker United Nations Office (QUNO), Geneva;

Patent monopoly confers rights, privilege and immunity on the patentee but subject to certain obligations and duties.[122] The patentee is bound to exercise its right in such a way so that it should not unfairly prejudice to the interest of public. Therefore, in case of abuse

This was also discussed by the African Group in Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Joint Communication from the African Group in the WTO, IP/C/W/351 dated 24th June 2002 where the African Group decried the tendency seen in bilateral and plurilateral arrangements between developed and developing countries where developing countries have been asked to give up not only the flexibility due to them under the TRIPS Agreement but to go for much higher level of patenting monopoly which essentially amounted to extending the monopolistic control of the patent holder who predominantly happened to be from developed countries. Peter Drahos, *Bilateralism in Intellectual Property,* Oxfam Policy Paper December 2001 available at http://www.oxfam.org.uk/policy/papers/bilateral/bilateral.html;

[121] The Agreement on the Revision of the Bangui Agreement signed on 24th February 1999 and came into force on 28th February 2002 was prepared by the World Intellectual Property Organization as a revision of the Agreement Relating to the Creation of an African Intellectual Property Organization which came into force on 8th February 1982. The Revised Bangui Agreement imposed one of the most restrictive patenting provisions on some of the poorest countries of the world. Also *see* Enyinna S. Nwauche, *An Evaluation of the African Regional Intellectual Property Rights Systems,* 6 Journal of World Intellectual Property, 101 (2003).

[122] *See* P. NARAYANAN, PATENT LAW, Fourth Edition, Eastern Law House, Kolkata, New Delhi, p.264 (2006).

of patent, the provision for granting compulsory licence[123] or revocation of patent, under certain circumstances[124], has been enshrined.

If patent monopoly is abused, the provisions of Section 3[125] of the Competition Act, 2002 would be applicable. The party asserting the fact that patent monopoly has been abused; it has to prove that such patent abuse has appreciable adverse effect on competition within India.

Patent monopolist may not be in dominant position[126] in rare[127] case but generally patent monopolist is assumed enjoying dominant position.[128]

[123] *See* Section 84 of the Patent Act, 1970. Compulsory can be given under certain conditions as mentioned in the aforementioned provision.

[124] *See* Chapter 15 of the Patent Act.

[125] Here the writer intends for the application Section 3 excluding the provisions Section 3(3) of the Competition Act, 2002 because already the writer has discussed the application of this provision.

[126] "Dominant position" means a position of strength, enjoyed by an enterprise, in the relevant market, in India, which enables it to—

(i) operate independently of competitive forces prevailing in the relevant market; or

(ii) affect its competitors or consumers or the relevant market in its favour. For further clarification see; Explanation (a) of the Section 4 (2) of the Competition Act, 2002.

[127] The writer uses the word 'rare' because only in rare case it is possible that patentee does not enjoy dominant position in the relevant market because patent can be given only when the invention has industrial application

Sec. 3 (d)[129] of the Patent Act 1970 as amended in 2005 is the provision which has been of much used to safeguard interests of the patients against the Pharma companies in granting unnecessary patents. The object of this section has been held to be to provide life saving drugs available to Indian citizens and fulfilling the constitutional objective of decent health and life. These provisions by laying down higher criteria of patentability rule out the possibility of undesirable patents and promote generic competition.

Compulsory Licencing to deal with patent monopoly

Compulsory licensing under TRIPS regime- Sometime where the patent monopoly is abused, the remedy may be provided by granting compulsory licenses.[130] Article 31 of TRIPS Agreement makes provisions for granting of compulsory license. A firm having IP

and patent gives monopoly right. Therefore, the writer infers that patentee is generally assumed in dominant position.

[128] There is difference between patent monopoly and dominant position. Firm which is in dominant position, may not be monopolist but a monopolist firm may be in dominant position.

[129] Sec. 3 (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, ure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy

[130] Granting compulsory license may be considered one of the tools to regulate the patent moriopoly.

rights may be in dominant position but sometimes the dominant position may be abused in a number of cases such as non-working of the patent.[131] While granting compulsory license, below mentioned conditions should be fulfilled:

- The license must be nonexclusive[132] and non-assignable[133]
- The license should be granted for a limited period of time for stipulated object[134] and it is liable to termination when the circumstances cease to exist.[135]
- The adequate remuneration should be provided to the patent holder;[136] and
- The opportunity for review should be provided so as to any decision to authorize a compulsory license.[137]

Under Indian Patent Act, 1970 partial remedy is available in case if patent monopoly is abused. If patent monopoly is abused, according to the provisions of Sections 84

[131] *See* WILLIAM A. W. NEILSON, ROBERT G. HOWELL AND SOUICHIROUS KOZUKA, INTELLECTUAL PROPERTY RIGHTS AND COMPETITION LAW AND POLICY: ATTEMPTS IN CANADA AND JAPAN TO ACHIEVE RECONCILIATION, 1 Washington University Global Studies Law Review 323 (2002).

[132] *See* Article 31(d) of TRIPS Agreement.

[133] *Ibid* Article 31(e)

[134] *Ibid* Article 31(c)

[135] *Ibid* Article 31(g)

[136] *Ibid* Article 31(h)

[137] *See* Article 31(i) and Article 31 (j) of TRIPS Agreement. (review refers to the judicial review or review by any other independent authority)

compulsory license may be given. According to Section 140 of the Patent Act, 1970 certain restrictions have been imposed on the patent monopolist to exercise its right while granting license but if patent monopoly is abused by the patentee itself without granting license, there may not be sufficient provision under patent law to take appropriate measures and therefore, the provisions of Competition law are applicable in this case.

Competition law for abusing patent monopoly, the action can be taken under Section 3(1) and Section 3(4) read with Section 3(5) of the Competition Act, 2002 but the provisions of Section 3(3) are not applicable because patent monopoly itself does not confer economic monopoly on the patentee and therefore, unless the patentee has market power, patent may not be abuse by the patentee. Therefore, the complainant has to prove that patentee enjoys the market power and the abuse of patent monopoly has appreciable adverse effect on competition within the territory of India.

The NATCO Case[138] - In a landmark decision, India's intellectual property office on Monday allowed Hyderabad-based Natco Pharma Ltd to make and sell a copycat version of German drug maker Bayer AG's patented cancer treatment Nexavar. It's the first time that an Indian company has been granted the so-called compulsory licence to market a generic version of a patented drug.

The drug, patented by Bayer in India in 2008, is used in the treatment of liver and kidney cancer, and costs Rs. 2.8 lakh for a month's dosage. After Bayer rejected Natco's request for a commercial licence to manufacture Nexavar, the Indian company in September

[138] http://www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf

applied for a compulsory licence to make a copy of the drug, claiming the patent holder had failed to meet the needs of the local market.

The Compulsory License[139], first of its kind granted, enables **NATCO** to sell the drug at a price not exceeding Rs. 8880 for a pack of 120 tablets (one month's therapy) against Rs. 284,428 being the cost of Naxavar sold by Bayer. The license is valid till the expiry of the patent – 2021.The order is subject to certain conditions such as maintaining account of sales, and payment of royalty at 6% of the net sales on a quarterly basis etc. The order also makes it obligatory for NATCO to supply the drug free of cost to at least 600 needy and deserving patients per year.

It is for the first time that India has used this compulsory licensing provision to facilitate availability of life saving drug. The order paves the path for using the flexibilities provided by trade-related intellectual property rights against the abuse of patent rights[140]."

The order by the patents office said Natco was being permitted to produce a generic version of Nexavar because it had established that the drug wasn't affordable in the local market. The patentee continued importing the drug, but was able to provide it to only a small fraction of patients.

[139] Section 84 lays down that three years after the grant of a patent, any entity may apply to the patents office for a licence to sell a generic version of the drug on grounds that the patented version has not worked in India, that the requirements of the public haven't been met or that it isn't available to users at a reasonable price.

[140]

This decision is a milestone laying and would encourage many other generic companies to follow the same route. It would redress the public health and pricing issues and will facilitate access to medicine. The issue of differential pricing structure for different section of consumers was discussed which possibly may see light of the day. The biggest contribution of this decision will towards the cause of poor cancer patients who can now imagine saving their life. it serve as an inspiration for the other developing countries incorporate and use such provisions in their patent law regime. Further it will act as a precedent for Future cases being the first of its kind.

Perhaps Natcos' baby step in this regard may pave the way for a giant leap of sorts, where many more drug patents are subjected to this "stick" so as to help bring down what are by most standards, highly excessive prices for a country like India. In fact, given that more than 90% of MNC drugs are imported into India, this order may pave the way for wholesale compulsory licenses to be issued against a wide spectrum of drugs in the near future. This interpretation of "working" to mean "local working" (local manufacture within India) may in fact prove the most controversial part of the order and may perhaps attract a TRIPS challenge as well. Further, it must be noted that both Cipla and Natco have challenged the validity of Bayer's patent in a separate proceeding before the Delhi High Court If this challenge is successful, then the compulsory license by Natco becomes in fructuous. All generics are then free to manufacture this drug without paying any royalty to Bayer[141].

[141] http://spicyipindia.blogspot.in/2012/03/breaking-news-indias-first-compulsory.html

Regarding the observations on the working status of a patent, intellectual property expert Shamnad Basheer said this part is likely to prove controversial, since almost 90 per cent of all patent-protected pharmaceutical products are imported. "Therefore, under the terms of this order, all these drugs are now susceptible to compulsory licences in India[142]"

Compulsory Licence may be also justified under the public policy principle of "Essential Facilities Doctrine" whereby the monopolist/dominant firm is required to grant access to a facility that it controls and that is necessary for effective competition provided that a refusal of access would have significant anti-competitive effects. The European Commission (EC) had adopted this doctrine in the compulsory licensing of intellectual property rights in downstream markets in the Magill case[143]. Another example of its adoption is found in the famous Microsoft case[144]. While generally the doctrine is applied in network industries (such as telecom, electricity etc.), however public benefit and welfare models make it an important tool to be applied in other sectors like pharmaceuticals, particularly in the context of patent and access to drugs.

[142] http://business-standard.com/india/news/natco-to-sell-bayer-patented-cancer-drug-nexavar-/467537/

[143] In the 1995 case *RTE & ITP v. European Commission* (often referred to as the 'Magill case'), the European Court of Justice had to decide whether the Irish public broadcasting company (RTE) had abused its dominant position by using its intellectual property rights (IPR) to restrict its competitors from entering the market of weekly TV magazines. when IPR are exercised in a way that does not match with their purpose, but for a purpose of distorting the market. RTE abused its dominance because it hindered the introduction on the market of a new product for which there was a consumer's demand, by using its IPR not to protect and reward its creative efforts but rather to maintain its monopoly on the market.

[144] *Supra note 82*

There is little doubt that developing countries who issue compulsory licenses also face additional risks in attracting global capital. Particularly for MDCs, a compulsory license can trigger the loss of significant FDI. Thus, each nation has to weigh the benefits as well as the disadvantages of issuing such a license for the benefit of its citizens. Developing nations, however, may attempt to use their compulsory licenses strategically by acting collectively with countries that have similar interests.[145]

[145] Robert Bird & Daniel R. Cahoy, The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach, American Business Law JournalVolume 45, Issue 2, Summer 2008, pp48

CHAPTER SIX

RIGHT TO ACCESS TO MEDICINE AND PRICING ISSUES OF DRUG PRICING

About 14 million people die each year from infectious diseases, many of which preventable or treatable, such as acute respiratory infections, diarrhoeal diseases, malaria and tuberculosis. a vital factor in the promotion of public health - and very often, a matter of life and death - is the supply of effective and affordable medicines and peoples' access to such medicines and treatments. Public interest worldwide has been aroused by the health crises in the developing countries, caused by the exorbitant prices of drug treatments. Prices of patented medicines are very much linked to the monopolies enjoyed by pharmaceutical companies, protected and maintained by patent rights. The TRIPS Agreement obliges WTO Members to adopt and enforce high standards of intellectual property rights protection, which were derived from the standards used in developed countries. The minimum term of 20-year patent protection required by TRIPS effectively allows a pharmaceutical company a monopoly over the production, marketing and pricing of patent protected medicines. It will be able to keep the price of the drug high during the protection period, free from competition. By virtue of TRIPS protection, no generic equivalent can come into the market until expiry of the 20 years, denying patients cheaper alternatives.

The following points are important in the light of TRIPS and Access to medicine-

- Prices of branded or patented products are often far higher than the prices of similar medicines produced by alternative or generic sources.

- When generic competition is introduced, prices of the patented product will fall.

- When a drug company sells the same product in different countries, it adopts a policy of price differentiation, setting price levels "according to what the market can bear.
- Multinational drug companies practice transfer pricing in the trade of raw materials used in the drugs, and that this raises the cost of medicines in developing countries.
- There is also a belief that drug companies sell their branded products cheaper in developing countries. This is often not the case. Prices of some products are higher in many developing countries. This makes medicines even less affordable, as countries with much lower per capita income have to pay much higher prices for the same medicine as compared to prices in developed countries[146].

Access to Medicine-

Access to essential medicines has been discussed at length in a recent order of the Delhi High Court in the case of *F. Hoffman-La Roche Ltd. and Anr. Vs. Cipla Limited*[147] where the court refused to grant an interim injunction to La Roche (Plaintiff hereinafter) and permitted Cipla (defendant hereinafter) to market its generic version of lung cancer

[146] THIRD WORLD NETWORK BRIEFING PAPER June 2001,TRIPS, PATENTS AND ACCESS TO MEDICINES:PROPOSALS FOR CLARIFICATION AND REFORM ,available at: http://www.twnside.org.sg/title/drugs2.htm

[147] 148 (2008) DLT 598

treatment drug 'Erlocip', a copy of the plaintiff's patented drug 'Tarceva' in public interest. This order is one of the most crucial judicial pronouncements relating to patents in India after its accession to TRIPS standards in 2005 as the court largely based its order on the 'balance of convenience' principle rather than statutory patent law in India. in its order, the court considered that the between two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a life saving drug, the court held that the balance has to be tilted in the favour of the latter. *Courts while deciding applications seeking interim injunction, involving claims for infringement of patents especially when life saving drugs are involved have to strike a balance between the imponderables such as the likelihood of injury to unknown parties and the potentialities of risk of denial of remedies.*"

In USA in ***Carter v. Wallace***[148] the court of claim stated the maximum price at which the medicines can be sold and access of such medicines can be ensured to poor people. 65% of

[148] Carter Wallace v. United States, 196 Ct. Cl. 35, 50-51 (Ct. Cl. 1971) ("Second, and of particular importance here, the maximum price which plaintiff can charge its pharmaceutical-house customers for meprobamate is $20 per pound, adjusted from time to time by changes in the Consumer Price Index over the last index for the month of June 1962. This pricing arrangement was expressly agreed to by the Government and plaintiff in the earlier antitrust litigation, and was adopted by the District Court as Article IV© of the consent judgment. It is pertinent to note that the Government's brief in the antitrust case stated that the "Government is satisfied that the maximum .price of $20.00 per pound of meprobamate compound will encourage and permit the entry of competitors in this hereto for pre-empted market." Also the District Court opinion 211 F. Supp at 148, noted that "maximum price of twenty dollars will enable

the Indian population still lacks access to essential drugs, and the need for affordable and high-quality medicines is critical for the sustainable growth of the Indian economy.

Good quality healthcare should be accessible, affordable, and available to all in need and the poorest person should get the same quality of healthcare as the richest person. Obviously in India this would be seen as a daydream. the Indian pharmaceutical industry is seen as a success story; and it is indeed so in comparison with most developing economies with the possible exception of China. The irony, and the tragedy, of course is that this success has not translated into availability or affordability of medicines for all. Therefore the easiest way to restore faith in the system is to stock quality medicines at all levels of public healthcare[149].

Suggestions that can help to have better access to medicine-

Restrict the list of medicines available in this country to essential medicines. The current National List of Essential Medicines (NLEM 2003) and WHO's Model List (2010) have around 350 medicines. This can be increased to 500 to include medicines for rare conditions and unnecessary fixed dose combinations and drugs of doubtful or no value can be removed.

- Price regulation of all these medicines.

them [i.e., other pharmaceutical houses], as well as Carter and American [Home Products Company], to make a handsome profit and at the same time substantially reduce the price of the tranquilizing and combination drugs to the consuming public]

[149] S Srinivasan, Medicines for All', the Pharma Industry and the Indian State Economic & Political Weekly EPW June 11, 2011 vol xlvi no 24 pp46

• A national vaccine policy to regulate the entry of new vaccines as also in the Expanded Programme on Immunisation (EPI).

• Proactive use of Trade Related Aspects of Intellectual Property Rights (TRIPS)

- flexibilities including issue of compulsory licences on patented drugs that are high priced and/or are not easily available.

Price regulation of Drugs-

While making or revising it policies on drug pricing any government has to maintain a balance between its obligation to protect health of its citizen and developing nations's ability in research & development.

Some mechanism to control prices of drugs in widely recognised even in most of the open economies also. It has been revealed through study that more than 60% of the top-selling 300 drugs which accounted for nearly 80% of the retail sales are not to be found in the national essential drug list. There are also other ironic consequences due to susceptible users making decisions in distress and out of ignorance.

Drug prices vary from country to country, for a number of reasons, including patent regulations, government controls, purchasing power, currency exchange fluctuations, etc. Due to the price control and patent regime, drug prices fell considerably, in India, and were

Among the lowest in the world. The main regulatory mechanism, which enforces price control, is the Drug Price Control Order, which is revised periodically[150].

Price control orders have been issued under the Essential Commodities Act, from 1970 onwards The Drug Price Control Order (DPCO) in 1970 was a measure to safeguard the interests of the consumer, while providing for a restricted but reasonable return to the producers. the government controls under DPCO 50 per cent of the pharmaceutical market in India (ICRA, 2000). The government announced a new pharmaceutical policy in 2005, wherein it was proposed to bring an additional 354 drugs under a National List of Essential Medicines (NLEM) under price control.[151]

In June 2010 the competition commission of India initiated an investigation to assess alleged anticompetitive practices of the All India Association of chemists and Druggists' (AIOCD) controlling about 90% of the Rs. 60,000 Crore domestic drug trade in the country. The common complaint against the associations arise from the guidelines issued by them to their members as well as the pharmaceutical companies dictating terms and conditions on routine developments such as the launch of new products, appointment of wholesale agents or clearing and forwarding agents. The industry complains that the medicine trade has completely been monopolised by the associations.

[150] AVAILABLE LEGAL OPTIONS- A CRITICAL ANALYSIS, http://whoindia.org/LinkFiles/Trade_Agreement_Chapter04_Final_Report_IND_GPE_002-3rd.pdf

[151] Narayan S. **PRICE CONTROLS ON PHARMACEUTICAL PRODUCTS IN INDIA,** ISAS Working Paper No. 20, 2007, available at: *kms1.isn.ethz.ch/serviceengine/Files/ISN/30719/...cb7f.../20.pdf*

For the purpose of implementing provisions of Drug price control Order, powers of the Government have been vested in the National Pharmaceutical Pricing Authority (NPPA). A grave concern has been, the decreasing number of drugs under statutory control in the wake of liberalization and economic reforms.

The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy 2011 are based upon (1) Essentiality of Drugs (2) Market Based Pricing as distinct from cost based pricing (3) Control of Formulations prices only[152].

The Central government responding to the Supreme Court's concern over spiralling prices of essential medicines has promised to make all-out efforts to put under strict price control regime all the 348 drugs included in the National List of Essential Medicines (NLEM), 2011[153].

The generic medicine pricing & Competition- The principal reason for the relatively low price of generic medicines is that competition increases among producers which prevents any single company from dictating the overall market price of the drug. With multiple firms producing the generic version of a drug, the profit-maximizing price generally falls to the ongoing cost of producing the drug, which is usually much lower than the monopoly price. There is extensive good quality evidence from OECD countries, and some evidence from LMIC that competition can reduce prices for essential medicines[154].

[152] *supra note 43*

[153] http://articles.timesofindia.indiatimes.com/2011-11-18/india/30414539_1_nlem-essential-medicines-dpco

[154] ***(WHO/HAI Working Paper, 2011).***

A study found that, for drugs that are available in both generic and brand-name versions, the average price of a generic prescription was approximately half of the average price of a brand-name prescription. competition from generic drugs could generate large additional savings. Price competition from low-cost imitators threatens the profits of brand-name manufacturers and reduces their returns on innovative activity, spurring them into actions that may blunt the impact of competition. Price competition also limits the profits of generic-drug manufacturers Change in the Average Relative Price of a Drug as the Number of Generic Versions Increases.) and leads them to seek ways of insulating themselves from intense rivalry. some manufacturers have entered into arrangements whereby a generic-drug company agrees to delay market entry in exchange for a payment that settles its patent litigation. such practices are obviously anti competitive[155].

Pricing of Vaccines- Indian government has already outlined the draft guidelines for new national vaccines policy[156] to bring all kinds of vaccines under the purview of the Drugs Price Control Order (DPCO) in order to ensure stable and affordable supply of vaccines to the national immunization programme.

Pricing of all vaccines should be brought under the Drug Price Control Order (DPCO) and subjected to regulation in accordance with the objectives of this policy. Pricing of vaccines should be done on a transparent basis and agreed principles of reasonable returns on

[155] The ongoing regulation of generic drugs, available at : http://www.nejm.org/doi/full/10.1056/NEJMp078193

[156] Policy Document Evidence based National Vaccine Policy, Indian J Med Res 131, May 2010, pp 617-628,available at http://icmr.nic.in/ijmr/2010/may/6.pdf

investment, rates of royalty and costing of R&D efforts, reports said quoting the final draft of new vaccine policy. The difference between maximum retail price (MRP) and the price at which vaccines are supplied to wholesalers, retailers, hospitals or even to doctors will also be minimized to deter monetary incentives for unethical vaccine promotions, according to the final draft.

CONCLUSION-

Affordability and availability of essential medicine has been a grave concern in India. Right to access to quality and affordable medicines is an important component of right to health. At times, the right to access to medicines gets violated in the midst of many anticompetitive practices therefore the need arises for regulation of competitive behaviour by the player in pharmaceutical sector. To protect the interest of deprived Indian population cheap availability of life saving drugs is among the top agendas of any government of the day. Therefore National competition policy is expected to cater to the need of the hour.

Another issue that needs to be addressed is that of public procurement because competition is most effective when purchaser is Institutions rather than Consumers. Institutional purchasers of essential medicines may be able to achieve lower prices for off-patent, multi-source essential medicines by using competition, rather than by using price regulation or other forms of price restraint[157].

The Public Procurement Bill, 2012 as brought by Government of India has the objective of to ensure transparency, fair and equitable treatment of bidders, promote competition and enhance efficiency and economy in the procurement process. The problem with regard to availability of medicines is not about their production rather they are not stocked due to collusive practices. Further collusion between manufacturer retailer and doctor to promote particular expensive brands also hinders access.

[157] WHO/HAI Project on Medicine Prices and Availability, Working Paper 4, Lauraine Hawkins, May,2011, available at: http://www.haiweb.org/medicineprices/05062011/Competition%20final%20May%202011.pdf

Collusion among doctors, pharmaceutical firms, diagnostic laboratories etc can have damaging implications for consumer wellbeing and productivity therefore effective strategy is needed to identify it and induce needed policy and regulatory action because the very nature of dispensation of health services is marked by not sovereignty of consumers rather dictate of physician.

Further all the essential vaccines covered under universal immunization programme (UIP) such as TT, DT, DTP, BCG, polio, measles must continue to be produced by the public sector[158].

With regard to the pricing issue which is one of the main constrain in way of access to medicine the researcher is of the view that there is need for active promotion of generic drugs and de-branding of some of the drugs can also be a way out.

At the end of this thesis the researcher has come to the conclusion that object of Competition law & Policy and the Pharmaceutical law& policies being the same both should be harmonised so that the end goal of both i.e. the interest of Consumers/patients could be guaranteed.

[158] http://www.dancewithshadows.com/pillscribe/india-may-bring-vaccines-under-price-control-reports/

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